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Young Women Living with HIV: Outcomes from a Targeted Secondary Prevention Empowerment Pilot Trial

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Abstract

Women account for 1 in 5 new HIV infections in the US, make up 24% of people living with HIV, and represent a quarter of AIDS diagnoses. Despite the need for continued prevention among young women living with HIV, there is very little in the literature on how best to reduce sexual risk and increase the health and well-being of young women living with HIV. This article explores the primary and secondary outcomes of a randomized controlled pilot trial of an intervention entitled *EVOLUTION: Young Women Taking Charge and Growing Stronger*. This behavioral intervention aimed to decrease sexual risk and empower young women living with HIV by enhancing young women's knowledge and skills pertaining to HIV risk reduction as well as to the factors that increase women's vulnerability, such as sexual inequality, gender, and power imbalances. Findings from this trial demonstrate that group-based behavioral interventions for young women living with HIV have promise to reduce the total number of sexual partners and reduce unprotected vaginal and anal intercourse. However, more work is needed to understand how best to address the challenges young women face in their day to day lives that impact their sexual risk as well as their overall health and access to care and treatment.

Introduction

Women accounted for 1 in 5 new HIV infections in the US in 2011, made up 23% of people living with HIV in 2010, and represented a quarter of AIDS diagnoses in 2013.[1] Condomless heterosexual sex remains the predominant risk factor for HIV infection among young women and is also a concern for women living with HIV/AIDS, due to chances of other STI infections.[1] Women living with HIV have a myriad of issues in their lives that not only impact their quality of life but also influence their ability to reduce their HIV risk behaviors, including engagement in and adherence to treatment.[2–5] In 2011, the majority of women living with HIV were not retained in medical care, and only 32% were virally suppressed.[1] In order achieve viral suppression and decrease HIV transmission, young women living with HIV must be linked to, engaged in, and retained in care.[6] However, gender inequality, including lack of access to resources and power, acts as a major barrier to women's participation in their own health care.[7] For young women living with HIV, their health care and secondary prevention efforts are often constrained by poverty, gender roles, cultural norms, and limited perceived control over sexual relationships.

Despite the need for continued prevention among young women living with HIV, literature on how best to reduce sexual risk and increase the health and well-being of young women living with HIV is scarce. An extensive literature search of existing primary and secondary HIV interventions for young women living with HIV was conducted both in 2008 and in 2015 among multiple databases, including PubMed, the Cochrane Collaboration, PsycINFO and Center for Disease Control and Prevention, and publications on the topic of secondary prevention among young women living with HIV was very limited. Rather the majority of intervention studies in the literature targeting young women focused on primary HIV prevention through HIV risk reduction information, skills, and motivation.[8,9]

This publication explores the primary and secondary outcomes of a randomized controlled pilot trial of an intervention entitled ''EVOLUTION: Young Women Taking Charge

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and Growing Stronger,'' which was conducted through the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) at clinical sites in Baltimore, Maryland, Chicago, Illinois, and Tampa, Florida. The EVOLUTION intervention was guided by the Theory of Gender and Power[10] and developed based on data collected from focus groups held with young women living with HIV, along with a review of existing interventions.[2] EVOLUTION was piloted as a group-based comprehensive secondary prevention empowerment intervention for young women. The intervention attempted to address the moderating factors of young women's sexual risk behavior such as gender roles, cultural norms, perceived control over sexual relationships, social support, and self-efficacy and self-confidence. The intervention provided young women with sexual HIV risk reduction education along with behavioral and cognitive skills building activities to reduce the risk of transmitting HIV to others and to lead healthier lives.

Methods

Study arms

The EVOLUTION intervention and the HEALTH/LIFE SKILLS control arm both consisted of nine sessions (7 group and 2 individual sessions), each lasting 2–3 h and taking place approximately every week for 9 weeks. Each group was comprised of 6–8 young women. Session activities in the EVOLUTION intervention arm were designed to empower the young women with the knowledge, skills, and tools to accurately identify and assess their social environment and emotional state. Activities were aimed at developing life goals and gaining power over their actions in order to reduce their risk of transmitting HIV to others and to lead healthier lives.

Session topics included traditional HIV risk reduction education and sexual negotiation skills, as well as forgiveness, emotional regulation, communication, and relationships. The HEALTH/LIFE SKILLS control arm aimed to build life skills. Activities focused on topics such as health, internet safety, nutrition, and exercise, as well as life skills needed to manage finances and prepare for the workforce. Details of the intervention content, development, and process evaluation are reported elsewhere.[2,11]

Participants

Eligible participants were young women living with HIV, between the ages of 16–24, receiving medical care at one of the three participating ATN sites (Baltimore, Maryland, Chicago, Illinois, and Tampa, Florida) or their community partners, able to understand both written and spoken English, free of any active, serious psychiatric symptoms that would impair their ability to meet the study requirements, and not intoxicated at the time of study enrollment. A total of 43 young women were enrolled into the trial: 22 were randomized to the EVOLUTION intervention arm and 21 to the HEALTH/LIFE SKILLS control arm.

Procedures

Institutional review board (IRB) approval was obtained by the participating clinical sites prior to the trial implementation, and a waiver of parental permission was granted by each IRB. Potential participants were approached by research staff members at each clinical site to explain the study, gauge interest in participation, and gather written informed consent for those interested and eligible. All participants completed a baseline behavioral assessment using audio computer-assisted self-interview (ACASI).

Participants were then randomized at each site to one of two study arms in a 1:1 ratio: (1) the EVOLUTION intervention, or (2) a HEALTH/LIFE SKILLS focused time and attention matched control condition. Participants returned for post-intervention assessments via ACASI immediately after the intervention sessions were completed and 3 months post-intervention. Participants were compensated for their time as determined by each site's IRB.

Measures

Measures were selected based on the content and aims of the intervention activities. General demographic questions included the participants' age, ethnicity, education, sexual orientation, pregnancy history, date of HIV diagnosis, and experience with HIV medications. The primary outcome measure was The Sexual Activity and Sexual Risk Questionnaire [ATN Behavioral Leadership Group (BLG) Secondary Prevention Working Group], which assessed participants' condom/barrier protected and unprotected oral, vaginal, and anal sexual activity with both HIV-positive and HIV-negative/unknown status males and females in the 3 months preceding the assessment.

Secondary outcomes included Self-Efficacy for Limiting HIV Risk Behavior,[12] a nine-item scale (alpha in our sample, 0.72) used to assess the self-efficacy for limiting HIV risk behavior among adolescents; Self-Efficacy for Sexual Discussion,[13] an eight-item subscale of the Health Belief Model scale used to assess self-efficacy to have sexual discussions among adolescents (alpha, 0.84); Condom Use Self-Efficacy,[14] a 28-item scale used to assess an individual's perception of his/her ability to use condoms (alpha, 0.95); and Sexual Beliefs[15] (alpha, 0.93), a 40-item scale developed to measure five beliefs related to rape: (a) that women often indicate an unwillingness to engage in sex when they are actually willing, (b) that if a woman leads a man on, then the man is justified in forcing her to have sex, (c) that women enjoy force in sexual situations, (d) that men should dominate women in sexual situations, and (e) that women have a right to refuse sex at any point, at which time men should stop their sexual advances. Each scale had a 4- or 5-point Likert-type responses with anchors that ranged from strongly disagree to strongly agree or not sure to very sure. Higher scores on each scale indicated higher self-efficacy/more positive sexual beliefs.

Training and quality assurance procedures

Facilitators were trained during a 3-day training session led by the Principal Investigator and Project Director. The training included protocol and data management procedures, group facilitator expectations, group facilitation techniques, intervention fidelity monitoring, and a session-by-session walk-through of the intervention manual. The facilitators then practiced delivering both intervention conditions during the training. Interventionists were given feedback based upon their knowledge of the material, their ability to maintain fidelity to the intervention manual while building rapport with mock participants.

After the training, interventionists were required to hold mock sessions for both conditions prior to the launch of the trial. The mock sessions were recorded and reviewed for fidelity by the Project Director. Once the trial was launched, interventionists recorded every session and sent it to the Project Director for review. The recorded sessions were compared to the manuals and feedback to interventionists was provided during weekly supervision calls.

Data analysis

Participant characteristics were compared at baseline using Pearson chi-square tests for categorical variables and *t*-tests or Wilcoxon rank-sum tests for continuous variables. Fisher's exact chi-square tests were used for comparison of categorical variables with cell sizes <5. Analysis of intervention efficacy was based on an intent-to-treat approach. Effects of the intervention on each of the primary and secondary outcomes were evaluated using generalized estimating equations (GEE) to account for correlation among repeated measures, with link functions as appropriate based on the distribution of the outcome variable. We fit models that included an indicator for group, time, and a group by time interaction to assess whether the intervention and control groups differed in response to the intervention over time.

In the absence of a significant interaction, average group differences across the entire follow-up period were also assessed. Effect estimates from the models presented reflect average group differences from baseline and immediate post-intervention and the 3-month post-intervention follow-up, and are represented as odds ratios for binary outcomes, rate ratios for count outcomes, and mean differences for continuous outcomes. Adjusted models included an indicator for time, age at baseline, and the value of the outcome at baseline.

Other potential confounders that were considered empirically or conceptually important and those for which baseline comparisons yielded $p < 0.2$ (including ATN site, age, and number of sex partners) were assessed in multivariable models but were not included in the final models because they were not statistically significantly associated with the outcome and did not alter the intervention effect estimates significantly.

Results were similar when we excluded participants who never attended a group session ($n = 4$) or who withdrew from the trial ($n = 2$). Findings presented here are based on the intent-to-treat analysis. The data were also analyzed using ANOVA with mean differences for continuous outcomes and yielded similar results. Therefore, it was decided to present the data using GEE, while recognizing the limitation of the small sample size. Data were analyzed using SAS software version 9.3 (SAS Institute, Cary, NC).

Results

Participants

Of 43 young women who were enrolled into the trial, 36 (84%) women completed the baseline, immediate post and 3-month post assessments; 1 completed the baseline and immediate post assessments but not the 3-month assessment; 2 completed only the baseline and 3-month post assessments; and 4 completed only the baseline assessment as shown in Table 1. There were no statistically significant differences by intervention group or patient characteristics between women who completed all three of the assessments compared to those who did not, although those who completed all three assessments tended to be somewhat older (median age 21 vs. 17, $p = 0.111$) and more likely to be taking antiretroviral therapy at baseline (64% vs. 29%, $p = 0.110$) than those who did not complete all three assessments.

Demographic and clinical characteristics of participants at baseline are shown in Table 2. The young women were median age 21 (IQR 17–22), primarily African American (81%), and heterosexual or straight-identified (79%). Nearly half (49%) had less than a high school education: 41% among the intervention group and 57% among the control group. Eleven percent of participants had been diagnosed with HIV in the 12 months prior to enrollment, and 58% of all participants were taking antiretroviral therapy at enrollment. No statistically significant differences in sociodemographic characteristics were observed between the intervention and control groups at baseline.

In terms of HIV transmission risk behaviors, 36% of women reported two or more sex partners in the past 3 months: 43% among intervention group participants and 29% among control group participants ($p = 0.094$). Among women who were sexually active (74%), 47% reported any unprotected vaginal intercourse (UVI) in the past 3 months, and 38% reported UVI with an HIV negative or unknown serostatus partner, with no statistically significant differences between groups.

Intervention effects on primary and secondary outcomes

Reductions in total male sex partners were observed from baseline to post 3 months intervention in both groups, from mean 1.48 to 1.24 partners in the intervention group, and from mean 1.38 to 1.00 partners in the control group, with no differences between groups (Table 3). Among sexually active participants, the proportion reporting any unprotected vaginal or anal intercourse (UVAI) declined in both groups from baseline to immediate post-intervention (from 41% to 20% in the intervention group and from 54% to 33% in the control group) but increased again from immediate post-intervention to 3 months post-intervention in both groups (Table 3). Across

Table 1. Distribution of Participants Who Completed Study Assessments

Distribution of assessments completed by study group	*Total* (N = *43*), n *(%)*	*Intervention* (N = *22*), n *(%)*	*Control* (N = *21*), n *(%)*	*Fisher's Exact chi-square* p *value**
Baseline, immediate-post, 3-month	36 (83.7)	17 (77.3)	19 (90.5)	0.412
Baseline, immediate-post	1 (2.3)	1 (4.6)	0 (0.0)	
Baseline, 3-month	2 (4.7)	1 (4.6)	1 (4.8)	
Baseline only	4 (9.3)	3 (13.6)	1 (4.8)	

*Comparison is completed all 3 sessions vs. <3 sessions.

Table 2. Demographic and Clinical Characteristics of Participants

	Total N = *43* *Frequency (%)*	*Intervention* N = *22* *Frequency (%)*	*Control* N = *21* *Frequency (%)*	p *Value*
ATN site				0.974
Tampa	14 (32.6)	7 (31.8)	7 (33.3)	
Chicago	13 (30.2)	7 (31.8)	6 (28.6)	
Baltimore	16 (37.2)	8 (36.4)	8 (38.1)	
Age				
16–18 years	14 (32.6)	5 (22.7)	9 (42.9)	0.159
19–24 years	29 (67.4)	17 (77.3)	12 (57.1)	
Median (IQR)	21 (17–22)	21 (19–23)	20 (17–22)	0.184
Race				0.457
African-American/non-Hispanic	35 (81.4)	19 (86.4)	16 (76.2)	
White/Hispanic/other race/ethnicity	8 (18.6)	3 (13.6)	5 (23.8)	
Highest level of education completed				0.287
Less than high school	21 (48.8)	9 (40.9)	12 (57.1)	
High school/GED/college/technical	22 (51.2)	13 (59.1)	9 (42.9)	
Currently in school				0.835
No	15 (34.9)	8 (36.4)	7 (33.3)	
Yes or graduated	28 (65.1)	14 (63.6)	14 (66.7)	
Sexual orientation				0.281
Straight	34 (79.1)	19 (86.4)	15 (71.4)	
Bisexual	9 (20.9)	3 (13.6)	6 (28.6)	
Time since diagnosis ≤12 months	5 (11.6)	2 (9.1)	3 (14.3)	0.664
Taking ARV medications	25 (58.1)	13 (59.1)	12 (57.1)	0.897
Ever pregnant	26 (60.5)	11(50.0)	6 (28.6)	0.151
Not in contact with father	26 (61.9)	15 (68.2)	11 (55.0)	0.380
Not in contact with mother	14 (33.3)	8 (36.4)	6 (30.0)	0.662
No. male sexual partners past 3 months				0.094
0	10 (23.8)	2 (9.5)	8 (38.1)	
1	17 (40.5)	10 (47.6)	7 (33.3)	
2 or more	15 (35.7)	9 (42.9)	6 (28.6)	
No. partners known to be HIV positive[a]				0.999
0	27/31 (87.1)	16/18 (88.9)	11/13 (84.6)	
1–2	4/31 (12.9)	2/18 (11.1)	2/13 (15.4)	
No. partners known to be HIV negative or unknown[a]				0.189
0	7/30 (23.3)	6/17 (35.3)	1/13 (7.7)	
1	13/30 (43.3)	7/17 (41.2)	6/13 (46.2)	
2 or more	10/30 (33.3)	4/17 (23.5)	6/13 (46.2)	
Any UVI in past 3 months[a]	14/30 (46.7)	7/17 (41.2)	7/13 (53.9)	0.713
With HIV+ partner	3/31 (9.7)	2/18 (11.1)	1 (7.7)	0.999
With HIV- or unknown partner	11/29 (37.9)	5/16 (31.3)	6/13 (46.2)	0.466
Any UAI in past 3 months[a]	3/29 (10.3)	1/16 (6.3)	2/13 (15.4)	0.573
With HIV+ partner	1/30 (3.3)	1/17 (5.9)	0/13 (0.0)	0.999
With HIV- or unknown partner	2/29 (6.9)	0/16 (0.0)	2/13 (15.4)	0.192

[a]Among sexually active participants ($N = 32$); denominators vary due to missing data.

the entire follow-up period, the intervention was associated with lower odds of reporting UVAI but the association was not statistically significant (aOR 0.26; 95% CI 0.05–1.51; $p = 0.135$). Small increases in self-efficacy for limiting HIV risk behavior and sexual beliefs were observed in both groups but there were no statistically significant differences between groups for any of the secondary outcomes (Table 3).

Discussion

This randomized, controlled pilot trial was designed to assess the preliminary efficacy of the intervention to reduce sexual risk for young women living with HIV. Literature is very limited regarding secondary prevention for young women living with HIV; therefore we are unable to compare our findings with other published interventions. However, it is known that young women living with HIV engage in unprotected intercourse and use condoms inconsistently.[16,17] It is also known that unprotected vaginal and anal intercourse is related to young women's overall self-efficacy, self-efficacy to discuss safer sex with one's partner and self-efficacy to refuse safe sex[16] and that behavioral interventions targeted to adolescents have the ability increase condom use and decrease overall number of sexual partners.[18]

Table 3. Intervention Effects on Sexual Behavior and Psychosocial Outcomes

	Intervention		*Control*		*Effect estimates*	
Sexual behavior outcomes	N	n *(%) or Mean (SD)*	N	n *(%) or Mean (SD)*	*Unadjusted OR/RR (95% CI);* p *value*	*Adjusted OR/RR*[a] *(95% CI);* p *value*
No. of male partners in past 3 months					1.11 (0.72–1.70) $p=0.648$	Model did not converge
Baseline	21	1.48 (0.87)	21	1.38 (2.06)		
Post-test	18	1.33 (0.91)	19	1.37 (1.21)		
3-month	17	1.24 (0.83)	19	1.00 (0.82)		
Any unprotected VI or AI in past 3 months[b]					0.43 (0.10–1.89) $p=0.262$	0.26 (0.05–1.51) $p=0.135$
Baseline	17	7 (41.2)	13	7 (53.9)		
Post-test	15	3 (20.0)	15	5 (33.3)		
3-month	12	6 (50.0)	13	6 (46.2)		
Secondary outcomes	n	n *(%) or Mean (SD)*	N	n *(%) or Mean (SD)*	*Unadjusted mean difference (95% CI);* p *value*	*Adjusted mean difference*[a] *(95% CI);* p *value*
Self-efficacy for limiting HIV risk behavior					0.11 (-0.10, 0.31) $p=0.306$	0.04 (-0.14, 0.21) $p=0.667$
Baseline	19	3.76 (0.38)	21	3.57 (0.62)		
Post-test	18	3.75 (0.34)	19	3.68 (0.35)		
3-month	18	3.80 (0.36)	19	3.67 (0.44)		
Self-efficacy for sexual discussion subscale					0.01 (-0.25, 0.26) $p=0.970$	–0.16 (-0.36, 0.04) $p=0.110$
Baseline	19	3.65 (0.49)	21	3.35 (0.68)		
Post-test	18	3.58 (0.43)	19	3.59 (0.51)		
3-month	18	3.49 (0.53)	20	3.49 (0.49)		
Condom use self-efficacy					0.28 (-0.001, 0.561) $p=0.051$	0.14 (-0.10, 0.37) $p=0.250$
Baseline	19	4.67 (0.34)	19	4.32 (0.60)		
Post-test	18	4.47 (0.56)	18	4.36 (0.53)		
3-month	18	4.58 (0.45)	18	4.15 (0.52)		
Sexual Beliefs Scale					0.002 (-0.28, 0.28) $p=0.987$	0.05 (-0.15, 0.24) $p=0.631$
Baseline	16	3.18 (0.44)	18	3.32 (0.37)		
Post-test	17	3.32 (0.43)	18	3.33 (0.47)		
3-month	16	3.43 (0.40)	17	3.36 (0.51)		

[a]Adjusted for time point, age, and baseline value of outcome; [b]among those with 1 or more sex partners at each time point.
Effect Estimates reflect the average difference between the intervention and control groups over the immediate post-intervention and 3-month post-intervention follow-up, and are represented as odds ratios for binary outcomes, rate ratios for count outcomes, and mean differences for continuous outcomes.

Therefore it was hypothesized that by designing a comprehensive intervention that empowered young women living with HIV with risk reduction information, skills, and motivation, the intervention would lead to an increase of young women's self-efficacy, especially surrounding safe sex negotiation, and reduce unprotected vaginal and anal intercourse and a decrease of unprotected sexual intercourse and inconsistent condom use.

Findings from this trial demonstrate that group-based behavioral interventions for young women living with HIV have promise to reduce the total number of sexual partners and reduce unprotected vaginal and anal intercourse. Reduction in sexual risk appears to occur whether the intervention content is specific to HIV or not. While this finding may reflect the small sample size, it may also suggest that the Theory of Gender and Power, the theory that informed the study, was not strong enough to influence the moderating variables as expected, or that the theory itself may need further articulation and testing. It may also indicate that providing general life skills assistance, such as resume building and finance management, can be as equally empowering to create behavior change as HIV-specific content when delivered in a group-based format. Despite both arms showing promise in partner reduction, impact of the interventions faded over time once the study stopped and the intervention was not found to more efficacious than the control condition on the secondary or primary outcome measures.

This pilot trial illustrated that young women can benefit from coming together in a group setting to learn from both a comprehensive intervention's content and one another. While both intervention arms showed promise, it is important to note that there are several limitations to the trial. Although the small sample size was appropriate for the objectives of a

feasibility trial, the sample size was too limited to conduct a robust or theory driven analysis and therefore limited the interpretation of the data and the intervention's relationship to the theory that guided it. Efficacy of this intervention could not be determined from this small trial and further research on the efficacy of the intervention in a larger sample is still warranted. Analysis was done to assess trends in primary and secondary outcomes and provide preliminary effect estimates for future larger studies. Potential reasons for lack of effects include limited power, sample selection issues, representativeness, and generalizability.

Young women in the trial reported far fewer sexual risks and higher empowerment and self-efficacy scores at baseline than anticipated from our initial pilot and from existing literature.[2,17,19] A little over half of the young women in the trial did not report any vaginal intercourse in the 3 months prior to baseline and 25% reported having no male sexual partners in the last 3 months. In contrast to our preliminary study where young women reported multiple sexual partners,[2] the mean number of male sexual partners in the last 3 months was 1.48 and 1.24 among the intervention and control group, respectively.

Finally, at baseline the young women in both groups scored very high on the self-efficacy scales and questionnaires, leaving very little room for significant change in outcomes such as self-efficacy for limiting HIV risk behavior. The observed low rates of HIV risk behavior coupled with high self-efficacy was not seen in the formative research.[2] Blackstock and colleagues[20] found in their study looking at the differences among women living with HIV engaged and not engaged in care, that women living with HIV who were not engaged in care were more likely to report high-risk and drug use behaviors. Thus, we are unsure if the young women in the trial are representative of young women living with HIV in the general population or if this phenomenon is a product of sample selection from the clinical sites where young women are already engaged and retained in care.

The current literature suggests that for secondary prevention interventions to make a meaningful and lasting impact in the lives of young women living with HIV, they should address the concerns and issues that go beyond traditional HIV prevention and education and address young women's day to day needs, improve self-efficacy, and address barriers to care, including retention and re-engagement in care and viral suppression.[6,19,20] While the intervention condition attempted to address relevant issues in young women's lives pertaining to their social and emotional well-being, EVOLUTION did not address life skills areas while the control condition did. Both EVOLUTION and the control condition did not address barriers to engagement and retention in care and viral suppression.

If the EVOLUTION intervention were to be developed into a full-scale, randomized trial of the EVOLUTION intervention, sessions with life skills content should be incorporated to better address some of the moderating factors to risk, treatment, and care. Knowledge and skills that address issues surrounding poverty, housing, and independence would be beneficial. In addition, young women might find these life skills easier to adapt in their lives than other behavioral and cognitive skills relating to relationships and communication.

With only a third of women living with HIV in the US being virally suppressed,[1] the existing curriculum should be supplemented with knowledge, skills, and linkage to support surrounding medication adherence and engagement, retention, and re-engagement in care and treatment. The trial design would also benefit from targeting young women who are higher risk of transmitting HIV (i.e., those who are nonadherent to ARVs, report multiple partners and unprotected intercourse) than those already engaged in regular care with less transmission risk behavior and higher overall self-efficacy.

Young women living with HIV face a number of challenges that limit their ability to reduce the risk of HIV transmission to others, increase their retention and engagement in care, and reach and maintain viral suppression.[2,4,18–20] Comprehensive behavioral interventions that extend beyond HIV risk reduction education have the potential to not only decrease sexual risk but to empower young women to address some of the moderating factors that impact their overall health and well-being and access to treatment and care. However more work is needed on how best to address those challenges.

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Author Disclosure Statement

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