Study Title: Reaching 90 90 90 in Adolescents in Zambia: Using all our SKILLZ

Version 1.2a

**Short title:** SKILLZ Study

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#### **Ethical reviews by other institutions**

The protocol has been submitted for review to the Institutional Review Boards (IRBs) of the University of Zambia and the University of Alabama—Birmingham.

#### **Funder's Role**

The NIH's role is non-engaged and will not include access to identifiable data. The NIH solely will provide funding for the activity.

### Acronyms

AFS Adolescent Friendly Services

ART Antiretroviral Therapy

**ARVs** Antiretrovirals

CIDRZ Centre for Infectious Disease Research in Zambia

**CRF** Case Reporting Forms

**DHS** Demographic Health Survey

DMPA-SC Depo Medroxyprogesterone Acetate
EMR Electronic Management Records

**FGD** Focus Group Discussion

**GRS** Grassroot Soccer

**HIV** Human Immunodeficiency Virus

**HIVST** HIV Self-Testing

HTC HIV Testing & Counselling

ICER Incremental Cost-Effectiveness Ratio

**IDI** In-Depth Interview

LIMS Laboratory Information Management System

MOU Memorandum of Understanding
MOGE Ministry of General Education

**MoH** Ministry of Health

NHC Neighborhood Health Committee

NIH National Institute of Health
QALY Quality-Adjusted Life Years

**ROI** Return on Investment

**SBHP** Sports-based HIV prevention programs

**SOC** Standard of Care

SRH Sexual Reproductive Health
STI Sexually Transmitted Infection

UAB University of AlabamaVLS Viral Load Suppression

**YFHS** Youth Friendly Health Services

**ZAMPHIA** Zambia population-based HIV impact assessment

#### 1. Introduction

#### a. General information on the research issue/topic

Zambia is struggling to meet the 95-95-95 targets for adolescent women. Despite available public health services, including free HIV testing, prevention, care and treatment, uptake of most health services amongst adolescents in Zambia remains suboptimal, especially for sexual and reproductive health (SRH).<sup>1,2</sup> HIV testing rates remain low; only 47.5% of girls and 28.5% of boys aged 15-19 years have received an HIV test and learned their results, compared to 86.6% of adult women and 69.1% of men.<sup>3</sup> Preliminary results from the 2015-2016 Zambia population-based HIV impact assessment (ZAMPHIA) study show that adolescent girls and young women aged 15-24 years have higher rates of HIV infection compared to their male counterparts and that HIV prevalence among 20-24 year-olds is four times higher among females (8.6%) than males (2.1%).4 In addition, whereas over 70% of HIV-infected adults have achieved viral load suppression (VLS), only 34% of adolescent girls have. To further support 95-95-95 targets, contraception is considered the most cost-effective strategy to reduce the burden of mother-to-child HIV transmission among women living with HIV who wish to prevent unintended pregnancy.<sup>5</sup> The most recent Demographic Health Survey (DHS) showed that while 73.3% of unmarried, sexually active adolescent girls reported not wanting a child in the next two years, only 20.6% were using any contraceptive method to prevent pregnancy.<sup>3</sup> Further to this, approximately 7.2% of sexually active adolescents (aged 15-19) reported having had a sexual partner who was 10 or more years older<sup>3</sup>, placing them at an increased risk of HIV infection and early child-bearing<sup>6</sup> and the Ministry Of General Education (MOGE) has recorded a five-fold increase in teenage pregnancies among girls in grades 1-12 between 2002 and 2015<sup>7</sup>. The Government of Zambia has recognized that this data clearly points to the need to increase adolescents' awareness and utilization of available health services and ensure innovation in the way these messages are delivered.

#### b. Overview of research and research gaps (contribution to policy and practice)

In a review of adolescent-specific service delivery programs over 2001-2014,<sup>8</sup> only 11 studies were identified that addressed the HIV treatment cascade among adolescents, none of which met criteria for a rigorous, adequately powered, longitudinal program. Although the evidence base is thus weak, programs that are easily accessible, and provide integrated services and peer counseling were highlighted as promising strategies. Recent research from the Southern African region has shown that effective programs for suppressing viral load in adolescents focus on quality of clinical services, including adequate drug inventory, dedicated staff time for adolescents, staff who are kind and non-judgmental, funded mechanisms for adolescent clinical accompaniment.<sup>9</sup> Little research has been done as to what effect these programs could have on uptake of contraceptive services and whether a more holistic approach with a more integrated program (encompassing contraception, distribution of commodities, and the availability of HIV self-testing kits) could provide improved HIV-testing uptake as well as uptake of other contraceptive services.

We therefore seek to evaluate an enhanced school-based intervention for girls aged 16 and over that combines the innovative demand-generating sports-based program for empowering adolescent girls, supported by Grassroot Soccer (GRS) combined with adolescent-friendly clinical services (SKILLZ-girl and enhanced SKILLZ-girl) delivered through a combination of community and facility-based approaches. The

SKILLZ Package removes barriers to services across multiple levels of influence by creating a fun, interactive environment for meaningful discussions and reflection about SRH, future orientation, and goal-setting (see **Figure 1**) using a school-based curriculum, peer mentorship, community soccer events and enhanced events, and referrals for and direct service provision. The program also provides opportunity for ongoing engagement with all enrolled girls (regardless of HIV status) through the form of school-based clubs that provide on-going discussion around positive messages of empowerment, strategies to prevent STI infection (including HIV), and direct linkages to access for contraceptives and repeat HIV testing. A rigorous, mixed methods evaluation will assess the effectiveness of this intervention following a cohort of enrolled girls over two years.

The findings from our research will be shared with both the Ministry of Health (MoH) and MOGE and will guide Zambia's national strategic plan for improved uptake and retention of SRH services by adolescents. We are working closely with these partners and Lusaka District Education Board Secretary to pave the way for complete integration of the SKILLZ Package into the public education system should this intervention prove effective. Our team will work closely with the MOH and MOGE throughout study implementation to ensure that services are integrated, streamlined and sustainable as well providing guidance on sustainable forms of distribution at the community level.

#### c. Overall purpose of the research and area/site where the research will be conducted

As part of routine activities, GRS is already implementing an approved, school-based curriculum at the majority of secondary schools in Lusaka however, it is unclear as to whether this curriculum, in itself, will improve health seeking behaviors and ultimately decrease HIV infection and unintended pregnancies amongst this high-risk group.

The overall purpose of the research is to assess the impact of the enhanced SKILLZ GIRL Package, including different components of the program aimed at both HIV-infected and uninfected adolescent school girls over two years on the outcomes of (1) HIV testing and subsequent retention in care, and (2) contraceptive uptake and continuation for pregnancy prevention. We will also assess the impact of school-based SKILLZ clubs, on 1) HIV testing and subsequent retention in care, and (2) contraceptive uptake and continuation for pregnancy prevention. The study will take place across several high density population areas of Lusaka where CIDRZ supports government MoH clinics with ARV services, electronic data management, and youth-friendly trained clinical personnel and where GRS has been implementing their basic SKILLZ curriculum and events in secondary schools.

# 2. Statement of the problem

# a. Short summary of the background on the problem

As mentioned above, the ZAMPHIA study showed that adolescent girls and young women have very high, disproportionate rates of HIV infection with a prevalence among 20-24 year-olds four times higher than that seen in males.<sup>4</sup> According to DHS, girls in Zambia have a sexual debut at 13 years of age, highlighting the need for early educational and behavioral interventions. Empowering girls and giving them access to SRH and broader health related information remains a key strategy to reducing risk of HIV acquisition and

encourages more positive health seeking behavior as part of a comprehensive health care package. Whilst many adolescent programs are based on the premise that understanding risk and providing adolescent-friendly services (AFS) translates into participation along all steps in the SRH care cascade, this is not always the case. AFS are necessary, but insufficient; furthermore, the link between risk and uptake of AFS is tenuous. Compared to individuals at other life stages, adolescents are more likely to engage in novelty-seeking and risky behaviors and less likely to consider the consequences as they transition to adulthood and assume more independence and responsibility.<sup>10-15</sup>

#### b. Importance of relevance of the research

Strong evidence for what works for improving SRH outcomes among adolescent in resource-poor, but high disease burden settings remains poor despite the plethora of studies and investments into SRH programming. For example, guidelines in a 2016 WHO review of recommendations for care of HIV-positive youth were based on "low" and "very low" quality evidence, strongly suggesting the need for greater research. Similarly, in a recent report, the Institute of Medicine concluded that there is a lack of evidence for effective models of adolescent health care and a need for further research, particularly on how health services are delivered and by whom. Although a systematic review of sports-based HIV prevention programs (SBHP) has found evidence for effects on a range of social and behavioral outcomes (i.e., reduced stigma, increased self-efficacy, HIV-related knowledge, uptake of HIV testing a counselling (HTC), and condom use) Rigorous evaluations that can attribute causality and verify pathways for change are lacking. Sa mentioned previously, GRS has already been rolling out a validated SKILLZ girl curriculum. In collaboration with their team, we have developed an enhanced curriculum which includes a comprehensive module on HIV self-testing, contraceptive choices and pre-exposure prophylaxis (PrEP) combined with increased access to these services through an enhanced soccer event.

In this study, we are proposing a pragmatic trial (based on real-world implementation) that will provide a robust evaluation of effectiveness and cost-effectiveness (CE) between a standard SKILLZ- girl curriculum, that has been delivered in many Lusaka secondary schools already, and a more robust, integrated, enhanced approach that includes additional SRH service offerings, including HIVST, PrEP and an expanded contraceptive method mix.

# 3. Rationale/Justification

# a. Contribution of the study to science or body of knowledge

Few prospective studies have been conducted in sub-Saharan Africa (SSA) among adolescent girls to gauge uptake of SRH services, including contraception uptake and continuation and HIV testing, adherence and retention in care. Lall et al. reviewed 26 studies on adherence to and retention in care among HIV-positive youth and adolescents, but none were conducted in SSA.<sup>20</sup> Another review examined data from nine studies in SSA, but all were cross sectional and only one used viral load to assess HIV treatment adherence (as opposed to self-report).<sup>21</sup> Specifically, in Botswana, Lowethal et al. reported that 77% of 692 youth were virally suppressed, but again this was cross-sectional.<sup>22</sup> Finally, a third review examined data from 53 countries and reported higher ART adherence rates among African adolescents 84% (95% CI 79–89; I2:93%) compared to other regions of the world, but this too used cross-sectional data.<sup>23</sup> Furthermore, no studies have examined contraceptive continuation among adolescents, despite the burden of early pregnancy among young girls during their critical years in the transition to adulthood.

#### b. Changes to be made by the study

In Zambia, SRH services for adolescents remains a challenge with services primarily being provided through main-stream, clinic-based services. Uptake of both prevention and curative services remain low. For example, adolescents disproportionately contribute to the number of new HIV infections each year<sup>3</sup>. Standard of Care (SOC) for SRH and HIV services designed specifically for adolescents is scant and includes provision of basic SRH/HIV education, including HTC in schools by trained health workers and referral for other prevention services to general (mainly adult) ART/ SRH clinics. Adolescent girls found to be HIV-infected are also referred to these clinics for treatment and other services, however adherence and retention in care is low with only 34% reported to be virologically suppressed<sup>4</sup>. Furthermore, access to contraceptive services including long-acting methods is largely limited to clinical settings where adolescents face stigma (perceived and actual) from healthcare workers and risk lapses in confidentiality<sup>24,25</sup>.

Our central hypothesis is that an enhanced SRH curriculum (including a comprehensive module on HIVST, contraceptives and PrEP) and the additional offering of HIVST and contraceptive services at the event along with ongoing engagement the SKILLZ-Club program (Enhanced Arm), will increase HIV testing and contraceptive uptake compared to the standard SKILLZ curriculum & standard event (SOC Arm). Furthermore, supporting subsequent ongoing education as well as linkage to services through SKILLZ school clubs in the enhanced arm will improve ongoing uptake of services and retention and will allow us the opportunity to measure the effect of the intervention longitudinally. We further hypothesize that our intervention will positively and directly affect a number of mediating factors: attendance to soccer events where community-based SRH services are offered, SRH knowledge, empowerment, self-confidence, and perceptions of gender balance, and (reduced) stigma. For girls found to be HIV-positive, we further expect the follow-on SKILLZ intervention (SKILLZ-Plus) aimed at linkage to HIV care and treatment, will reduce HIV-related stigma, increase disclosure to family and partners, increase feelings of social support, empowerment, self-efficacy, and ultimately adherence to ARVs, viral load suppression (VLS) and retention in HIV care and treatment.

The SKILLZ program trains young adult mentors ("Coaches") as community change agents that deliver ageappropriate, gender-transformative curricula through a pedagogical approach that combines soccer metaphors and activities with accurate health information. The aim is to build the health and social assets of adolescents, facilitate access to health and social services, and support adherence to medical treatment and positive protective behaviors.

#### c. Evidence supporting the justification

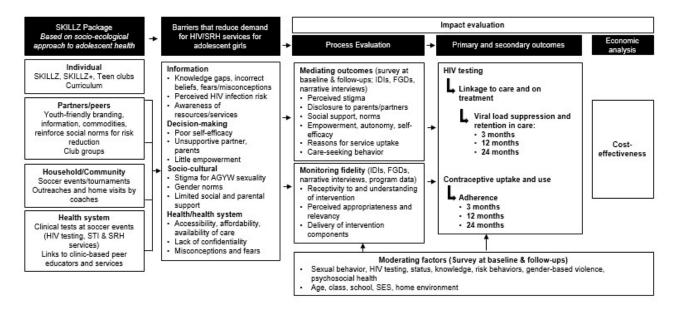
Adherence to protective behaviors, treatment and psychosocial support for adolescents remains inconsistent. Care services are largely inefficient, ineffective and undifferentiated, lack psychosocial support elements, and rely on ineffective referral mechanisms between the schools and health facilities.<sup>26</sup> Our soccer-based SKILLZ Package has already demonstrated proof-of-concept, increasing knowledge about key risk factors (i.e., age disparate relationships and multiple partners) and changing harmful attitudes related to stigma and gender issues.<sup>27</sup> In 2010-2012, GRS also analyzed the SKILLZ program compared to sub-regional DHS data, showing that among 11,000 youth (males and females) participants in Zambia, 62%

tested for HIV, 100% learned their HIV test results, and 95% of those testing positive for HIV were linked to care. Accompanying qualitative research also revealed high program acceptance by parents, health providers and adolescents themselves, although the sentiment to have a girl-only program were salient. At that time, the program was linked to only one clinic, no formal evaluation was employed with a meaningful clinical outcome (i.e. viral load), and little focus on pregnancy prevention, contraceptive use, and more general SRH risks were measured.

# 4. Theoretical/conceptual framework for Grassroot Soccer SKILLZ Curriculum

The SKILLZ Package is based on a multi-level socio-ecological conceptual framework of HIV-related behaviors and outcomes among adolescent girls (see **Figure 1**).<sup>29,30</sup> Barriers to accessing services and adhering to risk reduction strategies through the continuum of care exist across all levels of influence: individuals may hold fears and misconceptions of HIV and suffer from stigma surrounding adolescent sexuality; fears and anxiety can lead to a lack of social support from partners and peer groups that would otherwise be protective; families and communities are often the source of perceived stigma, and further reinforce inequitable gender and social norms that amplify girls' vulnerability; health systems are often inaccessible and unfriendly to young people.<sup>31-33</sup> These myriad factors collide to prevent adolescent girls from reducing risk, accessing HIV and SRH services, and remain in care over the longer-term.

**Figure 1**. To improve HIV testing, linkage to treatment, and retention in care, SKILLZ targets multiple barriers to service utilization based on a socio-ecological approach to adolescent health.



<u>The SKILLZ Adolescent SRH program</u> (SKILLZ Package) aims to improve uptake of HIV testing, treatment and adherence and SRH services among adolescent girls. The model focuses on removing barriers to critical services by creating a fun, interactive environment for meaningful discussions and reflection (see **Figure 1**).

Designed to be integrated into both secondary school education and clinical services, the SKILLZ Package is unique in that it offers holistic and continued support to adolescent girls through several avenues. First, it focuses on agency and empowerment by providing mentorship as well as accurate sexual health information with a trained age-peer coach. Second, the SKILLZ Package provides direct linkages to facility-based, youth-friendly care, leveraging existing community- and facility-based resources. Third, the SKILLZ Package ensures that comprehensive sexual and reproductive health education and services are

continuously given, including a focus on pregnancy and HIV prevention, the two largest risks that adolescent girls face in their pursuit of security and independence in adulthood.

The SKILLZ Package entails three integrated programs that work together to build a continuous support system that not only encourages uptake of contraceptive and HIV services, but also adherence and continued engagement with health services over the long-term (whether to contraceptive methods, HIV repeat testing, preventive services such as PREP and/or HIV treatment and care).

- 1. **SKILLZ-Girl** is a school-based program that provides adolescent girls (aged 16 and over regardless of HIV status) with a 10-12-week, soccer-based comprehensive sexuality and SRH education curriculum; gender and power dynamics in relationships are also addressed. This program is run during extra-curricular hours as part of the school syllabus. The program culminates in a soccer tournament where girls are provided the opportunity to access community-based SRH services offered at mobile clinics, including testing for HIV. The program was originally piloted in Zambia in 2015. Permission to continue to run the program was most recently granted in 2019 by the MOGE
- Enhanced SKILLZ-Girl is based on the curriculum described however we have modified the regular SKILLZ-Girl curriculum to include a focused module on HIVST, PrEP and contraception. In our study we will be comparing the 'regular' SKILLZ girl curriculum with this 'enhanced curriculum. The enhanced curriculum is based on the same premises and methodology as SKILLZ-girl.

Both SKILLZ-Girl and SKILLZ-Girl enhanced focus on building adolescent girls' health and social assets, culminating in a soccer tournament to address detrimental social norms and attitudes towards girls and disrupt traditional service delivery models with several salient features:

- Building individual self-efficacy, empowerment and future orientation through the SKILLZ-Girl and enhanced curriculum: A series of 10-12 x 1.5-hour sessions will be delivered by coaches (1 coach for every 25 girls) over approximately 12 weeks at school during normal school hours. The curriculum validates experiences of puberty and sexuality while building life skills and other critical assets that are broadly applicable to many spheres of girls' lives. It provides a link to a range of behavioral outcomes including stigma prevention, SRH and contraception, all designed to create an integrated health package for young women. The curriculum culminates in a soccer event where participants will be offered an opportunity to either test for HIV at the event or (depending on intervention arm) take home a HIVST kit, take up a contraceptive method or be assessed for uptake of PREP. The Permanent Secretary for MOH has provided support to conduct this assessment particularly in improving access to PREP for at-risk adolescent girls (see Appendix C).
- 3. Following the community soccer event, in the enhanced arm, all girls (regardless of HIV or testing status) will be invited to participate in **SKILLZ-Club.** These school-based clubs are run in the afternoons during extra-curricular hours and provides students with an opportunity to continue to engage in a deeper discussion about SRH, empowerment, HIV prevention and HIV testing. SKILLZ-Club also focuses on contraception initiation and continuation as a tool for future planning, self-care and empowerment. It also includes participation in a community change project that continues to build self-efficacy and agency. The club is an

ongoing activity that students can participate in until they leave or graduate from school. Girls participating in the SOC Arm (SKILLZ-Girl) are able to join any of the other clubs currently offered at their school (SOC Clubs).

Clubs have been operating in schools in Zambia since 2017 with the MOGE's consent as part of the Memorandum of Understanding (MOU) signed in 2010 (see Appendix B). The CLUB component is currently evolving to include a more formalized education component, and will be piloted in Zambia at the same time as this evaluation.

4. All girls who test positive for HIV (whether prior to the SKILLZ-Girl event, during the event or as part of their participation in SKILLZ-Club) are referred to **SKILLZ-Plus**, a clinic-based initiative which provides HIV-infected girls access to ongoing support through a 12-week curriculum. During follow-up in the SOC Club arm, study staff will refer any newly identified HIV-positive girls to SKILLZ-Plus. In additional, study staff will refer newly diagnosed girls aged 16 years from neighboring clinics to the SKILLZ-Plus intervention.

For girls who test positive for HIV, either through a:

- 1. school referral either at the event, during club participation, are identified during follow-up or with a previously known diagnosis or
- 2. clinical referral (newly diagnosed only)

In addition, all girls found to be HIV-positive at any point throughput the SKILLZ-Program will be provided with intensive counselling support. Coaches will facilitate a family visit to facilitate disclosure and work with CIDRZ networks to provide additional psycho-social support as needed on a case-by-case basis by the participant.

#### SKILLZ-Plus provides several additional features:

- Enhanced linkage to care: HIV+ positive girls are matched with trained coaches (~6 girls per coach) who use soccer-based activities to guide participants through issues such as acceptance, disclosure, healthy living and adherence. The coach will be responsible for providing the girl with the support and the guidance she needs to access ART services at MoH clinics. This support will include both psychological support and logistical (i.e. where to go, who to see, the expected outcome of each visit, etc.) The program consists of 12 modules (conducted during intensively over approximately 6 weekends) that address different aspects of living with HIV delivered in a private, confidential and non-judgmental platform at the clinic, to individuals, during regular clinic visits. The curriculum for HIV+ girls encourages girls to have discussions about living with HIV, to make healthy life decisions, to work to achieve their goals, and to become positive role models within their community. SKILLZ-PLUS received written support from MOH in 2013 (see Appendix C).
- Ongoing peer support for six months through monthly interactions and virtual forums.
- After graduation from SKILLZ-Plus, HIV-infected adolescent girls will be linked to support groups, which meet twice every month at health facilities when they go for clinical visits or drug refills.
- All SKILLZ-Plus groups are led by GRS trained coaches.

CIDRZ will work closely with the MOH to ensure adolescent services are available. To accomplish this, CIDRZ will support a hybrid model of community-based services and clinic-based adolescent-friendly clinics to meet the specific demands of adolescents including HIV testing, SRH services and stigma-reducing initiatives. In addition to existing testing venues, HIV testing and mobile SRH services will be offered on site during and after the tournament and a trained nurse will available to provide a larger set of SRH services including issuing of contraceptives (including injectables, pills, and barrier methods, emergency contraception), pregnancy tests, and STI diagnosis and treatment (pending availability of supplies). All supplies will be obtained from MoH medical stores, through established mechanisms.

Within SKILLZ-Girl and SKILLZ-Club, our study will examine the additional benefits of offering access to two new health service offerings that are expressly designed to overcome barriers to uptake especially difficult for adolescents to overcome—HIV self-testing (HIVST) kits and access to an expanded method mix for contraceptive methods. Referral for contraceptive and SRH services will be made to the PEPFAR-funded DREAMS Houses or youth corners at local government facilities which are located within close distance to all schools where the SKILLZ package will be implemented.

Our mixed-methods evaluation will assess the effects of the enhanced SKILLZ offering (SKILLZ-Girl Enhanced & SKILLZ Club programs) compared to the SOC SKILLZ offering of SKILLZ-Girl only. Although the SKILLZ Program (Enhanced or SOC pending school allocation) will be offered to all girls enrolled in Grade 10 at selected study secondary schools, only girls aged 16 and over at the commencement of SKILLZ-Girl will be enrolled into the research study.

We will examine outcomes for school girls aged 16 and over enrolled in Grade 10 at the start of the intervention in up to 16 schools where the SOC SKILLZ Package is offered, compared to outcomes in up to 16 schools where the enhanced SKILLZ-Package is offered, including HIVST, the availability of expanded contraceptive services and the SKILLZ-Club following completion of SKILLZ-Girl. Therefore, all schools will be preassigned prior to the intervention into the following 2 categories (see **Figure 3** in *Section 8 - Methodology* below).

1. **SOC:** SKILLZ-Girl → Club SOC

2. **ENHANCED:** SKILLZ-Girl enhanced → SKILLZ-Club

Our central hypothesis is that the additional offering of HIVST and contraceptive services in an enhanced SKILLZ-Girl combined with the SKILLZ-Club offering will increase HIV testing and contraceptive uptake and continuation.

In addition to SKILLZ-Girl and SKILLZ-Club, girls testing HIV-positive at any time during the study intervention period will be additionally offered to participate in the SKILLZ-Plus facility-based curriculum for HIV-infected adolescents. The effect of the SKILLZ-Plus curriculum will be tested using a SmartCarederived matched (i.e., on clinic, age, ART start date and gender) population.

The impact of the SKILLZ Package on our primary outcomes—HIV testing and its care sequelae and contraceptive use—is likely to be moderated by girl's sociodemographic characteristics, such as age, SES status, and her home environment (i.e., siblings, parental HIV status).

#### 5. Literature review

While historically overlooked, the consequences of neglecting to provide adolescents with strong SRH services and potentially causing a painful or damaging transition into adulthood are now well understood. For adolescent girls, pregnancies are much more likely to be high risk. Early pregnancies can also compromise their ability to complete their education, creating a knock-on effect to their future economic earning potential<sup>34</sup>. They also face an increased risk of exposure to HIV and sexually transmitted infections (STIs) as well as being involved in sexual coercion, and acts of gender-based violence<sup>35</sup>. Obstacles to receiving access to AFSRH services include inadequate social support, stigma, and detrimental gender and social norms associated with adolescent sexuality including high rates of intergenerational sex and intimate partner violence.<sup>36-41</sup> Health care workers often judge, reprimand and may also deny SRH services to adolescents because they believe they are too young to engage in sexual activity.<sup>42</sup> These issues are magnified for HIV-infected adolescents, where, unlike other chronic diseases among young people, adolescent HIV infection is set apart as a highly stigmatizing disease during a developmentally sensitive time when transitions in self, body and health care are at play.<sup>43</sup>

The most recent Demographic Health Survey (DHS) showed that while 73.3% of unmarried, sexually active adolescent girls reported not wanting a child in the next two years, only 20.6% were using any contraceptive method to prevent pregnancy and only 40.4% of sexually active adolescent girls aged 15-17 had had an HIV-test in the last 12 months<sup>3</sup>. The report also indicated that by age 19, more than a third of Zambian adolescent girls report having experienced sexual violence from a male partner and by age 18, a third have been pregnant.<sup>3</sup> Furthermore, programmatic data from CIDRZ suggest almost 50% of HIV-infected adolescents that know their status drop out of care within two years of initiating ART.

Cultural factors, such as the widespread belief in Zambia that a girl or woman should not say no to sex or propose the use of a condom, have obvious consequences to a poor understanding and access to SRH services.<sup>44</sup> These barriers to accessing services and adhering to risk reduction strategies exist across all levels of influence: individuals may hold fears and misconceptions of HIV and suffer from stigma surrounding adolescent sexuality; fears and anxiety can lead to a lack of social support from partners and peer groups that would otherwise be protective; families and communities are often the source of perceived stigma, and further reinforce inequitable gender and social norms that amplify girls' vulnerability; health systems are often inaccessible and unfriendly to young people.<sup>31-33</sup> These myriad factors collide to prevent adolescent girls from reducing risk, accessing HIV and SRH services, and remain in care over the longer-term.

There is however increasing access to cost-effective and easy to use long-acting methods of contraception such as the 3-month intramuscular administrated depo medroxyprogesterone acetate (DMPA-SC). This has been specifically designed to overcome some of the major barriers to contraceptive use, including difficulty in accessing facility-based SRH services. Research to date has consistently demonstrated its safety, effectiveness and acceptability to both users and health care providers<sup>45</sup> <sup>46,47</sup>. Furthermore, use of a contraceptive method has been associated with an increased likelihood to be tested for HIV and a decrease in high-risk sexual behaviors<sup>48</sup>. Unfortunately contraceptive failure and discontinuation is more common amongst adolescent girls than among older women<sup>49</sup> and only 20.6% of sexually active adolescent girls who reported not wanting to become pregnant reported that they were using any contraceptive method to prevent pregnancy.<sup>3</sup> While DMPA-SC is currently being scaled up in over 22 countries around the world, including Zambia, the national strategy for Zambia does not provide specific plans for addressing the SRH needs among adolescent girls. Thus, there is an urgent need to fill this gap and identify effective strategies

for ensuring health equity whereby adolescent girls have access to the same expanded contraceptive method mix in Zambia.

HIVST is another recent technological innovation that has emerged as a promising strategy to provide individuals with an opportunity to test while bypassing some of the stigmatizing concerns of the clinical environment that are especially salient among adolescents. A pilot study amongst adolescents in South Africa using HIVST found fidelity to be very high (96.4%), with participants reporting high rates of acceptability and usability<sup>50</sup>.

A review of adolescent-specific service delivery programs over 2001-2014,<sup>8</sup> only 11 studies were identified that addressed the HIV treatment cascade among adolescents, none of which met criteria for a rigorous, adequately powered, longitudinal program. Although the evidence base is thus weak, programs that are easily accessible, and provide integrated services and peer counseling were highlighted as promising strategies.

Programs integrating contraceptive services and HIV prevention and testing have showed promising results for reaching adolescent girls. A recent Teenage Pregnancy Prevention Program in South Africa showed improved attitudes amongst its participants, including plans to communicate with partners about teenage pregnancy and increased reports of condom use in those that were exposed to the intervention<sup>51</sup>. A Youth Friendly Health Service (YFHS) model in Malawi offering contraception alongside HIV-testing supplies, and using a curriculum based on gender empowerment and self-efficacy, led to higher health services utilization, including uptake of HIV testing services, condoms and hormonal contraception<sup>52</sup>.

GRS has shown that soccer-based interventions combined with strong school and community partnerships and referral networks can change behaviors and make a significant impact on the health of young people. In 2009 in South Africa, GRS piloted the SKILLZ-Girl program which addresses the unique needs of young women and adolescent girls. This program was then scaled in South Africa and expanded further into 13 countries in SSA. A recent evaluation of the SKILLZ-Girl program showed that participants significantly improved their knowledge and attitudes surrounding HIV risk for young women, negotiation skills, and sense of self-efficacy. In fact, 68.5% of girls that participated in the SKILLZ-Girl program underwent testing for HIV at the conclusion of the school-based curriculum. Although SKILLZ-Girl has now served over 26,000 girls in 14 countries, it has never been rigorously evaluated for cost effectiveness and effectiveness.

#### 6. Research questions

Our mixed-methods evaluation aims to assess the effect of the enhanced SKILLZ- girl on HIV testing and SRH related prevention services uptake (Aim 1), the effect of SKILLZ-Plus on HIV retention to care and VLS amongst HIV-infected girls (Aim 2) and identify mediating pathways and moderating factors leading to observed effects (Aim 3). Aim 3 will also assess the cost-effectiveness of the SKILLZ Package.

Our research questions are thus:

- a. What is the impact of enhanced SKILLZ-Girl vs regular SKILL-girl curriculum on HIV testing uptake among adolescent girls (aged 16 and over) over a 24-month period?
- b. What is the impact of enhanced SKILLZ-Club on HIV testing uptake among adolescent girls (aged 16 and over) over a 24-month period?
- c. Among HIV-positive adolescent girls, what is the impact of the SKILLZ-Plus intervention on:
  - a. retention in care and treatment at 6, 12, and 24 months
  - b. viral load suppression at 12 months?

- d. What specific barriers to access to services do the SKILLZ interventions (SKILLZ Girl, enhanced SKILLZ-girl, SKILLZ-Club & Plus) overcome?
- e. What are the mediators of the observed effects?
- f. What are the moderators of the observed effects?
- g. To what degree was the intervention implemented per protocol (fidelity)?
- h. What is the short- and long-term cost-effectiveness of the SKILLZ Package intervention?

# 7. Research aim(s)/General Objective and Specific Objectives

**Aim 1:** Assess the impact of SKILLZ over two years on:

- (i) (a) HIV testing and (b) SRH-related prevention services uptake among adolescent girls aged 16-19 in up to 9 intervention schools (with enhanced HIVST, PrEP, and contraceptive method offerings) compared to up to 9 control schools using a quasi-experimental difference-in-difference approach; and
- (ii) linkage to care and treatment, and viral load suppression and retention at 6, 12, and 24 months through a cohort model using pre-existing SmartCare data on HIV+ individuals in care to match to adolescent girls aged 16 and over from the same district (Lusaka) who are identified to be HIV+ at any time during SKILLZ Girl or SKILLZ Club participation and enrolled in SKILLZ-Plus.

This will be achieved by i) using a quasi-experimental difference-in-difference approach that compares girls aged 16 and over in 9 SKILLZ control schools compared to 9 schools where enhanced SKILLZ will be delivered with the enhanced HIVST and a variety of contraceptive method offerings; and ii) through a cohort model using pre-existing SmartCare data on HIV+ individuals in care to match to adolescent girls aged 16 and over from the same district (Lusaka) who are identified to be HIV+ at any time during SKILLZ-Girl or SKILLZ-Club participation.

Aim 2: Examine how the intervention works including lessons learned for future implementation by

- (i) conducting a process evaluation to identify mediators, predictors, and barriers to uptake of the SKILLZ-Girl, Club, and Plus curricula both quantitatively through mediation and moderation analyses and qualitatively through a sequential explanatory approach using focus groups discussions, interviews and observation with coaches and girls; and by
- (ii) monitoring fidelity

**Aim 3**: Estimate the short- and long-term cost-effectiveness and return on investment of the SKILLZ Girl, Club, and Plus curricula for improving health outcomes for adolescent girls.

# 8. Methodology

#### a. Study design

We will conduct a mixed-methods evaluation of the SKILLZ intervention using the following approaches:

A quasi-experimental cohort of school-aged 16-year old and over females to be followed for a two-year period will be evaluated with a difference-in-difference (DID) approach to estimate HIV testing uptake and sexual/reproductive health services use. Primary and secondary outcomes will be measured at several

timepoints longitudinally across up to 9 schools offering the enhanced SKILLZ-Girl and SKILLZ-Clubs program and up to 9 schools offering the "standard of care" (SOC) SKILLZ-Girl and SOC Clubs (see Figure 3). Recruitment will take 12 months on a rolling basis. The order in which schools will be selected will be random. Participants will be clustered at the school-level; we will enroll all girls aged 16-years at the commencement of SKILLZ-Girl and in Grade 10 from each participating school.

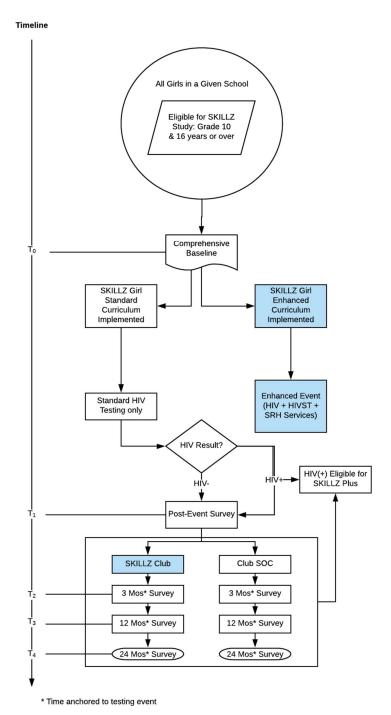
All enrolled girls will be followed over the two-year time period to assess SRH service uptake, including HIV testing. It is estimated that the majority (~98%) of girls testing for HIV will likely be HIV-negative, based on estimates from programmatic GRS data. While HIV-positive girls will continue to participate in the school-based SKILLZ-Girl and Clubs activities and followed for SRH use, they will also be offered contemporaneous enrollment into SKILLZ-Plus upon infection; retention in care and Viral Load Suppression (VLS) at 6, 12, and 24 months will be measured for this subset. See **Figure 2** for details of enrolment flow.

Process evaluation: We will conduct a process evaluation to better understand the casual pathways and effect mediators and moderators using mixed methods approaches, including supplemental qualitative data collection. To investigate reasons why the program components (SKILLZ-Girl, Club & Plus) might fail or succeed in different schools or communities and assess intervention effect mediators and moderators for HIV testing and contraceptive use uptake we will use a mixed methods approach involving: (1) quantitative analyses of baseline survey data for testing how variables can moderate the observed impact of the intervention, and (2) qualitative data collected from a subset of SKILLZ participants in the evaluation cohort and their coaches to further understand potential mediating pathways outlined in Figure 1.

**Fidelity monitoring:** We will also include measures to monitor fidelity of the intervention implementation, including receptivity to and understanding of the intervention amongst participants, the perceived appropriateness and relevancy of the intervention for adolescent girls in school, and the extent to which the intervention was delivered per protocol in different communities and schools.

**Economic evaluation:** We will estimate the short- and long-term cost-effectiveness and return on investment of SKILLZ for improving health outcomes for adolescent girls.

Figure 2. Evaluation enrolment flow



# b. Study site and population/Research materials

Lusaka is the capital and the most inhabited city in Zambia. Home to 2 million people, it has the highest HIV prevalence at 14%<sup>4</sup>. The study will take place across all the highly densely populated areas of Lusaka where

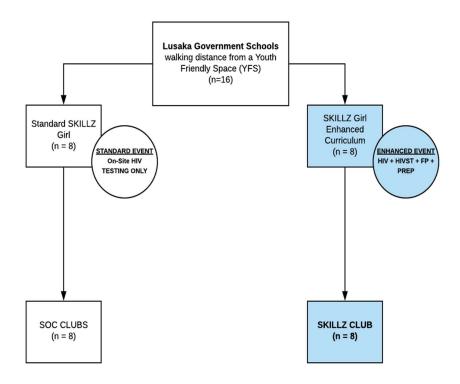
CIDRZ supports government MoH clinics with ARV services, electronic data management, and youth-friendly trained clinical personnel, and where GRS has been implementing their basic curriculum and events. All schools selected will be secular government schools. Approximately 80% of school-age girls are reported to be in school in Lusaka. To facilitate the evaluation of SKILLZ, all girls enrolled in up to 18 government secondary schools in Urban Lusaka that GRS currently serves will be eligible to participate in the SKILLZ program and will be randomly allocated to either the enhanced or SOC SKILLZ implementation. For measuring impact, only girls aged 16 and over enrolled in Grade 10 at the start of the intervention period will be surveyed and followed because youth aged 16 and over can consent for SRH/HIV services without additional parental permission<sup>55</sup>. (See *Section 9: Ethical Considerations* for details on waiver of parental consent).

#### c. Selection of participants, sampling methods and sample size

**Study Population:** In each school, we will recruit all girls in Grade 10 who are at least 16 years old at the start of the intervention period (i.e., the commencement of SKLLZ-Girl). Of the 30,000 youth in Lusaka that have benefitted from GRS services to date, GRS has seen HIV testing uptake of 62% as compared to a baseline of 13% (internal program data). We have powered the sample for our primary endpoints in Aim 1ii to account for attrition anticipated along the cascade (see below). For HIV testing, all eligible girls (estimated to be an average of 100 girls per school) in up to 18 schools is large enough to detect a significant difference in testing uptake if setting statistical significance at  $\alpha$ =0.05,  $\beta$ =0.2, ICC=0.1, and an expected testing uptake of 60% (control) and 80% (intervention).

Cluster randomized controlled trial: We will select up to 18 (2 pilot + 16 for full implementation) schools from the Urban District of Lusaka to receive the SKILLZ-Girl curriculum. Of the total (up to 18), half will be randomly allocated to host the standard SKILLZ-Girl curriculum, and the remaining half (e.g., up to eight) will be randomized to either enhanced SKILLZ-Club. Those schools randomized to standard SKILLZ Girl curriculum will only have access to SOC clubs. Those schools selected for enhanced SKILLS Girl curriculum will offer SKILLZ Club. See Figure 3 for study allocation flow.

Figure 3. School Selection Flow Chart



#### ONGOING REFERAL TO COMMUNITY CARE FOR SERVICES

We anticipate that most of our evaluation cohort will not be HIV-infected. Thus, the retention to SRH analysis drives the sample size calculation of 351 girls using contraception at the end of two years, with, and risk ratio difference of 0.3 (30%) between the SOC and enhanced SKILLZ-Club schools. To realize the 351 needed to meet requirements for estimate sensitivity, we augment the initial sample size receiving the SKILLZ-Girl curriculum accounting conservatively for 25% uptake of SRH methods and multiplying by two to assess the difference within each SKILLZ-Girl model (phase 1) and accounting for attrition across the two years of follow-up (12.5%) resulting in a starting sample size of 3159 (((351/0.25)x2)x1.025). SKILLZ-CLUBS will act as an extension to the SKILLZ-Girl curriculum enabling participants to seamlessly transition from the SKILLZ-Girl curriculum into the SKILLZ-Club. We anticipate minimal attrition (~15-20%). Participants will spend the majority of the study window in SKILLZ-Club and it is through the SKILLZ-Club affiliation that we will follow-up and ascertain outcomes for those enrolled longitudinally.

For the small minority of girls found to be HIV-infected across all schools where the study will be conducted, we will evaluate linkage to care and on treatment, VLS, and retention in care for a period of two years. These girls will be encouraged to continue on to the HIV positive-specific SKILLZ-Plus facility-based curriculum. We will quantitatively measure the impact of SKILLZ-Plus on linkage to care and treatment, retention and viral load at 6, 12, and 24 months after diagnosis (or since participant is identified by GRS as HIV+) using SmartCare data and compare to an existing matched cohort.

Process evaluation: From 8 purposively selected intervention (n=4) and control schools (n=4), a subset of evaluation cohort study participants will be invited to participate in the qualitative research based on their HIV and SRH outcomes. In this study, we will use a sequential explanatory mixed method design<sup>56</sup> to explain the outcomes after each evaluation time point (post-test, 3 mons, 12 mons and 24 mons). This means that participants will be selected based on the their SRH and HIV outcomes to join either IDIs, FGDs, or narrative interviews in (Figure 4). Six girls from each school (n=36) will be identified for IDIs after each survey time-point (n=4). We will select a mix of girls who have either opted to accept, engage with or decline the services being offered, in order to understand the drivers and barriers to acceptance of these services for the IDIs. We will conduct 1 FGD per school (n=6) each consisting of 8 girls (n=42). Girls enrolled in the SKILLZ Package will be selected for the FGDs. In order to gain a deep understanding of the barriers and mediators for retention into HIV care for those girls testing HIV positive, 1 HIV+ girl per school (n=6) will be invited to participate in narrative interviews. Girls will be chosen from different backgrounds (e.g., age, SES, single vs. dual parent homes) as assessed in the survey in order to compare responses between cases. For fidelity monitoring, we will verify that all three interventions are delivered as planned (fidelity of intervention both in inputs and outputs) and document participants' reception (understanding and use of the interventions), appropriateness of the intervention and equality in reaching all types of girls by verifying uptake by risk factors collected at baseline such as SES, sexual activity and HIV knowledge. The assessment will be supported by quantitative measurements coming from programmatic data (e.g., frequency and attendance at SKILLZ-Plus meetings, frequency of home visits), and from reports and interviews of program manager and coordinator, coaches, as well as from the programmatic-level information from the qualitative interviews.

SKILLZ Club + Enhanced Club + SKILLZ Plus SKILLZ Girl + SKILLZ Enhanced Post-test survey 3 Months survey 12 Months survey 24 Months survey IDIs and FGDs Narratives IDIs and FGDs Narratives 6 High SRH 6 Low SRH + Low SRH + High SRH + 1 HIV + HIV + + HIV HIV HIV Outcomes Outcomes Outcomes Outcomes

Figure 4: Sequential Explanatory Study Design

**Economic evaluation.** No human subjects will be enrolled for this component.

### d. Data collection plan and tools

**SmartCare electronic data:** All antiretroviral therapy services offered as part of the study will be captured in SmartCare, which permits measuring of utilization and clinical outcomes (i.e., Linkage to Care, VLS) at soccer events, mobile clinics, and public clinics in Lusaka. VLS is defined as below detection, i.e. less than 50 copies/ml. Retention in care will also be measured using SmartCare data on pharmacy visits and defined as accessing pharmacy within a 90-day window of visits. Consent will be requested from all participants as part of the consent process to access their SmartCare records.

Youth-Friendly services electronic data: Depending on the location of the school, the girl's residential address and/or her own personal preferences, participants will be referred to either the PEPFAR Funded DREAMS houses or the M.A.C. funded youth-friendly spaces based in local MOH clinics in order to access ongoing SRH services after the events (this will include accessing PrEP, STI testing and contraceptive methods). All interactions with the DREAMS houses or M.A.C centres (including meeting with counselors, referral and uptake of services) are captured in their respective electronic databases. Consent will be requested from all participants as part of the consent process to allow researchers to access either DREAMS or M.A.C data should they chose to access either of these services.

**Survey at baseline:** A baseline survey will be administered to all to collect information on school characteristics, sexual behavior, age, HIV knowledge, maternal education, baseline HIV status, and sexual/reproductive health uptake and retention. These variables will be used as covariates and moderators for service uptake and retention. The target sample of 3,200 girls will respond to a survey self-administered using REDCap software upon informed consent. The survey will be available in English, Nyanja and Bemba. Coaches and study staff will on site be help girls navigate the survey.

Survey post-SKILLZ-Girl event, 3-, 12-, and 24 months: All girls (regardless of HIV status) will respond to a REDCap survey to collect information on sexual behavior, HIV knowledge, maternal education, sexual/reproductive health uptake and retention. Post-SKILLZ-Girl survey data will be used to assess the effect of SKILLS Girl and SKILLZ-Club on the outcomes of interest. In schools selected to offer SKILLZ-Club, surveys will be conducted during club attendance approximately 3 months after the SKILLZ-Girl community soccer event; coaches will help them navigate the survey. If a participant has opted to not attend the clubs or has since left or changed schools, the coaches and study staff will attempt to trace participants in the community in order to complete the follow-up survey.

In the schools selected not to offer SKILLZ-Club, GRS will arrange for a 2-hour meeting session with all participants still enrolled at that school, where all participants will complete the surveys. If a participant opts to not attend the meeting or has since left or changed schools, the coaches and study staff will attempt to trace participants in the community in order to complete the follow-up survey.

The survey will record any changes to their home environment from baseline, again ask about self-reported sexual and risk behaviors and HIV knowledge (i.e., post-test for HIV education curriculum), and further quantitatively measure potential mediating pathways. Based on validated scales, the survey will include modules to assess stigma;<sup>57</sup> empowerment;<sup>58</sup> and self-efficacy<sup>59</sup> in general and specific to SRH/HIV;<sup>60</sup> disclosure, extent of social support from different sources (e.g., family, peers, teachers), and trust in health providers.<sup>61</sup> Individual lost to follow-up (LTFU) will be traced following standard procedures. Active follow up and tracing of late or lost patients enrolled into HIV care or receiving ART is part of the National treatment program. We will partner with pre-existing CIDRZ community volunteers responsible for follow up to ensure that efforts are synchronized, and that data are shared and entered into SmartCare. CIDRZ already has an international reputation leading effort to track those who are lost to ensure participants return for visits and viral load testing as per national guidelines.<sup>98</sup>

Qualitative methods: Because a number of hypothesized intervening pathway concepts may be difficult to quantitatively measure with sufficient precision in the survey (e.g., trust in health providers and facilities, 62 social support, empowerment), particularly for adolescents, we will also collect a variety of qualitative data to further investigate factors that SRH uptake and HIV treatment outcomes (see Table 1). Through a phenomenological and narrative study approach, we aim to understand factors involved in decision-making for uptake by learning from girls about how psychological, social and structural factors affected their health decisions also including personal beliefs, perceptions and motives. Additionally, we will document individual stories (narrative approach) regarding how HIV infected girls experience the mediating factors (such as stigma, disclosure, social support and trust in the health facility) and how they affect their adherence to care (see Figure 1). These narratives are valuable in revealing the process of problem identification to resolution. 63

Table 1. Qu	Table 1. Qualitative data collection methods for Aim 2i							
Outcome	Research Question	Method	Sample					
SRH	How do psychological, social	IDIs	N=36: 6 girls from each of the 6 schools					
Outcomes	and structural factors affect		selected based on their SRH outcomes.					
	SRH behaviors and the use of							
	contraceptives?							
	How do familial, social, and	FGDs	N=6: 1 (8 participants) per purposively selected					
	structural factors affect the		school (intervention and control). Girls enrolled					
	decision access and utilize		in the SKILLZ package will be selected					
	contraception?							
HIV	How do psychological, social	IDIs	N=36: 6 girls from each of the 6 schools					
Outcomes	and structural factors affect		selected based on their HIV testing outcomes.					
	HIV testing behaviors?							
	How has	Narrative	N=6: HIV-positive girls enrolled in SKILLZ-Plus					
	stigma/disclosure/social	interviews						
	support/trust in the health							
	providers influenced							
	adherence?							
	How do familial, social,	]						
	structural factors affect the							
	decision to stay in care?							
Fidelity	How closely do coaches follow	Passive	N = 6: 3 SKILLZ-Girl AND 3 SKLLZ Club sessions					
	the curriculum and how do they	Observations						
	adapt or modify their delivery							
	based on barriers to							
	implementation?							

**Extraction of programmatic data:** Quantitative measurements coming from programmatic data (e.g., frequency and attendance at SKILLZ-Plus meetings, frequency of home visits) will be collated from reports, supplemented with interviews of implementing staff (e.g., program managers and coordinators, coaches)

to track key process indicators. This may also be triangulated with programmatic-level information from the qualitative interviews.

#### e. Data management and storage

#### Quantitative:

We will collect individual-level data on clinical, laboratory, and demographic characteristics, including retention in care and VLS at 6, 12 and 24 months. Using case reporting forms (CRFs), we will collect study-specific data, including information obtained directly from participants, routine programmatic data from GRS and abstract routine clinical data from paper-based medical records, the SmartCare Electronic Management Records (EMR), CIDRZ Laboratory Information Management System (LIMS) and DREAMS electronic management system. Routinely collected individual-level clinical data are first written onto forms in the paper medical record and then entered into the SmartCare EMR. SmartCare serves as a repository of clinical data for HIV-infected individuals and includes such data fields as: ART initiation date, ART regimen, visit dates, and laboratory data.

GRS will collect programmatic data through a combination of paper and electronic data entry via tablets, with all data stored securely in RedCap. Where paper files are used for programmatic management, data will be manually entered by study staff directly into the RedCap database. De-identified data will made available to GRS co-investigators to allow them to view key fidelity and quality indicators in order to monitor implementation in real time.

All paper study files will be stored in secured, locked cabinets located in locked rooms available to study staff only. The keys to the locked cabinet will be kept by study staff and not made accessible to non-study personnel.

A secure server will be used to store encrypted study data, including the study database. The research database will be developed using REDCap (Research Electronic Data Capture, Nashville, Tennessee, USA) and hosted on the secure CIDRZ server. Scheduled backups will be done routinely. A password will be required to gain access to the study dataset, and access will be restricted to key study personnel only. All personal identifiers will be removed prior to generating the analytical dataset.

Qualitative: All data will be obtained using digital audio recorders. Recorded data will be transferred on to a lockable computer kept by the co-principal investigator leading the qualitative research. Recordings will be shared with transcribers who will transcribe the voice recorded data into verbatim. Transcripts will go through a QA/QC process where researchers will cross check randomly selected transcribed verbatim with the recordings. Where errors are found, changes will be made to reflect the recordings accurately. Once this process is done and the quality of transcripts has been assured, recordings will be destroyed. Transcripts will be kept by 3 researchers including the Co-PI and stored electronically in a password protected computers accessible only to the 3 researchers. Transcripts will also be printed for analysis purposes and kept in a designated room in locked cabinets accessible only to the Co-PI. All qualitative data will be destroyed after 3 years in line with MOH recommendations.

#### f. Data analysis plan

Difference-in-difference model. The primary outcome is the probability of testing for HIV at any time during the period when SKILLZ is delivered through to 24 months after the final soccer event. The primary analysis for Aim 1 will follow a difference-in-difference (DID) effect between study arms. The outcome of interest will be regressed on an indicator of study arm assignment interacted with a dichotomous variable POST which indicates the outcome after the intervention is implemented; this differentiates baseline and end-line for each study arm, controls for any time dependent variables that might confound the effect, as well as any time-invariant observed or unobserved confounders that might differ between study arm schools. Because of this, the DID is robust to time-invariant unobservable confounders (e.g., school quality) and time trends (e.g., secular increase in testing). Our estimator relies on the assumption of common time trends across intervention and control in absence of the intervention, and of static population. Additionally, we control for baseline individual and school-level moderators that may be unbalanced at baseline after randomization. School-level controls include size, promotion rates, sex composition and repetition and dropout rates (available in the district education office) and individual girls' controls include age, grade, maternal education, HIV knowledge. Clustering by school will be accounted for by a generalized estimating equation approach. We will estimate intention-to-treat (ITT) by including all girls in the evaluation cohort assigned to each arm rather than all girls who actually participated in SKILLZ.

Individual-level matched cohort analysis for HIV-infected: The analysis will follow an individual ITT estimator among individuals found to be HIV-infected, who will then be matched (based on clinic, age, ART state date, and gender) to HIV-infected individuals in the SmartCare database. The outcomes are the proportion of enrolled HIV+ girls who linked to care, who are virally suppressed and retained in care at 6, 12, and 24 months after diagnosis of HIV+ (using national electronic HIV medical record data). We will conduct an ITT analysis for the logistic probability of being suppressed at 6, 12, and 24 months after HIV+ diagnosis, where girl is the unit of analysis. All data will be analyzed using STATA.

**Process evaluation:** This will involve quantitative and qualitative analyses:

Quantitative analysis: Surveys conducted at baseline will be used to identify differential effects among girls who do and do not take up services according to baseline moderating variables as specified in **Figure 1** and as assessed by previous sexual behavior, HIV testing/status, knowledge, maternal education by interacting the main exposure by these indicators. Statistical mediation will be assessed using the causal inference-based approach of Valeri et al., which yields optimal estimates of indirect effects in the presence of binary outcomes and moderator-mediator interactions,<sup>64</sup> and robust standard errors to address clustering of individuals within facilities, and account for multiple causally depending mediators.<sup>65</sup> Significant indirect and total effects of integration markers on outcomes accompanied by non-significant direct effects will signify mediation. The interplay between exposure, effect modifiers, moderators and outcomes in the causal chain is represented in **Figure 1**. For analyses, we will use mixed effect structural equation models in STATA and MPLUS with bootstrapped standard errors to test the contribution of indirect effects.

<u>Qualitative analysis:</u> All interviews will be voice-recorded, transcribed and coded using a thematic analysis process<sup>66</sup> (e.g. in NVIVO or Atlas.ti). Analysis will begin with familiarization of the data that will involve

reading and re-reading of the transcripts to understand the data. Notes will be taken down at the point of familiarization to guide the development of the codebook. Codes will be extracted both inductively (bottom-up) and deductively (top-down). Inductively, open coding will be conducted to identify interesting and meaningful text in each line of the transcripts. Each piece of text will be grouped under a specific code that describes the meaning of the text. Once all the text has been coded, the researchers will then identify themes that tell something significant about the research questions and group a set of codes under each related theme. The themes will then be reviewed by reading each code and its associated text and rearranged or removed in order to refine the themes and their meaning. Secondary coding will be applied to uncover the latent meaning of each of the themes. Themes will then be re-coded to uncover the latent meaning of the themes and refine their definitions.

Deductively, attributes from the RE-AIM process evaluation framework will be used to create the themes.<sup>67</sup> These attributes are "reach, effectiveness, adoption, implementation and maintenance." Transcripts will be coded under each of these attributes and subsequently be refined using the same process described above.

**Fidelity monitoring:** *Fidelity* will be measured by recording number of visits for coaches in the intervention and attendance, number of soccer events and attendance, number of home visits by coaches (e.g. for missed visits), as well as with key-informant interviews with coaches and with the study coordinator to understand how the intervention was implemented and will report in any discrepancy from protocol. Reception of the intervention. During the FGDs we will assess how the participants understood and used the intervention. Appropriateness and relevancy: During the FGDs to coaches and girls we will inquire about appropriateness and relevancy of soccer as a platform for adolescent programs. Reach of program: this will be captured by number and proportion of referrals (using SmartCare) to the health facilities that were successfully linked, as well as the presence of adolescent friendly corners at facility, number and type of adolescent clinical services delivered.

Economic evaluation: We will assess cost-effectiveness in three steps. First, we will assess the net cost of the intervention and its consequences, using micro-costing and modeling techniques. Costs for the intervention itself will include mainly personnel to manage the intervention and the financial incentives. Costing of the intervention and control models will be captured in costing sheets that will be prepared before the start of the intervention aimed at capturing costs as they are spent; we will limit the costing from the provider perspective and will only limit costing to programmatic and not research costs. We will also cost the change in health care utilization precipitated by the intervention: both increased preventive care and decreases in curative care. This will be assessed combining utilization with standard values for unit cost (per MOH official records). Together, these generate net costs. Second, we will quantify the health benefits of the intervention, including health events (e.g., number and type of opportunistic infections, STIs) and Quality-Adjusted Life Years (QALYs) which translate morbidity in the short and long term (projected based on published longitudinal clinical studies) into a standard metric of health status. Health state utility data (for QALYs) will derive from studies in the literature. The analysis of expected costs and QALYs in the intermediate and long-term will be structured using a spreadsheet-based decision analysis created for this purpose in consultation with clinical experts. Third, we will calculate the economic outcome measures including the Incremental Cost-Effectiveness Ratio (ICER) and Return-on-Investment (ROI). The ICER is the ratio of net cost to health gain, comparing the SKILLZ-Plus to control (e.g., ICER for

HIV testing = (C\_intervention - C\_control)/(Testing rate\_intervention - Testing rate\_control)), and is indicated if the intervention has a net cost (i.e., does not save money) while improving health outcomes (QALYs gained). All analyses will be repeated for 1, 2, 5, 10, & 20 years, and subjected to extensive sensitivity analyses to test the impact of uncertainty on results.

#### 9. Ethical considerations

This study proposes to evaluate the impact of the SKILLZ Package (SKILLZ-Girl, SKILLZ-Club and SKILLZ-Plus) on the uptake of HIV and SRH services including uptake and adherence to contraceptive services, HIV testing, linkage to care and adherence, VLS and retention in care. This will be done by the review of GRS programmatic data, conducting surveys and implementing IDIs and FGDs with adolescent girls aged 16 and over as well as program staff involved in the implementation of the SKILLZ package. It will also require access to adolescents' medical records in order to evaluate impact on the HIV outcomes mentioned above.

Parental Consent. Prior to the commencement of the SKILLZ-Girl program, parents of all girls who will be aged 16 and 17 years and above and in Grade 10 at the commencement of SKILLZ-Girl, will be invited to attend a sensitization session for the study. During this sensitization they will be asked to give consent for their children to participate. Parents who do not attend the session, will be visited in their home by a member of the study team in order to sensitize participants. Study staff will only obtain assent from participants whose parents or guardians have previously given consent. Participant information sheets will be given to them in a language of their choice between Nyanja, Bemba and English, all common in Lusaka. If they are unable to read (i.e. illiterate), a witness aged 18 years and over (not directly involved in the study) will be invited to be part of the consent process to verify that the information being given by the research assistant is accurate. The information sheet will contain information including the purpose of the study, the procedures and risks and benefits. The right to withdraw at any time will also be emphasizes to all participants.

**Informed Assent.** Girls aged 16 and 17 years who plan to participate in the SKILLZ program, and whose parents have given prior consent, will be approached by the study team for their assent to participate. The same participant information sheets will be given to them in a language of their choice between Nyanja, Bemba and English, all common in Lusaka. If they are unable to read (i.e illiterate), a witness aged 18 years and over (not directly involved in the study) or a teacher (only of the adolescent is comfortable) will be invited to be part of the consent process to verify that the information being given by the research assistant is accurate. The right to withdraw at any time will also be emphasizes to all participants. Individuals will be consented privately, in a separate room, to maintain confidentiality.

#### **Informed Consent:**

Girls aged 18 years and above will be approached by the study team without prior consent from their parents and will be invited to complete a consent form in a language of their choice (Nyanja, Bemba or English). If they are unable to read (i.e. illiterate), a witness aged 18 years and over (not directly involved in the study) or a teacher (only of the adolescent is comfortable) will be invited to be part of the consent process to verify that the information being given by the research assistant is accurate. The right to

withdraw at any time will also be emphasizes to all participants. Individuals will be consented privately, in a separate room, to maintain confidentiality.

**Involvement of Vulnerable Populations.** We are targeting adolescent girls aged 16 years and over. We are aware that the population we would like to include in our study are considered a vulnerable population in line with the World Health Organization guidelines as well as the Zambian guidelines. The evaluation is targeted at this group to see whether the benefits of HIV prevention and treatment services empower girls to seek HIV and other family planning services without shame or fear and contribute knowledge that may be applicable to countries with similar settings.

Potential Risks and Protection against Risk.

#### **Psychosocial Distress**

The potential risks to participants of this study are minimal. We are aware that the adolescents targeted for this study share unique characteristics from the adult population that need to be considered throughout the roll out of the study. Adolescents participating in this study may experience psychological distress such as sadness, anxiety, distraction or stress when being surveyed or interviewed. To address this all field staff will be trained to offer referral resources and procedures for psychological, social service, and other emergency needs.

#### Stigma

Stigma may also arise as a result of follow-up visits by research assistants. Due to various HIV related studies and programs, follow-up visits in the community by an identifiable clinic staff is usually perceived as an adherence visit for one who is HIV positive. Therefore, follow-up visits conducted during the course of this study, may be perceived as such and lead to HIV related stigma for any members of a household. To avoid this, research assistants will be dressed as regular members of the community with no specific identifying information such as T-shirts, ID's or badges. ID's will only be shown once inside the home or when requested by local authorities.

#### **Loss of Confidential Data:**

It is highly unlikely that confidential data will be lost during this study. However, we know that it is possible that other unauthorized personnel may view the data, or the data may be stolen or lost. In such cases, measures will be implemented to ensure no harm is posed to pupils. Except for the consent form, no identifying information will be collected or documented during assessments, analysis and reporting. Teachers and other school staff will not be allowed to see any confidential information unless it is the wish of the parent. Only coaches and selected clinical study staff will be allowed to have contact information of pupils in order to facilitate HIV testing and adherence counseling services. It will be the responsibility of these staff to use their contact information for the purpose of follow-ups only. They will be trained in research ethics where confidentiality will be emphasized. All identifying information will be stored in a separate password protected database from other project data. Consent forms will be scanned by study staff and stored in the password protected database. The original paper copies will be kept in a locked cabinet in a secure room at the CIDRZ offices.

Potential Benefits.

Study participants will receive no direct benefits for participating in the study. They will not be given any money for participating in the study. Those pupils invited to attend a focus group discussion will be given refreshments during the discussion. In cases where focus group discussions are held on weekends, students will be given a transport reimbursement in addition to refreshments. A K100 will be provided for transport reimbursements and lunch allowances where necessary.

# **10.**Timelines

Timeline	2	018		2	019			2	020			2	021			2	022	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Protocol development and planning																		
IRB/ REC submission																		
IRB/REC Approval																		
Study preparation																		
Recruitment																		
Participant follow up																		
Data cleaning and analysis																		
Study close out activities																		
Dissemination of results																		

# 11.Budget

	Year 1	Year 2	Year 3	Year 4	Year 5	
Salaries and Wages	ZMK 235,082	ZMK 235,082	ZMK 235,082	ZMK 262,469	ZMK 262,469	
Fringe Benefits	ZMK 73,838	ZMK 73,838	ZMK 73,838	ZMK 83,536	ZMK 83,536	
Personnel Costs (Subtotal)	ZMK 308,920	ZMK 308,920	ZMK 308,920	ZMK 346,006	ZMK 346,006	
Travel				ZMK 37,624		
Other	ZMK 82,163					
Subaward/Consortium/Contractual Costs	ZMK 5,380,354	ZMK 4,901,077	ZMK 4,880,127	ZMK 4,835,098	ZMK 4,629,423	
TOTAL Direct Costs	ZMK 5,767,853	ZMK 5,292,159	ZMK 5,271,210	ZMK 5,300,891	ZMK 5,057,591	
Facilities and Administrative Costs	ZMK 423,522	ZMK 101,679	ZMK 101,679	ZMK 121,100	ZMK 111,318	
TOTAL COST	ZMK 6,191,375	ZMK 5,393,839	ZMK 5,372,889	ZMK 5,421,991	ZMK 5,168,909	

# 12. Appendices

# a. Letter of Permission from MOGE for GRS to continue working in schools in 2019

All Correspondence should be addressed to the District Education Board Secretary

Telephone: 0211 - 240250/240249/0955 623749 E-mail: desbsisk@yahoo.co.uk



In reply please quote

# REPUBLIC OF ZAMBIA MINISTRY OF GENERAL EDUCATION

DISTRICT EDUCATION BOARD SECRETARY
P.O. BOX 50297
LUSAKA

12th February, 2019

The Country Director Grassroot Soccer Lusaka District.

REF: PERMISSION FOR GRASSROOT SOCCER TO CONTINUE WORKING IN SCHOOL FOR THE YEAR 2019.

The subject above refers.

Our office is pleased to once again permit your organization to continue working with both private and government schools in Lusaka District for the year 2019.

We have felt compelled to renew your mandate with the schools as we have noted that the activities you have been implementing have continued to be beneficial to the adolescents in school.

As you proceed with your programs, kindly ensure that you do not disturb any teaching and learning programs in the schools.

We wish you well in your endeavours.

Beard H. Mwanza.
District Education Board Secretary
LUSAKA DISTRICT.

# b. MOU between GRS and MOGE

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	ZAMBIA DAVI ZATI D
_	Ministry of Education
	Ministry of Education
	MEMORANDUM OF UNDERSTANDING
_	BETWEEN
	MINISTRY OF EDUCATION
-	WINISTRY OF EDUCATION
	(ACTING ON BEHALF OF THE GOVERNMENT OF THE REPUBLIC OF ZAMBIA)
	AND
	GRASSROOT SOCCER EDUCATION LIMITED
_	GRANDSKOOT SOCIEDA ED COMMON EMISSEE
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#### WHEREAS:

- 1. GRS responds to the urgent need for innovative, large-scale, youth-focused, comprehensive prevention programmes. GRS is an initiative focused on preventing new HIV infection in youth using the game and principles of soccer and soccer role models (coaches, trainers, national and international players) as the innovative medium.
- GRS is a non-profit, non-governmental organisation using the power of soccer in the flight against HIV and AIDS, by providing Zambian youth with knowledge, skills, and support to remain HIV free.
- 3. The Parties intend, to the extent that their respective resources, interests, and abilities permit, to collaborate in providing HIV and AIDS awareness and prevention education to the people of Zambia.
- 4. The Parties to this MoU are desirous of co-operation with a view of decreasing the HIV prevalence rate in Zambia and providing opportunities for non-formal education to Zambian youth by facilitating interventions, VCT Tournaments, and Training of Coaches.
- 5. This MoU outlines the terms and conditions under which GRS can operate in cooperation with MoE.

#### NOW THIS MOU WITNESSETH as follows:

#### ARTICLE 1.

#### 1.0 Definitions

In this MoU unless clearly inconsistent with or otherwise indicated by the context the following terms shall have the following meanings:

"Beneficiaries" means Zambian youth between the ages of 12 and 18 who benefit from GRS programmes.

"HIV Prevention" means the critical relationships between the epidemiology of HIV infection, the risk behaviours that cause exposure to HIV transmission, and the collective social and institutional factors, such as sexual norms, gender inequality, and HIV related stigma, which will otherwise continue to fuel the HIV epidemic.

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PM

"Implementing Partners (IP)" means schools, organisations, clubs, academies and other entities working with GRS to incorporate GRS's specialized curriculum and programme into their programming.

"MoU" means this Memorandum of Understanding.

"NASF 2006 2010" means the current National AIDS Strategic Framework

"Peer Educator" means teachers, mentors, coaches and others trained in the GRS Curriculum

"Programmed Activities" include eight (8) week intervention programmes, VCT tournaments, and ToCs.

"ToC" means Training of Coaches in the GRS Curriculum.

To this end, the MoE and GRS agree as follows:

#### **ARTICLE 2**

- 2.0 Scope of the Agreement
  - 2.1 The terms of co-operation for each specific activity under this MoU shall be mutually discussed and agreed upon in writing by both parties.
  - 2.2 The Parties agree to promote and co-operate with the view to use the power of soccer in the fight against AIDS, by providing Zambian youth with the knowledge, skills, and support to remain HIV free.
  - 2.3 GRS offers HIV and AIDS prevention programmes that uses an evidence-based approach derived from current best practices in HIV prevention in youth, youth communication and sport-for-development to inform a comprehensive communication and outreach strategy.

2.4 GRS aims to make a significant contribution to the fight against HIV and AIDS by engaging youth in the fight against HIV and AIDS prevention.

- 2.5 MoE recognizes GRS as a national partner for the development and implementation of an effective, high quality HIV and AIDS prevention strategy that includes a community based model, advocacy, partnership and resource development.
- 2.6 MoE recognizes GRS as an institution responsible for developing Zambia's sportfor-development HIV and AIDS strategy.

#### **ARTICLE 3**

#### 3.0 Competent Authorities.

The competent authorities for purposes of the implementation of this Agreement shall be:

- 3.1 The GRS Secretary as designated below.
- 3.2 This MoU also recognizes the close relationship that exists between GRS and its implementing partners.
- 3.3 The Government of the Republic of Zambia recognizes that GRS needs to enter into partnerships with local organisations in order to effectively implement GRS's HIV and AIDS strategy.
- 3.4 The Government of the Republic of Zambia designated its MoE to be legally represented in this matter by the Permanent Secretary Human Resource and Administration (HRA) of MoE

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#### **ARTICLE 4**

#### 4.0 Obligations of both Parties

#### Obligations of the Ministry of Education

Under this agreement and subject to the Project Activity MoUs that may be entered into hereafter, GRS may furnish assistance to the people of Zambia for the purpose of education and development in accordance with the priorities of the MoE.

- 4.1 GRS shall identify, in consultation with the relevant Government Ministry departments and other MoE recognized organisations, specific geographical areas of Zambia and projects requiring external assistance.
- 4.2 The term "Project Activities" shall mean all activities carried out by GRS for the benefit of the youth of Zambia
- 4.3 The term "Project Materials" shall mean all approved commodities, equipment, vehicles, materials and other property that are used by GRS in support of its Project Activities, or for the distribution to the people of Zambia or to the refugees within the scope of the Project Activities.
- GRS may participate in implementing donor-funded projects, through various MoE departments as a sole consultant or in joint venture with other Government recognised Non-Governmental Organisations.
- 4.5 The MoE shall grant to GRS and its staff authorization to maintain and operate an external banking account for funds originating from external sources and the balance of such account shall be transferable into any freely convertible foreign
- 4.6 The MoE will grant GRS the right to visit any area of the country not otherwise prohibited by law, and to discuss Project Activities with current and potential Implementing Partners and others involved in the project.
- 4.7 The MoE shall co-operate with GRS in obtaining monitoring and evaluation reports on Project Activities to be used in informing GRS donors on the effectiveness of its contribution and in raising additional support.
- 4.8 The MoE shall allow GRS to enter into public/ or private donor agreements that support programmed requirements.
- 4.9 The MoE will enable GRS to participate in Ministry-organised trainings, workshops, seminars and conferences that are deemed relevant to the advancement of GRS Project Activities and to the health and education of the young people of Zambia.

#### **Obligations of GRS**

- 4.10 GRS will provide leadership in establishing standards of good practice, and in applying high quality, sustainable, evidence-based HIV and AIDS programmes.
- 4.11 GRS will recognize and co-operate with other key bodies of the Government of the Republic of Zambia including the Ministry of Sport and Child Development, Ministry of Community Development and Social Services, and the Ministry of Health.
- 4.12 GRS will assist in attaining the objectives of the NASF 2006 2010. In particular, GRS will:
  - (i) Work with the Government of the Republic of Zambia to intensify its prevention programmers by implementing the GRS evidence-based and

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comprehensive curriculum. The GRS curriculum encourages abstinence among unmarried youth, faithfulness among the married, and condom use for discordant couples, HIV+ individuals, and for individuals who are at risk and/or unable to abstain or to remain faithful to an uninfected partner. Additionally, GRS aims to break down stigma and discrimination against people living with HIV and AIDS (PLHA), open dialogue between Zambian youth and Peer Educators on HIV risk factors, and to teach young people life skills live HIV and AIDS free.

- (ii) Promote a comprehensive set of communication objectives aimed at improving knowledge, behaviour change towards safer sexual practices, accessing VCT and referrals to treatment, care and support services, as well as to mitigate stigma and discrimination.
- (iii) Strengthen the MoE's capacity by identifying potential peer educators to be trained through ToCs in the GRS curriculum.
- (iv) Collaborate with the Government of the Republic of Zambia in matters pertaining to the indicative core strategies of NASF 2006-2010 and in matters pertaining to the prevention of HIV and AIDS in Zambia.
- 4.13 GRS will seek to assist the educational community in Zambia to improve its outreach to Zambian youth in the field of HIV and AIDS, thereby promoting community benefits.
- 4.14 GRS shall maintain a Country Office in Zambia for the purposes of monitoring, coordinating and promoting all aspects of its work in Zambia. GRS will be responsible for the transportation and housing of all non-Zambian staff from the time of their arrival in Zambia.
- 4.15 GRS shall provide monitoring, evaluation, oversight and accountability on project activities and use of resources.
- 4.16 GRS shall recruit and pay wages of all local staff working under its employment and in accordance with the labour statutes and regulations of Zambia. GRS shall also remunerate all local staff according to the organisation's ability to pay.
- 4.17 GRS shall, where possible, raise funds and manage those funds received from donors for specific projects in Zambia.
- 4.18 In its role as MoE's partner, GRS will act in the national interests and take into account the priorities of Zambia's educational needs. GRS shall endeavor to have programming activities complement the MoE Vision and Development Plans.

#### **ARTICLE 5**

#### 5.0 Status Personnel

#### Status of Non-Zambian Personnel

- 5.1 Non-Zambian staff of GRS have volunteers status.
- 5.2 The non-Zambian Secretary shall be authorized to maintain and operate an external banking account with the provisions set down in Article III paragraph 4.6 of this MoU.
- 5.3 Non-Zambian staff will endeavor to embrace and respect Zambian culture, laws and policies of Zambia. Individuals who violate the above-mentioned will take responsibility and consequences thereafter.

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#### Status of Zambian GRS Personnel

- 5.4 Zambian GRS staff shall be employed in line with the provisions of the Zambian law
- 5.5 All Zambian staff employed by GRS shall be given equal opportunities for responsibility, growth and development as their non-Zambian staff colleagues and shall be treated with mutual respect.
- 5.6 Zambian GRS personnel shall be required to pay all the taxes in accordance with the relevant provisions of the Laws of Zambia.

#### ARTICLE 6

#### 6.0 Financial Obligations

- 6.1 This MoU imposes no financial obligations on either Party.
- 6.2 The Parties to this MoU understand that any financial arrangement entered into will have to be negotiated and will depend on the availability of funds.

#### **ARTICLE 7**

#### 7.0 Liabilities and Indemnities

- 7.1 Subject to the provisions of this agreement, GRS personnel shall at all times be subject to such laws and regulations that exist in Zambia
- 7.2 MoE shall not be liable to indemnify any third party in respect of any claim, debt, damage or demand arising from the action taken by GRS or its representatives acting not under authority of control of MoE.

#### ARTICLE 8

#### 8.0 Entry into Force, Duration, Termination and Addresses

- 8.1 This MoU shall come into force upon both Parties appending their signature thereto, pursuant to Article 8, and shall remain in force for a period of three (3) years and may be renewed for a further term of three (3) years by mutual written agreement of both Parties.
- 8.2 This MoU may be terminated at any time upon either MoE or GRS providing three (3) months notice in writing of intention to do so.
- 8.3 All notices or other communications under or pursuant to the Agreement shall be delivered in writing to the offices or addresses indicated hereunder.

### ARTICLE 9

#### 9.0 **Dispute Resolution**

9.1 Any dispute arising out of the interpretation, application or implementation of the provisions of this MoU shall be settled amicably through consultation, negotiations and mutual consent.



#### **ARTICLE 10**

#### 10.0 Jurisdiction

10.1 The Parties submit to the jurisdiction of the Republic of Zambia

#### **ARTICLE 11**

#### 11.0 Notices

- 11.1 The Parties choose their *domicilia citandi et exectuandi* for all purpose in connection with this Agreement at the following addresses;
  - (i) Andrew Phiri
    The Permanent Secretary
    Ministry of Education
    Corner Chimanga and Mogadishu Road
    P.O. Box 50093
    LUSAKA,
    ZAMBIA.
  - (ii) Naomi Walston
    Secretary
    Grassroot Soccer Education Limited
    252B Twin Palm Road, Ibex Hill
    LUSAKA,
    ZAMBIA.

#### **ARTICLE 12**

#### 12.0 Amendment

12.1 This Agreement may be amended or replaced by mutual consent in writing and with the signatures of the Parties.

#### **ARTICLE 13**

#### 13.0. General

- 3.1 MoE and GRS respectfully confirm that they have taken all actions and secured all approvals necessary to authorize the execution and performance of this MoU.
- 13.2 Headings in this MoU are for convenience and shall not affect the interpretation of any provision of this MoU.



· 7	IN WITNESS WHEREOF the undersigned being durepresentatives, have caused their hands and seals to be first before written.	aly authorized by their respective be to be hereby affixed the day and the year
	Done at LUSAKA this	July 2010
	For the Government of The Republic of Zambia:	For Grassroot Soccer Education Limited:
	Name: Andrew Phiri	Name: Naomi Walston
	Post: Permanent Secretary HRA	Post: Secretary
	Date: Signature:	Date: 19th July 2010 Signature: Naone : Dal 870n
	Name: WITNESS PM FULL PM MITNESS	WITNESS Name Thomas Lobben Post: Dir. Ops-GRS
	Post: Date:	Date: 19/7/10
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#### c. Letter of Permission between MOH and GRS

All Correspondence should be addressed to the Permanent Secretary Telephone: +260 211 253040/5 Fax: +260 211 253344



No.....

NDEKE HOUSE P. O. BOX 30205 LUSAKA

MH/101/15/17

20 June 2013

The Lusaka District Medical Officer

# RE: Authorization to carry out HIV positive adolescent evaluation in Lusaka health centers

The Ministry of Health (MoH) in collaboration with Grassroot Soccer, IDinsight and the Center for Infectious Disease Research of Zambia (CIDRZ) is working to improve policy and guidelines for the treatment, care, and support of adolescents living with HIV/AIDS.

One of the interventions being supported to increase this understanding is the Grassroot Soccer's SKILLZ Plus curriculum, an interactive HIV and life skills education program for adolescents living with HIV/AIDS led by HIV-positive peer counselors through support groups in Lusaka district health centers.

The MoH would like to assess the impact of the SKILLZ Plus curriculum in order to generate evidence for future planning.

A research team including the MoH, Grassroot Soccer, IDinsight, and CIDRZ has been organized to carry out this important intervention and evaluation in health centers in Lusaka district.

Your usual support and cooperation will be appreciated.

Dr. Peter Mwaba
Permanent Secretary
Ministry of Health

DISTRICT MEDICAL OFFICER
P.O. BOX 50827
LUSAKA, ZAMBIA

the team for

### d. Letter of Support from MOH regarding PREP uptake amongst adolescent girls

All Correspondence should be addressed to the Permanent Secretary Telephone: +260 211 253040/5

Fax: +260 211 253344



In reply please quote:

No.....

MH/101/23/9

NDEKE HOUSE P. O. BOX 30205 LUSAKA

13th February, 2019

Carolyn Bolton Moore, MD, MSc Centre for infectious Disease Research in Zambia (CIDRZ) University of Alabama Birmingham, USA LUSAKA, ZAMBIA

Dear Dr. Bolton Moore,

RE: LETTER OF SUPPORT FOR NIH-FUNDED APPLICATION: "IMPROVING PREP UPTAKE AND RETENTION AMONGST ADOLESCENT GIRLS IN LUSAKA, ZAMBIA."

lam delighted to write this letter of support regarding the above-mentioned project. The Ministry of Health very strongly supports this exciting and important work.

As you are aware, preventing new HIV infection, especially amongst adolescents, remains a priority to the Ministry of Health. Your proposal directly seeks to identify the causes of poor uptake and retention to PrEP amongst adolescents and ascertain different modalities for improving uptake and retention.

If successful, this proposal will compliment and accelerate the vision of the Ministry to end the HIV epidemic through targeted, age-appropriate access to prevention interventions.

Thank you for your commitment in supporting our health sector.

Yours sincerely,

Ms. Kakulubelwa C. Mulalelo Permanent Secretary (A)

Ministry of Health

### e. Additional Letter of Support from MOH regarding PREP uptake amongst adolescent girls

All Correspondence should be addressed to the Permanent Secretary Telephone: +260 211 253040/5

Telephone: +260 211 25304 Fax: +260 211 253344



In reply please quote:

MH/101/24/6....

NDEKE HOUSE P. O. BOX 30205 LUSAKA

8th February, 2019

Carolyn Bolton Moore, MD, MSc Centre for Infectious Disease Research in Zambia (CIDRZ)/ University of Alabama Birmingham, USA Lusaka

# REF: LETTER OF SUPPORT FOR HIH-FUNDED APPLICATION: "IMPROVING PREP UPTAKE AND RETENTION AMONGST ADOLESCENT GIRLS IN LUSAKA, ZAMBIA

Dear Dr. Bolton Moore,

I am delighted to write this letter of support of the above-mentioned project. The Ministry of Health very strongly supports this exciting and important work.

As you are aware, preventing new HIV infection, especially amongst adolescents, remains a priority to the Ministry of Health. Your proposal directly seeks to identify the causes of poor uptake and retention to PrEP amongst adolescents and ascertain different modalities for improving uptake and retention.

If successful, this proposal will complement and accelerate the vision of the Ministry to end the HIV epidemic through targeted, age-appropriate access to prevention interventions.

You have the full support of the Ministry.

Dr. Kennedy Malama
Permanent Secretary – TS

MINISTRY OF HEALTH



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