Linking section 1: Innovative uses of web and mobile technology in the GOAL Trial

While the GOAL Trial adhered to standard best practices in the design and conduct of cluster-randomised trials, it also presented the opportunity to drive innovation in data collection and management. Web and mobile technologies—many of which are free or cheap for non-profits and institutions of higher education—offer many benefits to researchers over traditional pen/paper/spreadsheet approaches, including reducing costs of data collection and storage, providing more confidential survey methods, enhancing data security, and simplifying the jobs of survey staff. This section describes the use of (i) Open Data Kit (ODK) as a mobile phone-based, audio-assisted, self-administered sexual behaviour questionnaire tool, (ii) Force.com as an online database for storage of participation and identifying information, and (iii) SMS-Magic as a Force.com plugin used for composing and sending mass SMS messages.

Selecting a survey tool for the GOAL Trial

Prior to starting the trial, many colleagues and advisors had suggested we use an Audio-Computer-Assisted-Self-Interview (ACASI) method[1] with QDS software to carry out surveys. This recommendation came on the basis of strong evidence from 26 studies that ACASI can reduce reporting bias when used to assess self-reported sexual behaviours.[2] Indeed, the technology has numerous advantages over face-to-face interviews or paper-based self-administered questionnaires, namely that it reduces opportunities for survey administrators to influence participants' responses, it provides greater confidentiality, it negates the need for printing long paper-based questionnaires, it can handle skip patterns (simplifying the survey process), and it improves data quality by reducing the risk of human error by the survey administrator or the participant (i.e., accidentally skipping a question or marking the wrong response).[2,3] ACASI's main disadvantages are the complexity of developing a questionnaire (typically done via Nova Research's proprietary QDS™ software) and its cost (USD 295 for the survey-building software, USD 495 for the warehouse

manager and USD 236-495 per data collection unit). In the context of a clinic-based study where only one survey is conducted at a time, this cost could be manageable, as only one or two data collection units are required. In the context of a study like the GOAL Trial (i.e. collecting up to 50 questionnaires at once in three different sites), however, the costs quickly add up to more than USD 50,000. In this context, we researched alternative technologies that could provide the same advantages as ACASI but where we could afford to collect data on 150 devices.

Four strong alternatives to ACASI were identified, and the costs of carrying out the study via pen-and-paper were also estimated for comparison. iFormsBuilder is an app built for Mac OSx devices. The tool provides a simple user experience and has a user-friendly web-based tool for building surveys. However, it does not allow audio-assistance and, at the time of investigation in 2012, it had a per-device unit cost of USD 360, making it more expensive than ACASI. Mobile Researcher (now called Mobenzi Researcher) was built by a South African company with medical and epidemiological research in mind. Mobile Researcher's primary advantage is that it works on simple, non-smart phones and transmits data via the phone network. Its primary disadvantages are lack of an audio-assistance option and a unit cost based on pieces of data collected (i.e., individual survey questions; roughly USD 0.01 per item), making it a relatively expensive option for long surveys (more than USD 20,000 for three rounds of 4600 surveys with 146 items).[4] Episurveyor (now called Magpi) is similar to Mobile Researcher but requires WAP-enabled phones and does not have a per-question unit cost (rather costing USD 5,000 per year for up to 10,000 surveys and unlimited online storage).[5] It has an easy-to-learn online interface for designing surveys and managing data. Like Mobile Researcher, it does not have an option for audio-assistance, excluding it as an option for the GOAL Trial (though it would be a viable option for studies not needing audio-assistance). Lastly, ODK provides all of ACASI's features (audio assistance, displaying images, skip patterns, multiple languages, etc) plus a few additional benefits such as the ability to collect GPS coordinates, audio, photos, or videos. Surveys for ODK can be built either online via a user-friendly drag-and-drop form builder (ODK Build) or through a more powerful tool called XLSform, which converts a survey designed in Microsoft Excel®

into XML that can be used in ODK. Completed ODK surveys can be transmitted securely into an online database (hosted locally or on Google Appspot) via either Wi-Fi or the phone network. ODK is open-source, so there is no cost for downloading or using the survey-building, data management or data collection software. Table 1 compares the features and costs between the six data collection options we considered for the GOAL Trial (ACASI, ODK, EpiSurveyor, iFormsBuilder, Mobile Researcher, and pen-and-paper).

Table 1: Comparing features and costs of six data collection tools

Characteristic	ACASI (QDS)	iformsbuilder	Open Data Kit (ODK)	Mobile Researcher	EpiSurveyor	Pen-and-paper (SAQ)
Audio assistance	Yes	No	Yes	No	No	No
Display images & videos	Yes	Unclear	Yes	No	No	No
Skip patterns	Yes	Yes	Yes	Yes	Yes	Not automated
Easy to setup	No	Yes	Yes	Yes	Yes	Yes
Multiple languages	Not easy	Easy	Easy	Easy	Easy	Yes
Data transfer	Manual	Wifi	Wifi or network	Phone network	Wifi or network	Manual entry
Support	$$	$$	Online group	30 hrs included	Included	N/A
Costs						
Mgmt software	$ 1,200	0	0	0	0	N/A
Collection unit cost	$ 295	360	0	$ 20,148	$ 5,000	$ 3.00
Unit	per device	per device	N/A	per piece of data	up to 10,000 submissions	per survey (printing + data entry)
Handheld	PDA	ipod touch	Android	Any phone	WAP phone	N/A
HH unit cost	$ 100	$ 150	$ 130	$ 50	$ 50	N/A
Total Cost	**$ 60,450**	**$ 76,500**	**$ 19,500**	**$ 27,648**	**$ 12,500**	**$ 36,000**
Website	novaresearch.com/products/qds/index.cfm	iformbuilder.com	opendatakit.org	mobileresearcher.org	episurveyor.org	N/A
Overall Conclusion	Too expensive. Not as user-friendly as alternatives.	Very user-friendly but no audio and expensive.	Best value for audio-assisted survey. Much easier to setup than ACASI, no software costs. No ongoing costs.	Good option for non-audio-assisted survey. Cheaper than iforms and more appropriate. Each survey round would cost about $7,000 in "credits".	'dumb' phones if audio is not needed. Especially good option if relatively small numbers of surveys are conducted.	Lacks the features of new technology options, more expensive when considering data entry time

Note: Cost calculations assume 150 data collection units, 12,000 submissions, and 120 items

Key features of ODK for self-administered sexual behaviour questionnaires

The key features of ODK that made it stand out as the optimal tool for mobile data collection in the GOAL Trial (in addition to its cost advantages) were (i) skip patterns, (ii) validation, (iii) multi-language support, (iv) optional audio assistance, (v) the ability to send data through Wi-Fi or the phone network, and (vi) the ease of setup. Screenshots, explanations, and examples are provided below for each of these features.

Skip patterns and validation

One key feature of ODK is that simple and complex skip patterns can be easily configured. Of the 146-items in the baseline survey, 70 had skip-pattern logic built-in. The way skip patterns are configured into ODK is through the '*relevant*' XML attribute of a bind call. For example, the XML code below shows how the question 'Have you ever used a condom?' is only asked to participants who answer Yes to 'Have you ever had sex?'. The *relevant* attribute for the second question is shown in bold.

> *<bind nodeset="/GOAL-baseline/sex_ever" required="true()" type="select1"/>*
>
> *<bind nodeset="/GOAL-baseline/condom_ever"* **relevant=" /GOAL-**
>
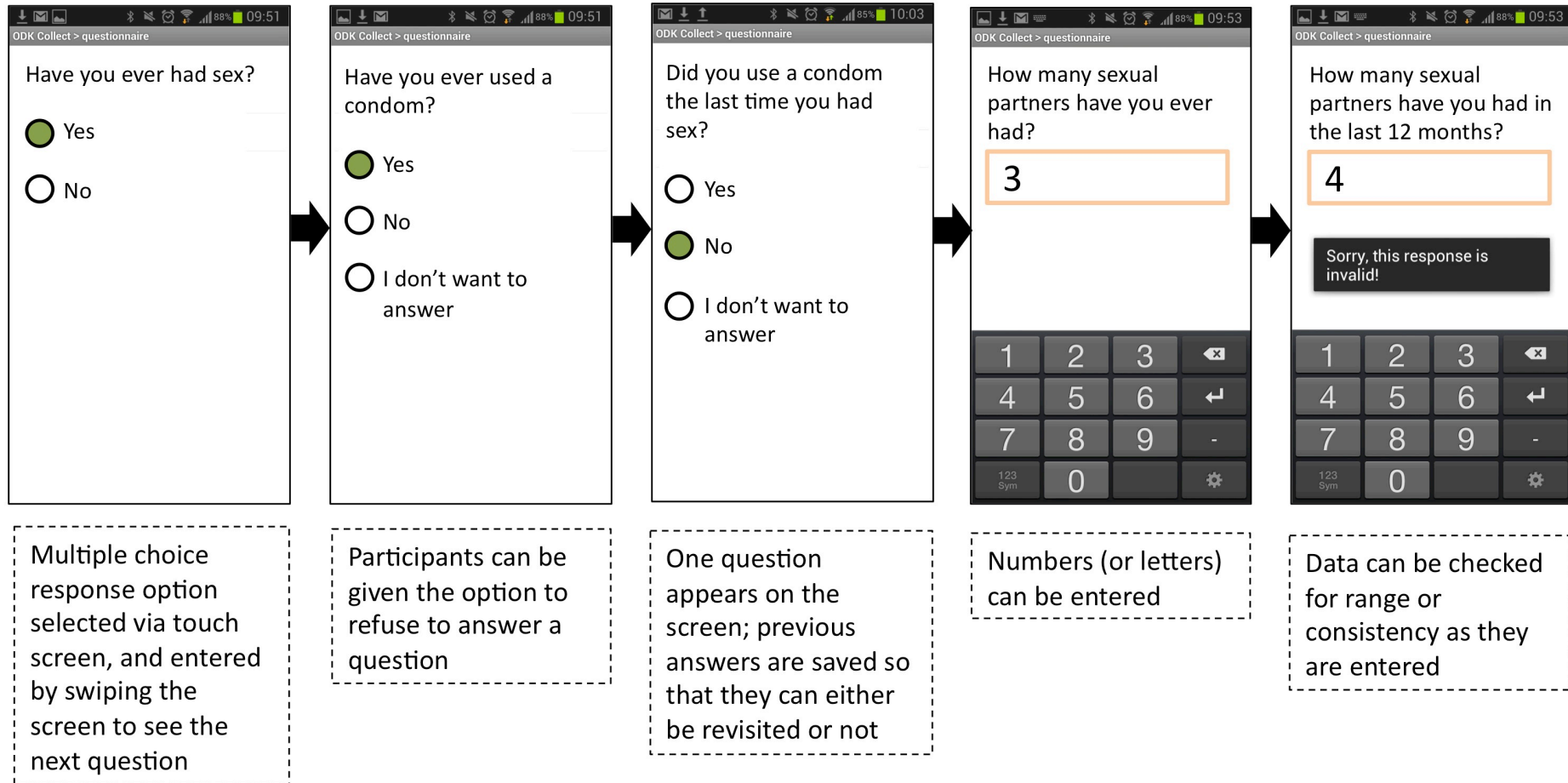> **baseline/sex_ever = 1"** *required="true()" type="select1"/>*

Multiple conditions can be used for the same item with appropriate AND / OR logic. On the surface, the logic for configuring an ODK skip pattern is backwards from building a skip pattern into a paper-based questionnaire. In the latter, one would put "If No, skip to Item 74" next to the question causing the skip, whereas in ODK the logic is coded into the item being skipped, essentially telling the device 'only show this item if Item 72 is Yes'. Validation is also a key element for self-administered questionnaires, to ensure that participants provide answers that are consistent. For example, we built in validation to ensure that the number of sexual partners reported in the last year was equal-to or less-than the number of sexual partners reported ever. The XML code below shows how this is accomplished using the '*constraint*' attribute and a period in reference to the given answer.

> *<bind nodeset="/GOAL-baseline/partners_ever" relevant=" /GOAL-baseline*
>
> */sex_ever = 1" required="true()" type="select1"/>*
>
> *<bind* **constraint=". <= /GOAL-baseline/partners_ever or . = 99"**
>
> **constraintMsg="Your answer must be less than or the same as your number**
>
> **of lifetime partners."** *nodeset="/GOAL-baseline/partners_12" relevant="*
>
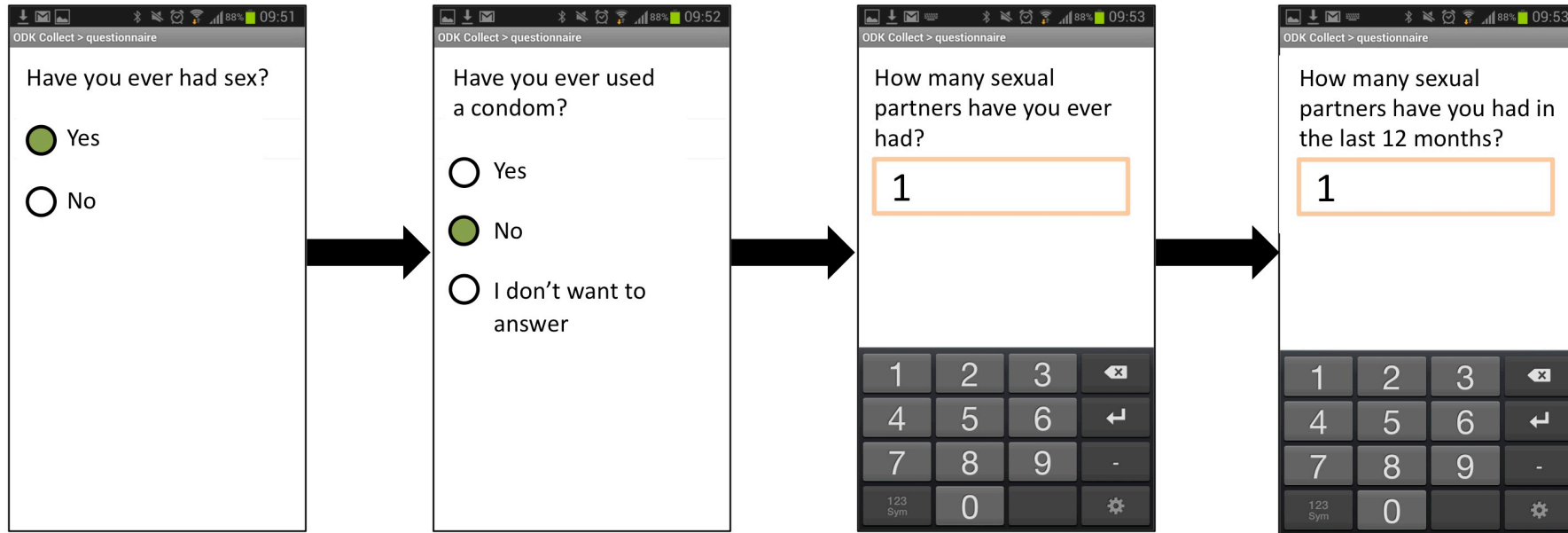> */GOAL-baseline/sex_ever = 1" required="true()" type="select1"/>*

The three figures below illustrate how this plays out on a mobile device.

Figure 1: Illustrative ODK screenshots showing skip patterns for three participants
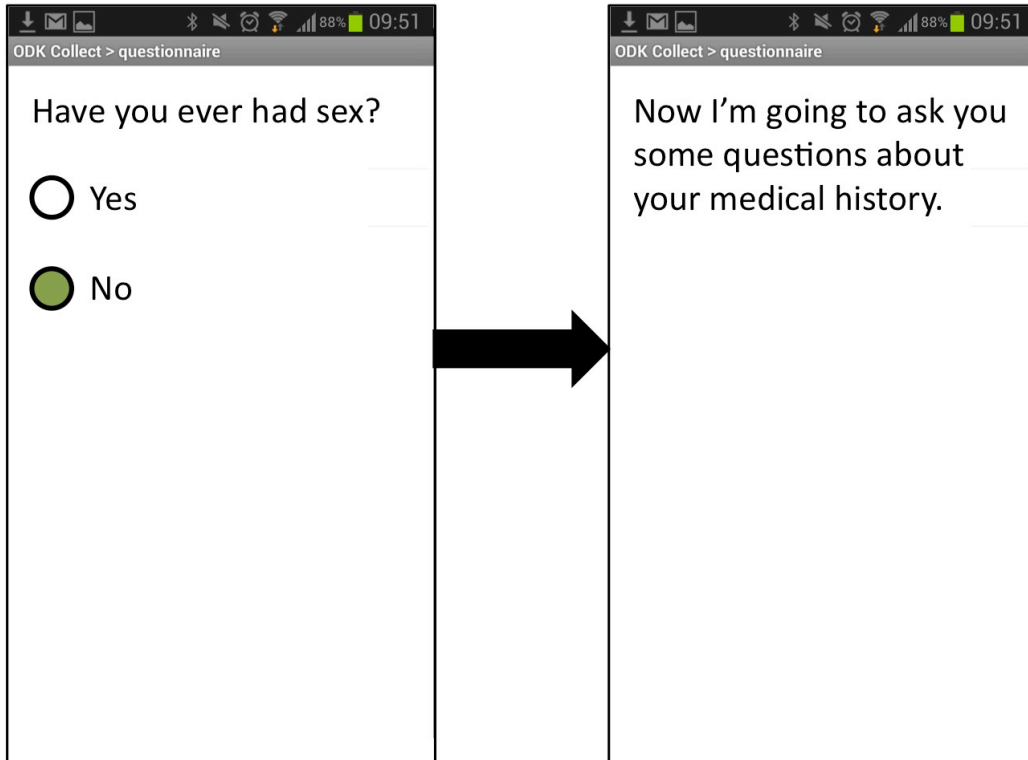
Participant A (has had sex and used a condom):

Have you ever had sex? 🟢 Yes ⚪ No	**Have you ever used a condom?** 🟢 Yes ⚪ No ⚪ I don't want to answer	**Did you use a condom the last time you had sex?** ⚪ Yes 🟢 No ⚪ I don't want to answer	**How many sexual partners have you ever had?** 3	**How many sexual partners have you had in the last 12 months?** 4 Sorry, this response is invalid!
Multiple choice response option selected via touch screen, and entered by swiping the screen to see the next question	Participants can be given the option to refuse to answer a question	One question appears on the screen; previous answers are saved so that they can either be revisited or not	Numbers (or letters) can be entered	Data can be checked for range or consistency as they are entered

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Participant B (has had sex but never used a condom):

Screen 1 — 09:51
ODK Collect > questionnaire

Have you ever had sex?

● Yes

○ No

Screen 2 — 09:52
ODK Collect > questionnaire

Have you ever used a condom?

○ Yes

● No

○ I don't want to answer

Screen 3 — 09:53
ODK Collect > questionnaire

How many sexual partners have you ever had?

1

1	2	3	⌫
4	5	6	↵
7	8	9	-
123 Sym	0		⚙

Screen 4 — 09:53
ODK Collect > questionnaire

How many sexual partners have you had in the last 12 months?

1

1	2	3	⌫
4	5	6	↵
7	8	9	-
123 Sym	0		⚙

Based on the "No" response to the "Have you ever used a condom?" question, the form was pre-programmed to skip the question "Did you use a condom the last time you had sex?"

Participant C (has never had sex):

|	
⬇ ✉ 🖼 ⁑ ✉ ⏰ 📶 88% 09:51	⬇ ✉ 🖼 ⁑ ✉ ⏰ 📶 88% 09:51
ODK Collect > questionnaire	**ODK Collect > questionnaire**
Have you ever had sex?	Now I'm going to ask you some questions about your medical history.
⭕ Yes	
🟢 No	

Based on the "No" response to the "Have you ever had sex?" question, the form was pre-programmed to skip to the end of the series of questions about condom use and sexual partners

Multi-language support and audio assistance

A critical element of any self-administered questionnaire is ensuring it is completed in a language that the participant understands. In the GOAL Trial, though nearly all participants were comfortable reading and writing in English, more than 95 percent were native Xhosa speakers, so it was important to have the option for participants to complete the questionnaire in Xhosa. Figure 2 shows how users can change from English to Xhosa as well as the button available to get audio assistance.

Figure 2: Illustrative ODK screenshots showing multi-language support and audio assistance
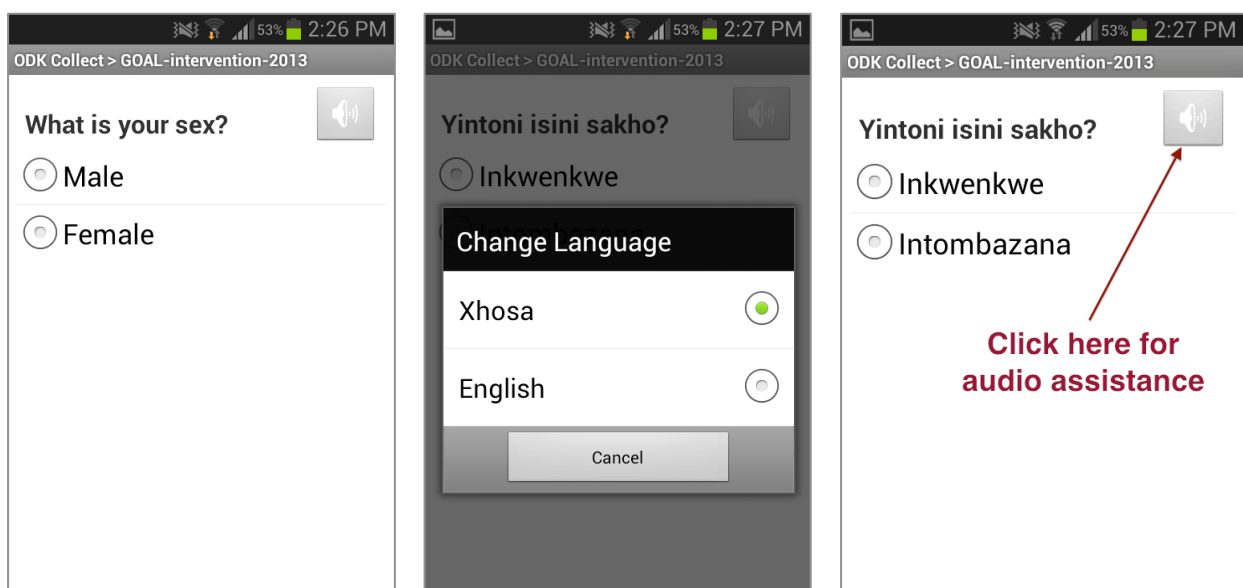
User can change the language by pushing the menu button. This brings up the middle screen where they can select which language they would like to use. More than two languages can be configured.

Submitting surveys through Wi-Fi or the phone network

Whereas computer-based ACASI tools either require storing completed survey files locally or transferring them manually from the collection device to a storage device, data collected using ODK Collect are stored in a secure ODK Aggregate database, which can either be stored online or locally. Unfinished ODK surveys can be saved on the device—not marked as finalized—and finished at a later time. When a survey is saved and marked as finalized (the default setting when reaching the end of the survey), the survey file is locked on the phone, making it impossible for anyone to review or modify the data. Data can then be transmitted to ODK aggregate either by transferring the file(s) to a computer (as with ACASI) and uploading them using ODK

Briefcase,[1] through a Wi-Fi connection or through the phone network. Figure 3 shows how this is done on a mobile phone after a survey has been completed.

Figure 3: Illustrative ODK screenshots showing how data are saved and sent to the online database
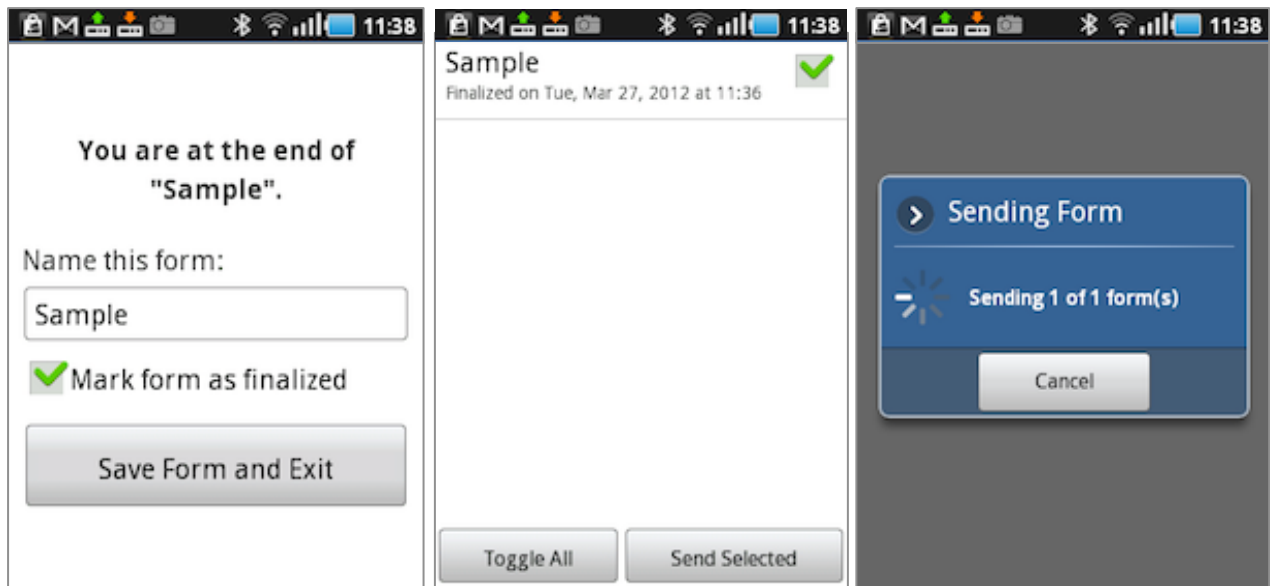
Ease of ODK setup

Another key advantage of ODK over QDS™ is the ease of setting up devices, surveys and the ODK Aggregate database. Setting up devices with the ODK Collect application is the simplest step, as the application is freely available with two clicks from the Google Play store. Once installed, the app can be opened directly on the device without further setup. ODK Aggregate is installed via a PC or Mac computer through a five-step process documented online.[2] Surveys then need to be configured and sent to both ODK Aggregate and the mobile devices. For the GOAL Trial, we configured the surveys in Microsoft Excel® and then converted the XLSX files into XML files (which are used by ODK) using ODK's XLSform conversion tool.[3] This approach is more efficient and less error-prone than writing XML code directly and more powerful than using ODK Build,[4] ODK's drag-and-drop online tool for survey-building that, at the time of GOAL survey building, did not allow for audio assistance, complex skip patterns or calculations. Figure 4 illustrates how the GOAL surveys were configured in Excel®. After the XLSX file was converted into XML, this file was uploaded to ODK Aggregate and then downloaded onto each mobile device (note: the files can be downloaded from ODK Aggregate or transferred directly from a

computer to a mobile device via USB or Bluetooth). Finally, the settings of ODK Collect need to be configured with the server address (e.g., https://goaltrial.appspot.com) and a username and password with data collection permissions on the relevant ODK Aggregate account.

Figure 4: Annotated screenshot of how the GOAL Trial survey was designed in Excel® before conversion to XML

Controls the type of question and which select options are used

Controls the question text displayed in English and Xhosa

Controls audio assistance files

	type	name	label::English	hint::English	label::Xhosa	hint::Xhosa	relevance	audio	required
76	select_one yesnoskip	Comm_fr	I have talked about HIV with a friend in the past 2 months		Ndithethile malunga ngentsholongwane kaGawulayo nomhlobo kw			Voice-062.amr	Yes
77	select_one yesnoskip	Comm_par	I have talked about HIV with a parent or guardian in the past 2 month		Ndithethile malunga ngentsholongwane kaGawula yo nomzali oka			Voice-061.amr	Yes
78	note	section5	Keep up the good work! Now I'm going to ask "For each one, select v		Qhubeka nomsebe! Kumbuzo ngamye, khetha ukuba kunqabe r			Voice-074.amr	
79	select_one ces_d	D1	During the past week I was bothered by things that usually don't both		Kwiveki ephelileyo bendikhathazwa zizinto ezingaqhelanga kund			Voice-075.amr	Yes
80	select_one ces_d	D2	During the past week I did not feel like eating, my appetite was poor		Kwiveki ephelileyo bendiziva ndingathandi kutya, ndingenamdla v			Voice-076.amr	Yes
81	select_one ces_d	D3	During the past week I felt I could not cheer myself up even with the		Kwiveki ephelileyo ndizive ndingenakuzikhuthaza khange ndince			Voice-077.amr	Yes
82	select_one ces_d	D4	During the past week I had trouble keeping my mind on what I was d		Kwiveki ephelileyo ndbenengxaki yokuzinzisa ingqondo yam kwir			Voice-078.amr	Yes
83	select_one ces_d	D5	During the past week I felt depressed		Kwiveki ephelileyo ndizive ndinoxinzelelo olungaphaya			Voice-079.amr	Yes
84	select_one ces_d	D6	During the past week I felt that everything I did was an effort		Kwiveki ephelileyo ingathi yonke ebendiyenza ibiyinzame			Voice-080.amr	Yes
85	select_one ces_d	D7	During the past week I thought my life had been a failure		Kwiveki ephelileyo bendicinga ukuba ndohlulekile ebomini bam			Voice-081.amr	Yes
86	select_one ces_d	D8	During the past week I felt fearful		Kwiveki ephelileyo ndizive ndisoyika			Voice-082.amr	Yes
87	select_one ces_d	D9	During the past week my sleep was restless		Kwiveki ephelileyo bendingalali kakuhle			Voice-083.amr	Yes
88	select_one ces_d	D10	During the past week I talked less than usual		Kwiveki ephelileyo ndithethe kancinane kunesiqhelo			Voice-084.amr	Yes
89	calculate	D_score	Depression Score		Depression Score				
90	note	section6	You're half way done! Now, I'm going to ask so	There are no right or v	Sowusesiphakathini Akukho mpendulo zilungileyo okanye ezi ng			Voice-085.amr	
91	select_one sd	G_1	A woman should obey her husband.		Umfazi kufanele athobele umyeni wakhe			Voice-086.amr	Yes
92	select_one sa	G_2	A woman should choose her own friends even if her boyfriend or hus		Umfazi kufanale azikhethele abahlobo bakhe nokuba iqabane lak			Voice-087.amr	Yes
93	select_one sa	G_3	Men should share the work around the home such as doing the dishe		Amadoda kufuneka ohlulelane ngomsebenzi wasekhaya onjengo			Voice-088.amr	Yes
94	select_one sd	G_4	Sometimes a man may have a good reason to hit his girlfriend or wife		Ngamanye amaxesha indoda inganesizathu esivakalayo sokubeth			Voice-089.amr	Yes
95	select_one sa	G_5	A woman can refuse to have sex with her husband if she does not wa		Umfazi angala ukwabelana ngesondo nomyeni wakhe xa engafur			Voice-090.amr	Yes
96	select_one sd	G_6	If a wife does something wrong she should expect her husband to pu		Ukuba umfazi wenze into engalunganga kufanale alindele umyeni			Voice-091.amr	Yes
97	select_one sd	G_7	A man cannot control himself when he gets sexually aroused.		Indoda ayikwazi ukuzilawula xa ivukelwe bubudoda bayo.			Voice-092.amr	Yes
98	select_one sd	G_8	A woman should expect to be taught how to behave by her husband.		Umfazi kufunele alindele ukufundiswa ngumyeni wakhe indlela yo			Voice-093.amr	Yes
99	select_one sd	G_9	A woman should not expect the fathers of her children to give her mc		Umfazi akufanelekanga ukuba alindele ootata babantwana bakhe			Voice-094.amr	Yes
100	select_one sa	G_10	A woman has the right to refuse to have sex if she knows her partner		Umfazi unalo ilungelo lokuba makale ukwabelana ngesondo ukub			Voice-095.amr	Yes
101	calculate	GEM	GEM score						
102	note	section7	Now I'm going to ask some questions about yo	Remember, your ansv	Ngoku ndizakubuza Khumbula iimpendulo zakho ziyimfihlelo. Un			Voice-001a.amr	
103	select_one yesnoskip	sex_ever	Some people your age have had sex and othe	This means penetrativ	Abanye abantu abali Oku kuthetha ukwabelana ngesondo apho il			Voice-002a.amr	Yes
104	select_one exp	exp_sex	Which of the following best describes your experience the first time y		Ngeyiphi kwezi zilandelayo echaza kakuhle u		${sex_ever} = 1	Voice-003a.amr	Yes
105	select_one age	age_1st_sex	How old were you the first time you had sex?		Wawuneminyaka emingaphi ukwabelana kwa		${sex_ever} = 1	Voice-004a.amr	Yes
106	select_one yesnoskip	condom_ever	Have you ever used a condom?		Wakhe wayisebenzisa ikhondom?		${sex_ever} = 1	Voice-005a.amr	Yes
107	select_one yesnoskip	condom_1st	Did you use a condom the first time you had sex?		Ingaba wawuyisebenzisile ikhondom ngelixa		${sex_ever} = 1 and	Voice-006a.amr	Yes
108	select_one partners	partners_ever	How many sexual partners have you had in yo	Even if you only had s	Mangaphi amaqabar Nokokuba ubukhe wabe		${sex_ever} = 1	Voice-007a.amr	Yes
109	select_one partners	partners_12	How many sexual partners have you had in the last 12 months?		Mangaphi amaqabane owabelana nawo nge		${sex_ever} = 1	Voice-008a.amr	Yes

survey | choices | settings | +

Separate tab controls select options

Controls skip patterns

Acceptability of ODK among GOAL Trial participants

A mixed methods approach was used to assess participants' acceptability of ODK. The methods used were three-fold. These data were presented in 2013 at the STI & AIDS World Forum in Vienna.[5] First, four questions were included at the end of the questionnaire to ascertain participants' reported understanding, comfort, honesty, and survey method preference (phone-based vs. pen-and-paper). The questions were analysed descriptively and also using random-effects logistic and linear regression to assess sex differences in acceptability. Secondly, five focus group discussions (FGDs) were carried out with a total of 20 participants and survey administrators in Cape Town, Port Elizabeth and Soweto (the latter during a survey pre-test). These FGDs were transcribed and analysed for themes, with quotes pulled out to illustrate commonly reported feelings. Lastly, non-response rates were analysed for selected sensitive questions. Participants had been given the option to select "I don't want to answer" – the proportion of participants who selected this answer was analysed descriptively.

Focus group discussions

FGDs found that the participants reported being comfortable and engaged when using the mobile phones to complete the self-administered questionnaire. Overall reported satisfaction with the phones and the tool was quite high among focus group participants, with both males and females unanimously endorsing the touchscreen phones as 'cool', 'fun' and 'new'.

> **"This is the *coolest!* If every exam was like this, we would do so much better [in school]."** – Male pre-testing participant, Soweto

There was a strong reported feeling that using the mobile phone provided increased privacy and confidentiality when answering sensitive questions, compared to self-administered paper-based sexual behavior surveys.

> **"I was honest with all the questions because I know no one will read my answer and I get privacy."** – Male participant; Port Elizabeth

> **"I felt comfortable and I was happy. It was like talking to someone that I trust."** – Female participant; Port Elizabeth

> **"It was like I was talking to myself...it felt like it was my diary."** – Female pre-testing participant; Soweto

These quotes illustrate sentiments that were echoed by other focus group participants, suggesting that the ODK approach created a suitable environment for collecting sensitive data. A more detailed analysis of the data collected from focus groups will be presented in a forthcoming paper.

Structured items on reported acceptability

Table 2 presents data on reported ODK acceptability and non-response rates from selected sensitive items from the GOAL baseline survey. In all, 4015 (78.1%) participants reported preferring the mobile-phone-based survey to pen-and-paper survey, while 716 (13.9%) reported preferring pen-and-paper. After adjusting for school and age, males had lower odds of reporting preferring the phone-based survey than females (p=0.048), reporting that the questionnaire was easy (p=0.001), reporting that they understood most or all of the questions on the questionnaire (p=0.03), reporting that they answered most or all of the questions honestly (p<0.001), and reporting that they felt comfortable taking the questionnaire (p=0.03).

Table 2: Reported acceptability, ease, understanding, and comfort of ODK survey (n=4482)

	Males (n=1989)		Females (n=2491)		Diff*
Questionnaire Item (answer)	**n**	**%**	**n**	**%**	**P value**
Do you prefer this type of questionnaire (on a phone) or a pen-and-paper questionnaire?					
Phone	1489	74.9	1952	78.4	
Pen-and-paper	177	8.9	197	7.9	0.05
No preference	323	16.2	342	13.7	
How easy or difficult was it to use this phone for the questionnaire? (Very easy or pretty easy)	1398	70.3	1931	77.5	0.001
How well do you feel you understood the questions on this questionnaire? (Most or all questions)	1086	54.6	1515	60.8	0.03
How well were you able to answer questions on the questionnaire honestly? (Most or all questions)	1079	54.3	1619	65.0	<0.001
How comfortable did you feel taking this questionnaire? (Very comfortable or pretty comfortable)	1191	59.9	1638	65.8	0.03

*Via random-effects logistic or linear regression, adjusting for age group and school-level clustering

Non-response rates

Table 3 presents descriptive data by sex on non-response rates for selected sensitive questionnaire items. After adjusting for age group and school-level clustering, more males (n=72, 3.6%) than females (n=48, 1.9) selected "I don't want to answer" for HIV testing (OR=1.73, 95%CI=1.18-2.53). Non-response on reported condom use ever was higher and differed by sex, with fewer males (n=53, 4.1%) than females (n=147, 14.3%) refusing to answer (OR=0.26, 95%CI=0.18-0.36). A similar pattern was observed for reported number of sexual partners in the last year, with fewer males (n=44, 3.4%) than females (n=109, 10.6%) choosing not to respond (OR=0.31, 95%CI=0.21-0.45). Non-response was slightly lower when asking participants about their frequency of alcohol consumption, with 111 males (5.6%) and 130 females (5.2%) choosing not to respond (OR=1.05, 95%CI=0.81-1.38). The item with the highest non-response was "Are you circumcised?" (only asked to males: 17.7% refused to answer).

Table 3: Non-responses on selected sensitive questions at baseline of the GOAL Trial (n=4485)

Questionnaire Item	Males		Females		Diff	
	n/N	%	n/N	%	OR	95% CI
Have you ever been tested for HIV?	72/1989	3.6	48/2491	1.9	**1.73**	**1.18-2.53**
Have you ever used a condom?	53/1287	4.1	147/1025	14.3	**0.26**	**0.18-0.36**
Have you ever had a sexually transmitted infection? (such as herpes, syphillis or gonorrhea)	116/1287	9.0	73/1025	7.1	1.26	0.93-1.73
How many sexual partners have you had in the last 12 months?	44/1287	3.4	109/1025	10.6	**0.31**	**0.21-0.45**
How often do you have a drink with alcohol?	111/1989	5.6	130/2491	5.2	1.05	0.81-1.38
Are you circumcised?	352/1989	17.7			N/A	

Using Force.com as a trial management database

The Force.com platform, provided as a service by Salesforce.com, is a cloud-computing platform used by more than 100,000 companies and 20,000 non-profits around the world.[6] The platform combines a highly powerful and flexible relational database core with a sophisticated and customizable security model and numerous other features, including workflow automation and user-friendly reporting and analytics. Non-profit

organisations and higher education institutions receive ten free licenses through the Salesforce.com Foundation's Power Of Us Programme and enjoy an 80 percent discount on corporate rates for further licenses.[7] In 2009, GRS transitioned its Excel®-based monitoring and evaluation system over to Force.com and has since used the platform to track the programme participation of more than 500,000 adolescents.[8] Given the success of the Force.com system at GRS and the local staff's familiarity with it, the decision was taken to build the trial participant database on the platform.

The platform was customized to track elements of RCT participation, including study ID, contact information, completion of baseline and follow-up surveys, completion of dried blood spots (DBS), and baseline and follow-up survey dates. A designated member of each survey team was responsible for capturing data (from consent forms and school registers) in Force.com daily. Each survey team only had access to its participants and was not able to see or edit participant records from the other sites. Figure 5 shows an anonymised detailed page of an example participant in New Brighton, Port Elizabeth

Figure 5: Example record detail page of an anonymised GOAL Trial participant

Participant Detail

[Edit] [Delete] [Clone] [Map]

First Name	▓▓▓	Intervention	Sophakama 9A
Last Name	▓▓▓	Community	New Brighton
Gender	Female	Study ID	104,101
		Age (calc)	14

▼ 2014 RCT

2014 Follow-up Completed	✓	2014 New Class	10b
2014 Follow-up Survey Date	3/19/2014	2014 Notes/Update	
2014 Tracing Update			

▼ 2013 RCT

12 Month Follow Up Completed	✓	New Class (RCT follow-up)	10A
2013 Follow-up Survey Date	4/26/2013	Drop-out?	☐
2013 Tracing Update		2013 Notes/Update	New number 084 ▓▓▓
Where are they?			

▼ 2012 RCT

2012 Survey Completed	✓	Assent	✓
2012 Survey Date	4/16/2012	Consent	✓

▼ Contact info

Phone Number	071▓▓	Parent/Guardian Name	▓▓la ▓▓
Phone with Country Code	277▓▓	Parent Phone Number	0787▓▓
Address	▓▓▓ New Brighton		

Force.com's list view feature enables users to easily filter based on any number of criteria and to generate a simple table of data. This was used to prepare class lists before visiting a school during a survey day. Figure 6 shows an example list view filter used at follow-up to filter to participants at Sophakama high school who completed the baseline survey. The list view feature was also used in conjunction with a Force.com-based application called SMS-Magic to send mass SMS's for the Generation Skillz SMS campaign.

Figure 6: Screenshot of list view feature, including filter criteria

See list view on next page

The system provided weekly analytics to survey teams and trial management staff on progress throughout the trial. Figure 7 shows Port Elizabeth 2's 2014 dashboard as of 21 March 2014; the dashboard updates weekly and emails out to the Team Leader and other trial staff. Each survey team has a dashboard that updates at the end of each week. The dashboards allow survey staff to see how they have done against their weekly survey target, how many surveys they have completed so far, and their follow-up rate school-by-school. Teams have reported that feeding these data back to them regularly helps to motivate them, increase mutual accountability, and give them a sense of ownership over and the data being collected.

Figure 7: GOAL Trial 2014 dashboard for Port Elizabeth 2 site, as of 21 March 2014
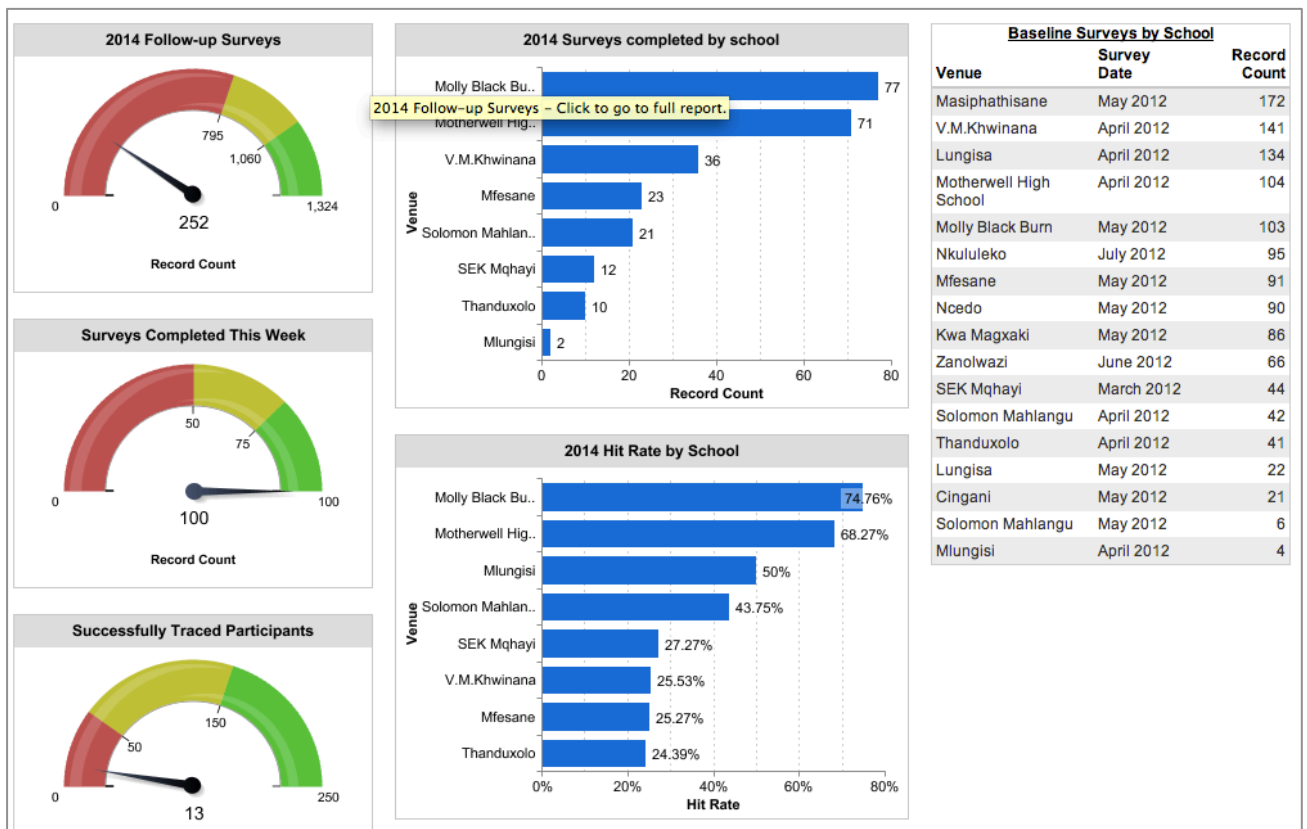
Using SMS-Magic for delivering bulk SMS's to GOAL Trial participants

Numerous web-based tools are available for sending bulk SMS's in South Africa. We chose to use SMS-Magic because it was a native Force.com plug-in. Rather than having to export data from the trial database, we could send SMS's from the same tool used to track schools, participants, and their phone numbers. Because SMS-

Magic requires that phone numbers be stored with their country code, a validation rule was configured into Force.com at baseline to ensure that all phone numbers entered began with 27 and had exactly 11 digits. Each of the SMS's for the campaign was configured and saved as an SMS Template, some using merge fields to personalize SMS's and some separating out different messages to deliver to males and females. Every two weeks, all participants in schools that had been randomised to receive SMS's were selected via a list view (see Figure 6). Figure 8 shows the screen used to select the template, review the content and send the SMS to the selected participants.

Figure 8: Sending a bulk SMS via SMS-Magic

Conclusion

In sum, the web and mobile technology tools utilized in the GOAL Trial—ODK, Force.com, and SMS-Magic—provided state-of-the-art yet low-cost mechanisms for streamlining and improving data collection and trial operations. As an open-source

application, ODK was selected as the mobile data collection tool over several other options, given its better value-for-money, ease of use and setup, and arsenal of features (including optional audio-assistance). ODK acceptability was quite high, with more than 75 percent of participants reporting they prefer the phone-based survey over pen-and-paper (this is consistent with previous research on computer-assisted self-interviews,[2] though participants in this study had not taken a pen-and-paper survey so they did not have a clear basis for comparison). Focus group discussions suggested that ODK provided a comfortable, safe environment for survey completion, though reported understanding, honesty and comfort levels on the questionnaire were slightly lower than expected. This may have been due to the sheer length of the baseline questionnaire, which took most participants over 30 minutes to complete (note: the ODK acceptability questions were at the very end of the questionnaire). Females generally reported greater questionnaire acceptability than males. These differences may indeed reflect differences in experiences of ODK by sex or may rather just reflect differences in the number of sensitive questions asked (e.g., males were asked questions about circumcision, rape perpetration and having sex with other men, whereas females were not asked these questions). Additionally, these differences may have been related to the higher proportion of males who reported ever having had sex, as participants who reported having had sex were asked 15 to 20 more questions than participants who reported having never had sex, and we hypothesize that there was an inverse relationship between questionnaire length and questionnaire acceptability.

Non-response rates on ODK were generally low (less than 10 percent on most sensitive questions), with high non-response among males on questions of circumcision status and STI experience and among females on questions about condom use and number of sexual partners. Some notable differences in non-response were observed between males and females, after adjusting for age and school-level clustering. Force.com provided a powerful, central online platform for storing participant information, with automated analytics that helped to keep trial staff informed of progress, and SMS-Magic plugged into this database to provide a simple mechanism for delivering bulk SMS's to participants.

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Sexual risk behavior, alcohol use, and social media use among secondary school students in informal settlements in Cape Town and Port Elizabeth, South Africa

Abstract

South Africa's HIV prevalence among young people remains among the highest in the world. A cross-sectional study was carried out in 2012 to estimate prevalences of sexual risk behavior and hazardous alcohol use (via the AUDIT) as well as to investigate potential associations between these outcomes and social media use. In all, 4485 students (mean age 15.66 years, SD 1.39) at 46 secondary schools in informal settlements in Cape Town and Port Elizabeth completed mobile-phone-assisted, self-administered baseline questionnaires within a cluster-randomized trial. In all, 312 females (12.5%) and 468 males (23.5%) screened positive for hazardous alcohol use (AOR=1.98, 95%CI=1.69-2.34). 730 males (39.9%) and 268 females (11.8%) reported having had two or more partners in the last year (AOR=3.46, 95%CI=2.87-4.16). Among females, having a Facebook account was associated with reported multiple partnerships in the last year (AOR=1.81, 95%CI=1.19-2.74), age-disparate sex in the last year (AOR=1.96, 95%CI=1.16-3.32) and hazardous alcohol use (AOR=1.97, 95%CI=1.41-2.74). Using Mxit—a popular mobile instant messaging application—was associated with higher odds of reported multiple partnerships in the last year among both males (AOR=1.70, 95%CI=1.35-2.14) and females (AOR=1.45, 95%CI=1.07-1.96) and with hazardous alcohol use among both males (AOR=1.47, 95%CI=1.14-1.90) and females (AOR=1.50, 95%CI=1.18-1.90). Further longitudinal and qualitative research should explore in more depth the observed links between social media and risk behavior.

Keywords: HIV, South Africa, Adolescents, Alcohol, Social Media

INTRODUCTION

South Africa is enduring the world's most severe HIV epidemic, with approximately 6.4 million people living with HIV and approximately 370,000 new infections per year.[1,2] The last two national health surveys have shown declining HIV prevalence among 15-24 year-olds, though it still remains among the highest in the world, with prevalence among 15-19 year-old females (5.2%) more than four-times higher than among males of the same age (1.2%).[2,3] While South Africa has seen tremendous success in scaling up access to HIV testing and treatment, with more than 2 million South Africans now on anti-retroviral treatment,[4] behavior change for HIV prevention remains a critical challenge and many barriers to ART adherence exist[5], underscoring the importance of adolescents remaining HIV-negative.

Numerous behavioral factors influence HIV risk among adolescents in South Africa. Multiple partnerships present a key risk factor for young men, with nearly one in three males aged 15-24 reporting having more than one partner in the last year.[3] Hazardous and harmful alcohol use, which is associated with increased HIV risk and with increased sexual risk behavior among young people, is also very common in South Africa, with 40-50% of adult men screening positive for risky drinking in urban settings.[6-8] Orphan status has also been found to be associated with sexual risk behavior among South African adolescents.[9] Since HIV prevalence increases with age, age-disparate sex (ADS) with older partners is an important risk factor, especially for young women.[10-13] More than 1 in 4 South African girls aged 15-19 report having ever had a male sexual partner who was five or more years older than

themselves.[3] Intimate-partner violence (IPV), which is also associated with HIV prevalence, presents another key risk factor for HIV in South Africa, with more than one in four men reporting having ever perpetrated rape and the vast majority of them starting before the age of 20.[14] Complex gender norms and the social constructions of manhood in post-Apartheid South Africa underlie many of these risk factors and fuel the HIV epidemic.[15,16] Few studies have provided estimates for the prevalence of these risk factors among youth in informal urban settlements, where HIV prevalence is highest (25.8% among 15-49 year-olds), compared to formal urban and rural settings.[17]

In the last decade, mobile phone access and ownership has greatly increased in South Africa, with over 50 million subscribers – the third highest number in Africa, behind Nigeria and Egypt.[18] Surveys estimate that roughly 84% of South African adults own or have access to a mobile phone, with 72% of young people aged 15-24 reporting owning a phone in a 2007 national survey.[18,19] A 2009 survey of low-income adolescents in Cape Town found that 96 percent reported using a mobile phone on a typical day, with many using phones for a popular social messaging application called Mxit, which enables instant messaging between users and is available and affordable on nearly every mobile phone model in SA.[20]

Social media platforms increase adolescents' connectedness with their peers and may facilitate their pursuit of sexual relationships.[21] A 2011 UNICEF study conducted with Mxit users across South Africa (85 percent 15-24 year-olds) found that the most commonly reported topic of conversation was "love life and dating" (46%).[22] Several

studies have identified the Internet as an STI risk environment among those seeking sexual partners online.[23,24] Concerns have been raised that social media use may create opportunities for sexual experimentation[25] and expose adolescents to sexually explicit material.[22] Little research, however, has examined the association between use of modern social networking applications and sexual risk behavior, though one study among homeless youth in USA found that social media may be associated with an increase or decrease in sexual risk behavior, depending on the nature of use.[26]

Research suggests that exposure to alcohol consumption in media is associated with increased alcohol use among adolescents.[27] This association may extend to social media, where users are exposed to alcohol-related advertising content[28] as well as user-generated content depicting alcohol consumption and overuse.[29] Since adolescents are heavily influenced by their perceptions of peer behavior,[30] we hypothesized that the aforementioned exposures in the context of online peer interactions might fuel sexual risk behavior and/or hazardous alcohol use among South African adolescents using social media. Figure 1 presents a hierarchical conceptual framework[31] that may explain these hypothesized associations, considering the potential role of upstream socio-demographic factors and telecommunications access.

[INSERT FIGURE 1 HERE]

Using baseline cross-sectional survey results of a two-year cluster-randomized trial among grade 9 secondary school students aged 12-20 years in informal settlements

of two South African cities, this paper (i) presents descriptive findings on reported sexual risk behavior and alcohol use, (ii) assesses differences in these outcomes by sex, and (iii) assesses associations between self-reported social media use and reported risk behaviors.

METHODS

Study Design

This study draws on baseline data from a two-year cluster-randomized trial to assess the behavioral effectiveness of an HIV prevention intervention delivered in informal settlement schools in Port Elizabeth and Cape Town. Ethics approval for the cluster-randomized trial was obtained from the Wits University Human Research Ethics Committee and the London School of Hygiene and Tropical Medicine Ethics Committee. A cross-sectional analysis was carried out on the trial's baseline data to better understand the risk profile of the study population.

Study Participants and Setting

Between March and September 2012, the study enrolled male and female Grade 9 learners (n=4485) at 46 public secondary schools in Cape Town (n=16 school) and Port Elizabeth (n=30 schools). Port Elizabeth was divided into two sites: Port Elizabeth 1 (urban townships in the city – Zwide, New Brighton, Kwazakhele) and Port Elizabeth 2 (peri-urban townships to the east of the city – Motherwell and Uitenhage). Participating schools in Cape Town were located in the communities of Khayelitsha, Gugulethu, and Langa.

Sampling and Recruitment

The 46 schools represented 56% of the 87 open public secondary schools in the participating communities. The schools were selected purposively, excluding those that had been exposed to the trial intervention during pilot testing of the intervention (n=10), and enrolling those that were most receptive to participating in the trial. In order to yield a reasonable cluster size for the trial, in schools with five or fewer classes of Grade 9 learners, all Grade 9 classes were invited to participate. In schools with six or more Grade 9 classes, five classes were selected using simple random sampling. All learners in the selected classes were invited to participate in the study. Only participants providing both written parental/guardian consent and assent were enrolled in the study.

Data Collection

A 146-item questionnaire was used to assess the individual learner's demographic status, social media use, reported alcohol use, reported IPV, and reported sexual behavior. The prevalence of IPV and its associations with other baseline variables will be the subject of a separate publication. Surveys were carried out using the Open Data Kit (ODK) application suite on Android mobile phones provided temporarily by the study for questionnaire completion.[32] ODK has been pilot-tested successfully in numerous resource-limited settings in Africa and Latin America,[33] with high participant acceptability in sexual behavior surveys in South Africa and Zimbabwe.[34] Similar, more expensive technologies—such as Audio Computer Assisted Self-Interview (ACASI)—for collection of data on sexual behavior have been shown to be more valid in cross-sectional surveys than self-administered questionnaires or face-

to-face interviews.[35] The questionnaire was translated into Xhosa and back-translated to English. Participants had the option to read and answer the survey in English or Xhosa and also had optional audio-assistance in Xhosa, but not English. The questionnaire was pilot-tested with grade 10 learners in Cape Town and Port Elizabeth. Surveys were confidential – participants were identified only with six-digit study ID's, and no personal identifying information was entered into the mobile phones. Data were transmitted daily through a secure wifi connection to an online database.

Measurement of outcomes and other factors

The primary behavioral outcomes of interest in this cross-sectional study were:

- Reported multiple partners in the last year: defined as reporting more than one sexual partner in the last 12 months. This is a self-reported measure commonly used on national health surveys.

- Reported age-disparate sex (ADS) in the last year: defined as reporting having had sex in the last 12 months with a partner who was 5 or more years older or younger. Participants who reported having ever had sex were asked the age of their oldest and youngest sexual partner in the last 12 months. Age disparities were calculated; those with a disparity of five or more years were considered to have had ADS.

- Reported hazardous alcohol use (HAU), measured via the 10-item Alcohol Use Disorder Identification Test (AUDIT); scores of 8 and above were classified as hazardous alcohol use)[36]. The AUDIT was developed by the World Health Organization as a screening tool for identifying problem

drinking, has been shown to be reliable and valid (especially when embedded into a questionnaire assessing other health-related behaviors), and has been used widely in South Africa.[37-39]

Secondary outcomes for the study include:

- Reported have ever had sex (defining sex as 'penetrative sex where the penis enters the vagina, anus or mouth');

- Reported condom use ever, at first sex, and at last sex (only asked to participants reporting having ever had sex);

- Reported current concurrent partners. Participants who reported having ever had sex were asked whether they currently have no sexual partners, one sexual partner, or more than one sexual partner.

Socio-demographic variables measured included:

- Socioeconomic status (SES): measured via a 5-item asset index (whether participants had in their household a TV, radio, piped water, car, or flush toilet)

- Language spoken at home (grouped into Xhosa and other for analysis)

- Self-identified race (grouped into Black and other for analysis)

- Living situation: number of people living in the household and whether participants were living with either, both or neither parent

- Level of mother's and father's education (none, primary, some secondary, completed secondary, higher)

- Orphan status: whether one or both parents were no longer living

Telecommunications access was measured in terms of whether participants reported that they owned a sim card, owned a mobile phone, and/or had an email address. Social media use was measured by asking participants whether they had a Mxit account and/or Facebook account and their reported frequency of social media use ('How often do you use Facebook, Mxit, or other social networks?' – Every day, Every 2-3 days, Once a week, Once every 2-3 weeks, Never or almost never).

Statistical Methods

Descriptive statistics were tabulated for all outcomes and variables of interest. Random-effects logistic regression was used to assess differences by sex. Further multivariable random-effects logistic regressions were conducted to assess differences in behavioral outcomes of interest by sex, adjusting for age group, site, and school-level clustering.

Multivariable random-effects logistic regression was used to assess the associations between social media exposure and the three primary behavioral outcomes, adjusting for age, site, school-level clustering, sim card ownership (included as a priori confounder in order to isolate the effect of social media use from the effect of telecommunications access) and other identified confounders. Given the stark differences in patterns of reported sexual behavior, alcohol use, and social media use, an *a priori* decision was made to assess these associations independently for males and females. A *post-hoc* decision was made to assess for effect modification by sex using likelihood ratio tests. Variables were considered potential confounders

and included in the multivariable analysis if found to have strong evidence (p<0.05) of a crude association with both the exposure and the outcome of interest. Statistical analysis was carried out using Stata Version 10.

RESULTS

Recruitment and sample characteristics

Based on school registers collected in January/February 2012, the 46 participating schools had 8226 enrolled grade 9 learners. Observation of recruitment at selected schools in all three sites suggested that the actual number of learners attending school on days when consent forms were distributed was 20-30 percent less than the number of participants on class registers, though the exact number of consent forms distributed was not recorded. Data on sex and age was not available from registers and was therefore only obtained for participants enrolling in the study. In all, 4485 participants (54.5% of those listed on registers) completed baseline surveys: 2494 (55.7%) females and 1991 (44.3%) males. Table 1 details the participants' characteristics. Almost all participants (95.8%) spoke Xhosa at home, and 89.5% self-identified as being 'black'. 1297 participants (28.9%) reported that at least one of their parents was no longer living. Significant sex differences were observed in whether participants were living with their parents, with males having higher odds of reporting living with their father only (OR=1.70, 95%CI=1.31-2.20) and lower odds of reporting living with neither parent (OR=0.75, 95%CI=0.65-0.87). More than half of participants (56.3%) reported personally knowing someone who has HIV or who died of HIV or AIDS. Males scored higher on the SES asset index (AOR=1.24, 95%CI=1.13-1.37).

[INSERT TABLE I HERE]

Details of telecommunications and social media use are presented in Table 2. Nearly two-thirds of participants reported that they owned a sim card (62.3%) and more than half reported they owned their own phone (55.5%), with no evidence of difference by sex (Table 2). Reported Mxit use was high—with more than half of participants reporting having an account (52.8%)—and was higher among males (54.5%) than females (51.5%). Additionally, more males (13.7%) than females (10.7%) reported having a Facebook account. After adjusting for age, site and school, reported frequency of social media use (AOR=1.17, 95%CI=1.02-1.34) and internet use for purposes other than social media (AOR=1.54, 95%CI=1.35-1.77) was higher among males than females (Table II).

[INSERT TABLE II HERE]

Reported sexual behavior

Selected reported sexual risk behaviors are presented in Table III, by sex. Among all participants, 1025 females (43.0%) and 1287 males (68.6%) reported having ever had sex. After adjusting for age, site and school, males had roughly 2-times higher odds than females of reporting having ever had sex (AOR=1.98, 95%CI=1.69-2.34).

Among participants who reported having ever had sex, 109 females (11.8%) and 170 males (13.7%) reported having ever had an age-disparate partner (5 or more years older or younger) (Table 4). Females had roughly 2.8-times higher odds of reporting having had a partner in the last year who was 5 or more years older (AOR=2.79, 95%CI=1.92-4.05), while they had roughly 2.5-times lower odds of reporting having had a partner in the last year who was five or more years younger (AOR=0.40,

95%CI=0.26-0.63). Only 31 males (2.4%) reported having had an age-disparate older partner in the last year, while 142 (11.0%) reported having had an age-disparate younger partner in the last year.

The number of reported lifetime partners and partners in the last year differed greatly by sex. Among participants who had ever had sex, 435 females (48.2%) and 267 males (21.7%) reported having only ever had one partner, with 648 females (70.7%) and 513 males (41.3%) reporting having only had one partner in the last 12 months. Meanwhile, 81 females (8.8%) and 276 males (30.2%) reported having had three or more partners in the last 12 months. After adjusting for age, site and school, males had 9-times higher odds than females of reporting five or more lifetime partners (AOR=9.11, 95%CI=6.42-12.9), more than 4-times higher odds of reporting three or more partners in the last year (AOR=4.50, 95%CI=3.46-5.86), and more than 3-times lower odds of reporting having only had one partner in the last year (AOR=0.29, 95%CI=0.24-0.35). Males (n=276, 22.5%) had more than 4-times higher odds than females (n=62, 6.0%) of reporting having more than one current sexual partner (AOR=4.15, 95%CI=3.09-5.57).

716 females (69.9% of those who reported having ever had sex) and 785 males (63.6% of those reporting having ever had sex) reported having ever used a condom. After adjusting for age, site and school, males who had ever had sex had roughly 2.5-times higher odds of reporting having never used a condom (AOR=2.53, 95%CI=2.06-3.11) than females who had ever had sex. Compared to females who reported having ever used a condom (n=716), males who reported have ever used a condom

(n=785) had roughly 2.3-times higher odds of reporting not having used a condom at first sex (AOR=2.29, 95%CI=1.78-2.95), but slightly lower odds of reporting not having used a condom at last sex (AOR=0.72, 95%CI=0.55-0.95). Fewer males (n=603, 31.5%) than females (n=885, 36.2%) reported having ever taken an HIV test (AOR=0.73, 95%CI=0.64-0.84). Only 327 males (16.6%) and 464 females (18.8%) reported having been tested for HIV in the past year.

[INSERT TABLE III HERE]

Reported alcohol use

Table IV presents self-reported alcohol use by sex. More females (63.2%) than males (51.1%) reported never drinking alcohol (AOR=0.76, 95%CI=0.66-0.87). After adjusting for age, site, and school, males reported greater frequency of alcohol use (p<0.001) and higher alcohol consumption per day (p<0.001). Overall, males (23.5%) had roughly 2-times higher odds than females (12.5%) of screening positive for hazardous alcohol use (AOR=1.98, 95%CI=1.69-2.34) and more than 2.5-times higher odds of screening positive for high-risk alcohol use (11.1% vs 4.2%, AOR=2.55, 95%CI=1.99-3.27).

[INSERT TABLE IV HERE]

Associations between hazardous alcohol use and reported sexual risk behavior

Table V details sex-specific univariable and multivariable analyses assessing differences in reported sexual risk behavior by whether or not participants screened positive for HAU. After adjusting for age, site and school, compared to those not screening positive for HAU, males screening positive for HAU had roughly 2.3-times higher odds of reporting having ever had sex (AOR=2.32, 95%CI=1.77-3.04), roughly 2.1-times higher odds of reporting having not used a condom at last sex (AOR=2.14,

95%CI=1.43-3.21), roughly 1.5-times higher odds of reporting having not used a condom at first sex (AOR=1.54, 95%CI=1.11-2.12), roughly 2.8-times higher odds of reporting having two or more partners in the last year (AOR=2.77, 95%CI=2.22-3.47), nearly 3.9-times higher odds of reporting currently having more than one sexual partner (AOR=3.93, 95%CI=2.91-5.33), and nearly 2.8-times higher odds of reporting having had an age-disparate sexual partner in the last year (AOR-=2.76, 95%CI=1.98-3.84). Females screening positive for HAU had nearly twice the odds of reporting having ever had sex (AOR=1.97, 95%CI=1.53-2.54), nearly 3.6-times higher odds of reporting having two or more partners in the last year (AOR=3.59, 95%CI=2.66-4.85), and roughly 3.6-times higher odds of reporting currently having more than one sexual partner (AOR=3.62, 95%CI=2.01-6.54). There was also weak evidence that females screening positive for HAU had higher odds of reporting not using a condom use at last sex (AOR=1.46, 95%CI=0.95-2.24). Very strong associations were observed for both sexes (p<0.001) between screening positive for HAU and a greater number of reported lifetime sexual partners.

[INSERT TABLE V HERE]

Association of telecommunications access and *social media use with multiple partnerships*

Table VI shows the associations for telecommunications access and social media use with reported multiple partners in the last year. After adjusting for age group, site, and sim card ownership, females with a Facebook account had roughly 2.1-times higher odds of reporting multiple partners in the last year (AOR=2.11, 95%CI=1.41-3.16). Females with a Mxit account had nearly 1.5-times higher odds of reporting multiple partners in the last year than those without (AOR=1.45, 95%CI=1.07-1.96).

Females reporting using social media every day had approximately 1.7-times higher odds of reporting multiple partners in the last year (AOR=1.70, 95%CI=1.23-2.35).

After adjusting for age, site, SES, household language, and sim card ownership, males who had Mxit accounts had roughly 1.7-times higher odds of reporting multiple partners in the last year than those without (AOR=1.72, 95%CI=1.39-2.13), while there was no significant multivariable evidence of association between Facebook and multiple partnerships among males. Males reporting using social media every day had nearly 1.9-times higher odds of reporting multiple partners in the last year (AOR=1.86, 95%CI=1.48-2.35).

There was strong evidence of effect modification by sex for the association between having a Mxit account and reporting multiple partners in the last year (p=0.04), with the association being stronger in males than in females. There was very weak evidence of effect modification by sex for the association between having a Facebook account and reporting multiple partners in the last year (p=0.12), with the association being stronger in females than in males. There was no evidence of effect modification by sex for the association between using social media every day and reported multiple partners in the last year (p=0.17).

[INSERT TABLE VI HERE]

Associations of telecommunications access and social media use with age-disparate sex

Table VII displays the associations for reported telecommunications access and social media use with self-reported ADS in the last 12 months. There was strong evidence that females owning a sim card had higher odds of reporting ADS in the last 12 months (AOR=1.71, 95%CI=1.07-2.72). After adjusting for age, site, sim-card ownership and school-level clustering, females with a Facebook account had nearly twice the odds of reporting ADS in the last 12 months than those without (AOR=1.96, 95%CI=1.16-3.32). There was very strong evidence that reporting using social media every day was associated with higher odds of reported ADS in the last 12 months for females (AOR=1.87, 95%CI=1.20-2.92) but no evidence of this association for males (AOR= etc). No associations were observed for males between telecommunications access or social media use and reported ADS in the last 12 months. There was no evidence of effect modification by sex for associations between having a Facebook account and reported ADS in the last 12 months (p=0.47) or having a Mxit account and reported ADS in the last 12 months (p=0.48). There was strong evidence, however, for effect modification by sex for the association between using social media every day and reported ADS in the last 12 months (p=0.02), with the association being stronger in females than in males.

[INSERT TABLE VII HERE]

Associations of telecommunications access and *social media use with hazardous alcohol use*

Table VIII displays the associations for reported telecommunications access and social media use with self-reported hazardous alcohol use. After adjusting for age, site, orphan status, sim-card ownership and school-level clustering, females with a

Facebook account had nearly 2-times higher odds of screening positive for hazardous alcohol use (AOR=1.97, 95%CI=1.41-2.74), while those with a Mxit account had roughly 41 percent higher odds (AOR=1.41, 95%CI=1.14-1.90). Females reporting using social media every day had roughly 61 percent higher odds of screening positive for hazardous alcohol use (AOR=1.61, 95%CI=1.23-2.10).

After adjusting for age, site, SES, household language, race, sim-card ownership and school-level clustering, males with a Mxit account had roughly 1.4-times higher odds of screening positive for hazardous alcohol use (AOR=1.40, 95%CI=1.12-1.77). Males reporting using social media every day had nearly 1.5-times higher odds of screening positive for hazardous alcohol use (AOR=1.48, 95%CI=1.15-1.90). No evidence of association was observed between hazardous alcohol use and having a Facebook account for males. There was weak evidence of effect modification by sex for the association between having a Facebook account and screening positive for hazardous alcohol use (p=0.07), with the association being stronger in females than in males. There was no evidence of effect modification by sex for associations between having a Mxit account (p=0.83) or using social media every day (p=0.49) and hazardous alcohol use.

[INSERT TABLE VII HERE]

DISCUSSION

Important differences were observed between males and females in reported sexual behavior and alcohol use. After adjusting for age and site, males had roughly 2.5-times higher odds of reporting having ever had sex, roughly 4.5-times higher odds of reporting having three or more sexual partners in the last 12 months, roughly 4-

times higher odds of reporting currently having multiple sexual partners, and 2-times higher odds of screening positive for hazardous alcohol use. Females, however, had 2-times higher odds of reporting having an age-disparate older partner – an important HIV risk factor.[10-12] These findings were generally consistent previous literature on differences by sex in reported sexual behavior among adolescents in South Africa,[40] including the 2008 South African national health survey, which also found that young men reported more partners than young women, while young women were more likely to have older partners.[3]

Our findings support previous literature from sub-Saharan Africa in the observed associations between hazardous alcohol use and sexual risk behavior.[6-8] For both sexes, very strong associations were observed between HAU and higher reported numbers of partners, and in males very strong associations were observed with increased age-disparate sex and reduced condom use at last sex. This supports previous findings that risky drinking is an important HIV risk factor,[6-8] and underlines the importance of designing and scaling up effective interventions that reduce hazardous alcohol use among adolescents in South Africa.

Though not the primary focus of the study, two interesting findings emerged with respect to reported condom use. Firstly, 36.4 percent of males and 18.4 percent of females reporting ever having had sex reported never having used a condom, with only 51.6 percent of males and 54.2 percent of females who reported having ever had sex reporting using a condom at last sex. These proportions are substantially lower than those observed in the 2008 national health survey among 15-24 year-olds

(87.4 percent among males; 73.1 percent among females)[3] and support the observation that reported condom use appears to have declined between 2008 and 2012.[2] In a 2010 cross-sectional study of 474 grade 8 learners in Cape Town, Gevers and colleagues' had observed a similar proportion of males reporting condom use at last sex (50.0%) but a much higher proportion of girls reporting condom use at last sex (73.9%). The difference in girls might be due to differences in sampling, study populations or their small sample. Secondly, after adjusting for age group, site and school, males had 2.5-times higher odds of reporting having never used a condom than females. This discrepancy also differs from the national health survey and from a 2012 cross-sectional survey of 3123 18-24 year-old men and women in four South African provinces,[41] both of which found higher reported condom use among males.

Our findings related to social media use and risk behavior provide interesting avenues for further research and potential intervention. That females using Facebook had nearly 2-times higher odds of reporting multiple partnerships in the last year, age-disparate sex in the last year, and hazardous alcohol use invites questions of causality—are adolescent girls who engage in riskier behavior more likely to use Facebook or does using Facebook fuel risky drinking and sexual behavior among adolescent girls? A previous study of low-income American MySpace users aged 18-20 found the majority (56%) made references to sexual activity and the vast majority (85%) made reference to substance use on their profiles, supporting the notion that using social media may reinforce risk behavior.[42] However, our finding may also be a result of residual confounding (e.g., girls who use Facebook may have different social networks than girls who do not, and these network differences may

explain the observed differences in reported risk behavior). The fact that Facebook use was not associated with riskier behavior among males, meanwhile, suggests that the associations may be unique to girls in this population. Indeed, evidence of effect modification by sex was observed for the associations between having a Facebook account and reported multiple partners in the last year and hazardous alcohol use. The tests for effect modification also revealed that the link between using social media every day and reported ADS in the last year was much stronger among females than males.

That males using Mxit had 1.5-times higher odds of reporting multiple partners in the last year and that both males and females using Mxit had roughly 1.5-times higher odds of screening positive for hazardous alcohol use merits further investigation. If the observed associations are indeed causal to a certain extent, then Mxit's role in increasing risk behavior would be of greater public health importance than Facebook's, due to Mxit's greater popularity and widespread accessibility (more than half of participants reported using Mxit, whereas only 1 in 8 participants reported using Facebook). Irrespective of whether these associations are causal— and, if so, the directions of causality—our findings suggest that these social media platforms—particularly Mxit—may provide an important avenue for targeting at-risk adolescents with interventions aimed at reducing sexual risk behavior and hazardous alcohol use.

The study had several important limitations. First, selection bias may have occurred due to the requirement of written parental/guardian consent for participants under

18 years, such that young participants who were less likely to obtain a parental/guardian signature—who may have had less involved parents—may have also been less likely to participate in this study. Considering previously observed associations between parent/child relations and reported risk behavior among adolescents in South Africa[43] and Sub-Saharan Africa[44] as well as associations between parental supervision and STI risk among low-income, urban African-American adolescents,[45] this may have resulted in underestimates of reported risk behavior. We do not have any reason to believe that this potential selection bias would have been differential for males and females. We also note that the sampling method may have resulted in slightly over-sampling small schools with fewer than five classes, thus potentially affecting generalizability. Secondly, social desirability bias (SDB) may have led male participants to over-report their sexual experience, number of sexual partners and/or alcohol consumption and female participants to under-report their sexual experience and number of partners. However, the confidential, mobile-assisted self-interview approach likely minimized SDB, as all answers remained private to the individual. Indeed, both the survey method and the results mirrored that of Beauclair and colleagues' recent ACASI sexual behavior survey in similar communities in Cape Town, from which they concluded that the method "may considerably reduce social desirability bias in sexual behavior surveys".[46] Thirdly, the purposive sampling of schools—a necessity to ensure the trial's validity—may have affected the study's generalizability. On the other hand, while the results should not be generalized to South Africa as a whole or to the entire Cape, they do likely provide an accurate profile of reported risk behavior

among grade nine learners in informal settlement secondary schools in Cape Town and Port Elizabeth.

Overall, this study provides useful insight into designing interventions aimed at reducing HIV and STI transmission and acquisition among adolescents in this setting. The findings suggest that interventions targeting this population should include a focus on reducing multiple and concurrent partners (especially among males), hazardous alcohol use (especially among males), and age-disparate partnerships as well as increasing condom use. Future qualitative and longitudinal studies should further examine the observed links between social media use and reported risk behavior among South African adolescents and other populations at-risk for HIV.

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Table I: Demographic characteristics of the participants, by sex (N=4485)

Characteristic	All N	All %	Female N	Female %	Male N	Male %	p value[a]
All participants	4485	100.0	2494	55.7	1991	44.3	
Age Group							
12-14	902	20.1	614	24.6	288	14.5	
15	1391	31.0	869	34.8	522	26.2	
16	1051	23.4	522	20.9	529	26.6	
17	627	14.0	281	11.3	346	17.4	
18-20	514	11.5	208	8.3	306	15.4	<0.001
Site							
Cape Town	1584	35.3	972	39.0	612	30.7	
Port Elizabeth 1	1577	35.2	817	32.8	760	38.2	
Port Elizabeth 2	1324	29.5	705	28.3	619	31.1	0.002
Self-identified race							
Black	4012	92.1	2243	92.4	1769	91.7	
Coloured	119	2.7	66	2.7	53	2.7	
White	176	4.0	92	3.8	84	4.4	
Indian	50	1.1	27	1.1	23	1.2	0.80
Language spoken at home							
Xhosa	4296	95.8	2393	96.0	1903	95.6	
English	86	1.9	44	1.8	42	2.1	
Sesotho	48	1.1	31	1.2	17	0.9	
Other	55	1.2	26	1.0	29	1.5	0.16
Orphan status							
Both parents living	3188	71.1	1752	70.2	1436	72.1	
Single orphan	1038	23.1	589	23.6	449	22.6	
Double orphan	259	5.8	153	6.1	106	5.3	0.22
Parents in Household							
Live w/neither parents	897	20.2	548	22.2	349	17.8	
Live w/mother only	1778	40.1	1002	40.5	776	39.5	
Live w/father only	252	3.6	108	4.4	144	7.3	
Live w/both parents	1510	16.9	816	33.0	694	35.4	<0.001
Mother's education							
None	357	9.1	177	8.0	180	10.5	
Primary	646	14.4	356	16.1	290	16.8	
Some secondary	1140	25.4	677	27.7	463	24.5	
Completed secondary	1257	28.0	710	25.7	547	25.4	
Higher	537	12.0	295	9.0	242	9.6	0.16
Father's education							
None	398	10.9	228	11.2	170	10.6	
Primary	579	15.9	320	15.7	259	16.2	
Some secondary	877	24.1	508	24.9	369	23.0	
Completed secondary	1167	32.0	652	32.0	515	32.1	
Higher	624	17.1	333	16.3	291	18.1	0.32
Household Size							
1 to 3	969	21.6	511	20.5	458	23.0	
4 to 6	2547	56.8	1463	58.7	1084	54.4	
7+	969	21.6	520	20.9	449	22.6	0.59
Asset Index							
Low	436	9.7	263	10.5	173	8.7	
Medium	1931	43.1	1122	45.0	809	40.6	
High	2118	47.2	1109	44.5	1009	50.7	0.001

[a] Difference by sex assessed via random-effects logistic regression, adjusting for clustering

Note: missing values not presented in the table. Percentages use available data as denominator.

Table II: Self-reported telecommunications access and social media use by sex

Characteristic	All		Females		Males		Comparing males vs females			
	N	%	N	%	N	%	OR[a]	95% CI	AOR[b]	95% CI
Own a sim card	2795	62.3	1562	62.6	1233	61.9	1.01	0.89-1.14	1.00	0.88-1.14
Own a cell phone	2488	55.5	1366	54.8	1122	56.4	1.09	0.96-1.23	1.08	0.95-1.23
Have a Mxit account	2369	52.8	1284	51.5	1085	54.5	1.16	1.03-1.32	1.19	1.05-1.35
Have an email address	1211	27.0	648	26.0	563	28.3	1.15	1.00-1.32	1.07	0.93-1.23
Have a facebook account	538	12.0	266	10.7	272	13.7	1.38	1.15-1.66	1.05	0.98-1.14
Frequency of social media use										
Never or almost never	1483	33.1	860	34.5	623	31.3				
Once every 2-3 weeks	370	8.2	186	7.5	184	9.2				
Once a week	686	15.3	380	15.2	306	15.4	1.18	1.04-1.35	1.17	1.02-1.34
Every 2-3 days	416	9.3	218	8.7	198	9.9				
Every day	1146	25.6	634	25.4	512	25.7				
Frequency of other internet use										
Never or almost never	1707	38.1	1035	41.5	672	33.8				
Once every 2-3 weeks	462	10.3	236	9.5	226	11.4				
Once a week	958	21.4	514	20.6	444	22.3	1.55	1.36-1.77	1.54	1.35-1.77
Every 2-3 days	328	7.3	161	6.5	167	8.4				
Every day	454	10.1	209	8.4	245	12.3				

[a]Random-effects logistic regression adjusted for school-level clustering

[b]Random-effects logistic regression adjusted for age group, site and school-level clustering

Table III: Self-reported sexual behavior by sex (N=4485)

Reported Sexual Behavior	Female N	Female %	Male N	Male %	AOR [a]	95% CI	p value
Ever had sex	1025	43.0	1287	68.6	2.56	2.24-2.93	<0.001
Never used a condom [b]	162	18.5	449	36.4	2.53	2.06-3.11	<0.001
No condom at first sex [b]	277	31.4	678	54.8	2.88	2.38-3.48	<0.001
No condom at last sex [b]	453	44.2	603	46.9	0.72	0.55-0.95	0.020
Lifetime partners							
None or declined to answer	1481	62.1	647	34.5			
One	435	18.3	267	14.2	1.00		
Two	252	10.6	285	15.2	1.84	1.46-2.32	
3 or 4	154	6.5	336	17.9	3.55	2.75-4.59	
5 or more	61	2.6	341	18.2	9.11	6.42-12.9	<0.001
Partners last 12 mo							
None or declined to answer	1467	59.5	633	28.1			
One	648	26.3	513	22.8	0.29	0.24-0.35	<0.001
Two or more	268	10.9	730	32.4	3.46	2.87-4.16	<0.001
3 or more	81	3.3	375	16.7	4.50	3.46-5.86	<0.001
Current sexual partners							
None	1609	69.2	857	47.2	1.00		
One	655	28.2	681	37.5	2.00	1.74-2.30	
More than one	62	2.7	276	15.2	8.55	6.38-11.45	<0.001
Age-disparate partner ever [b]	109	11.8	170	13.7	1.29	0.99-1.69	0.06
5+ year older partner	68	7.9	31	2.6	0.40	0.26-0.63	<0.001
5+ year younger partner	41	4.5	142	11.6	2.79	1.92-4.05	<0.001
Ever tested for HIV	885	36.2	603	31.5	0.73	0.64-0.84	<0.001
Tested in last 12 mo	464	18.8	327	16.6	1.12	0.90-1.38	0.32

[a] Assessed via random-effects logistic regression, adjusted for age group, site, and school-level clustering

[b] As percent of those who report having ever had sex

Note: Percentages do not include missing values in the denominator

Table IV: Self-reported alcohol use by sex (N=4485)

Reported Alcohol Use	Female N	%	Male N	%	Males vs Females univariable OR	95% CI	Males vs Females multivariable AOR[a]	95% CI
Frequency of alcohol use								
Never	1492	63.2	960	51.1	0.76	0.66-0.87	0.81	0.70-0.93
Once a month or less	665	28.2	558	29.7	1.00		1.00	
2-4 times a month	118	5.0	208	11.1	2.10	1.63-2.71	1.92	1.48-2.49
2-3 times a week	44	1.9	73	3.9	1.98	1.34-2.93	1.95	1.30-2.92
4 or more times a week	42	1.8	79	4.2	2.24	1.51-3.32	2.30	1.53-3.45
Number of drinks per day when drinking [b]								
1 or 2	507	59.7	413	46.7	1.00			
3 or 4	187	22.0	197	22.3	1.29	1.02-1.64	1.33	1.03-1.70
5 or 6	85	10.0	74	8.4	1.07	0.76-1.50	1.02	0.72-1.46
7 to 9	46	5.4	68	7.7	1.81	1.22-2.70	1.90	1.26-2.87
10+	24	2.8	133	15.0	6.80	4.24-10.9	7.50	4.70-2.87
Hazardous Alcohol Use [c]	312	12.5	468	23.5	2.16	1.84-2.54	1.98	1.69-2.34
High-Risk Alcohol Use [d]	105	4.2	220	11.1	2.85	2.23-3.63	2.55	1.99-3.27

[a] Assessed via random-effects logistic regression, adjusted for age group, site and school-level clustering
[b] As percent of those who report drinking alcohol at least once a month
[c] Defined as scoring 8 or higher on the AUDIT
[d] Defined as scoring 15 or higher on the AUDIT

Table V: Self-reported hazardous alcohol use (HAU) and reported sexual risk behaviors, by sex

Reported Sexual Behaviour	Females HAU vs No HAU: Univariable [a]		Females HAU vs No HAU: Multivariable [b]		Males HAU vs No HAU: Univariable [a]		Males HAU vs No HAU: Multivariable [b]	
	OR	95% CI	AOR	95% CI	OR	95% CI	AOR	95% CI
Ever had sex	1.97	1.53-2.54	1.83	1.40-2.37	2.63	2.01-3.44	2.32	1.77-3.04
Never used a condom [c]	0.87	0.56-1.35	0.86	0.55-1.34	0.92	0.71-1.19	0.99	0.76-1.28
No condom at first sex [c]	0.87	0.52-1.44	0.87	0.52-1.43	1.54	1.11-2.14	1.54	1.11-2.12
No condom at last sex [c]	1.46	0.95-2.24	1.44	0.94-2.20	2.13	1.42-3.20	2.14	1.43-3.21
Lifetime partners								
None	1.00		1.00		1.00		1.00	
One	1.37	0.97-1.93	1.28	0.90-1.82	1.00	1.46-3.53	0.91	0.59-1.40
Two	2.36	1.64-3.41	2.16	1.48-3.16	2.27	1.58-3.24	2.05	1.43-2.94
3 or 4	4.71	3.19-6.96	4.26	2.85-6.37	3.65	2.63-5.07	3.22	2.31-4.49
5 or more	3.76	2.07-6.82	3.37	1.84-6.17	4.22	3.06-5.84	3.65	2.63-5.07
Partners last 12 mo								
None	1.00		1.00		1.00		1.00	
One	1.09	0.83-1.42	0.98	0.74-1.29	0.66	0.51-0.84	0.65	0.50-0.84
Two or more	3.59	2.66-4.85	3.25	2.38-4.43	3.07	2.46-3.83	2.77	2.22-3.47
Three or more	3.70	2.28-6.01	3.23	1.98-5.27	2.74	2.15-3.50	2.49	1.95-3.19
Current sexual partners								
None	1.00		1.00		1.00		1.00	
One	2.46	1.90-3.18	2.25	1.72-2.94	1.74	1.36-2.24	1.52	1.17-1.96
More than one	3.62	2.01-6.54	3.26	1.79-5.91	4.34	3.21-5.86	3.93	2.91-5.33
Age-disparate partner last 12 mo	2.27	1.43-3.59	1.92	1.21-3.05	3.24	2.34-4.49	2.76	1.98-3.84
5+ year older partner	1.58	0.88-2.83	1.51	0.84-2.71	3.57	1.72-7.41	3.74	1.79-7.81
5+ year younger partner	1.75	0.85-3.61	1.67	0.80-3.49	2.28	1.59-3.26	2.08	1.45-3.00

[a] Assessed via random-effects logistic regression, adjusted for school-level clustering

[b] Assessed via random-effects logistic regression, adjusted for age group, site, and school-level clustering

[c] Restricted to those reporting having ever had sex

HAU = Hazardous alcohol use, defined as scoring 8 points or higher on the AUDIT scale

Table VI: Associations of reported telecommunications access and social media use with reported multiple partners (MP) in the last year, by sex

Characteristic	Females MP vs No MP: Univariable [a]		Females MP vs No MP: Multivariable [b]		Males MP vs No MP: Univariable [a]		Males MP vs No MP: Multivariable [c]	
	OR	95% CI	AOR	95% CI	OR	95% CI	AOR	95% CI
Socio-Demographic factors								
Age Group	1.61	1.45-1.79 [d]			1.36	1.26-1.47 [d]		
Socioeconomic status (Asset Index)	1.03	0.85-1.25			1.19	1.03-1.39 [d]		
Xhosa Speaker	1.38	0.68-2.82			0.61	0.40-0.95 [d]		
Self-identify as Black	0.78	0.50-1.24			0.95	0.62-1.46		
Father's Education	0.90	0.80-1.00			1.08	0.99-1.17		
Mother's Education	0.97	0.86-1.09			1.07	0.99-1.17		
Orphan (single or double)	1.13	0.85-1.49			0.92	0.74-1.14		
Household > 5 people	0.94	0.69-1.28			1.00	0.78-1.28		
Live with both parents	0.76	0.57-1.02			1.06	0.83-1.34		
Site								
Cape Town	1.00	[d]			1.00			
Port Elizabeth	0.44	0.29-0.68			0.95	0.72-1.25		
Uitenhage/Motherwell	0.77	0.52-1.15			0.88	0.66-1.17		
Telecommunications Access								
Own a sim card	1.18	0.89-1.56	1.02	0.74-1.42	1.09	0.85-1.38	1.07	0.85-1.34
Own a cell phone	1.15	0.88-1.50	1.01	0.72-1.44	1.10	0.87-1.39	0.90	0.67-1.23
Have an email address	1.51	1.14-2.00	1.32	0.97-1.80	1.06	0.83-1.36	1.06	0.86-1.32
Social Media Use								
Have a facebook account	1.66	1.12-2.47	**2.11**	**1.41-3.16**	1.45	1.05-2.00	1.26	0.96-1.67
Have a Mxit account	0.98	0.73-1.31	**1.45**	**1.07-1.96**	1.52	1.21-1.92	**1.72**	**1.39-2.13**
Use social media every day	1.45	1.08-1.93	**1.70**	**1.23-2.35**	1.86	1.50-2.31	**1.86**	**1.48-2.35**

[a] Random-effects logistic regression adjusted for school-level clustering

[b] Random-effects logistic regression adjusted for age group, site, and owning a sim card

[c] Random-effects logistic regression adjusted for age group, site, asset index, household language, and owning a sim card

[d] p<0.05, variable included in multivariable model as potential confounder

MP = Multiple partners (more than one sexual partner reported in the last 12 months)

Table VII: Associations of reported telecommunications access and social media use with age-disparate sex (ADS) in the last year

Characteristic	Females				Males			
	ADS vs No ADS Univariable [a]		ADS vs No ADS Multivariable [b]		ADS vs No ADS Univariable [a]		ADS vs No ADS Multivariable [c]	
	OR	95% CI	AOR	95% CI	OR	95% CI	AOR	95% CI
Demographic/structural factors								
Age Group	1.55	1.33-1.82 [d]			1.59	1.39-1.82 [d]		
Socioeconomic status (Asset Index)	0.96	0.71-1.28			1.32	1.01-1.72 [d]		
Xhosa Speaker	1.33	0.47-3.78			0.92	0.45-1.88		
Self-identify as Black	0.99	0.48-2.05			0.77	0.45-1.30		
Father's Education	0.88	0.74-1.04			0.86	0.76-1.01		
Mother's Education	0.92	0.77-1.10			0.87	0.75-1.00 [d]		
Orphan (single or double)	1.13	0.74-1.73			0.79	0.54-1.14		
Household > 5 people	0.79	0.51-1.23			0.74	0.52-1.06		
Live with both parents	0.71	0.46-1.11			1.39	1.00-1.92 [d]		
Site								
Cape Town	1.00			[d]	1.00			
Port Elizabeth	0.34	0.16-0.70			0.74	0.46-1.19		
Uitenhage/Motherwell	0.43	0.21-0.89			1.04	0.65-1.66		
Telecommunications Access								
Own a sim card	1.81	1.14-2.87	**1.71**	**1.07-2.72**	1.11	0.79-1.56	0.75	0.50-1.12
Own a cell phone	1.65	1.08-2.52	1.33	0.76-2.31	1.22	0.88-1.71	0.99	0.57-1.73
Have an email address	1.54	1.02-2.34	1.31	0.85-2.01	1.30	0.92-1.84	1.14	0.78-1.67
Social Media Use								
Have a facebook account	2.21	1.33-3.67	**1.96**	**1.16-3.32**	1.68	1.12-2.52	1.36	0.86-2.15
Have a Mxit account	1.03	0.69-1.53	1.05	0.70-1.60	1.34	0.96-1.88	1.41	0.96-2.08
Use social media every day	1.93	1.26-2.95	**1.87**	**1.20-2.92**	1.13	0.79-1.63	1.14	0.76-1.71

[a] Random-effects logistic regression adjusted for school-level clustering

[b] Random-effects logistic regression adjusted for age group, site, and owning a sim card

[c] Random-effects logistic regression adjusted for age group, site, SES, mother's education, living with both parents, and owning a sim card

[d] $p<0.05$, variable included in multivariate model as potential confounder

ADS = Age-disparate sex (sexual partner 5+ years older or younger) in the last 12 months

Table VIII: Associations of self-reported telecommunications access and social media use with reported hazardous alcohol use (HAU) by sex

	Females				Males			
	HAU vs No HAU Univariable [a]		HAU vs No HAU Multivariable [b]		HAU vs No HAU Univariable [a]		HAU vs No HAU Multivariable [c]	
Characteristic	**OR**	**95% CI**	**AOR**	**95% CI**	**OR**	**95% CI**	**AOR**	**95% CI**
Demographic/structural factors								
Age Group	1.20	1.09-1.32 [d]			1.34	1.23-1.45 [d]		
Socioeconomic status (Asset Index)	1.07	0.89-1.28			1.15	0.97-1.36		
Xhosa Speaker	0.68	0.40-1.16			0.61	0.38-0.97 [d]		
Self-identify as Black	0.98	0.62-1.53			0.69	0.49-0.99 [d]		
Father's Education	0.98	0.88-1.09			1.05	0.95-1.15		
Mother's Education	0.98	0.88-1.10			1.02	0.93-1.12		
Orphan (single or double)	1.34	1.04-1.72 [d]			0.95	0.75-1.20		
Household > 5 people	1.10	0.85-1.42			1.03	0.82-1.28		
Live with both parents	0.81	0.62-1.05			0.97	0.78-1.21		
Site								
Cape Town	1.00		[d]		1.00			
Port Elizabeth	0.63	0.45-0.90			0.79	0.58-1.08		
Uitenhage/Motherwell	0.63	0.44-0.90			0.83	0.60-1.14		
Telecommunications Access								
Own a sim card	1.40	1.08-1.82 [d]	**1.38**	**1.06-1.79**	1.07	0.86-1.34	0.89	0.69-1.14
Own a cell phone	1.36	1.06-1.75 [d]	**1.36**	**1.06-1.75**	1.18	0.95-1.47	1.03	0.78-1.36
Have an email address	1.21	0.93-1.58	1.16	0.88-1.52	1.30	1.04-1.64	1.23	0.97-1.38
Social Media Use								
Have a facebook account	1.97	1.42-2.74	**1.79**	**1.27-2.53**	1.30	0.97-1.75	1.18	0.87-1.60
Have a Mxit account	1.45	1.13-1.85	**1.46**	**1.12-1.89**	1.46	1.17-1.81	**1.40**	**1.12-1.77**
Use social media every day	1.63	1.25-2.11	**1.61**	**1.23-2.10**	1.48	1.17-1.88	**1.48**	**1.15-1.90**

[a] Random-effects logistic regression adjusted for school-level clustering

[b] Random-effects logistic regression adjusted for age group, site, orphan status, sim card ownership and cell ownership

[c] Random-effects logistic regression adjusted for age group, site, SES, household language, race and owning a sim card

[d] p<0.05, variable included in multivariate model as potential confounder

HAU = Hazardous Alcohol Use, defined as AUDIT score ≥ 8

Figure 1: Hierarchical conceptual framework for hypothesized associations between social media use and risk behavior

Socio-demographic Factors:
Age, Site, SES, Language,
Race, Living with parents,
Household size,
Parents' education,
Orphan status

Telecommunications Access:
Own a sim card
Own a cell phone
Have an email address

Social Media Use:
Have a Mxit Account
Have a Facebook Account
Use social media every day

Risk Behavior:
- Multiple partners
- Age-disparate sex
- Alcohol use
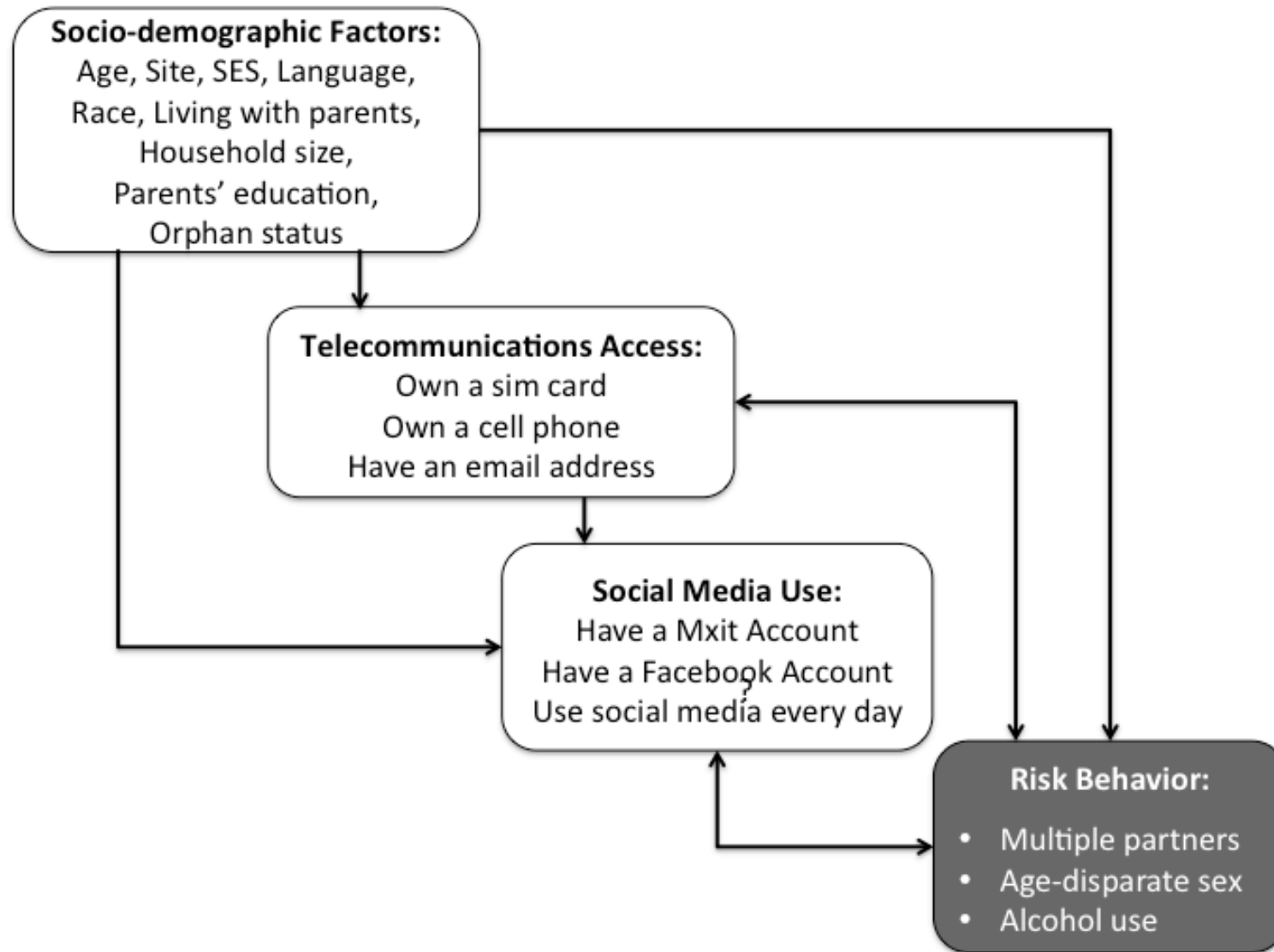
Linking section 2: Approach to follow-up in the GOAL Trial

Attrition in South African secondary schools

Entering the follow-up survey, we anticipated significant challenges with attrition. South Africa's dropout rate increases dramatically between Grade 9 (6.5%) and Grade 10 (11.5%).[1] This indeed is one of the reasons that Grade 9 is an optimal age group to target with school-based HIV prevention interventions; the majority of students are soon-to-become sexually active if not starting to engage in sexual intercourse, and many dropout of school - grade repetition is also high in South African secondary schools, with approximately 12.3% of male and 9.0% of female learners nation-wide repeating Grade 9.[1] This is especially problematic in the Eastern Cape, which consistently has the lowest matriculation pass-rate of any province in the country (64.9% compared to the national average of 78.2%) as well as one of the lowest secondary school gross-enrolment ratios.[2,3]

Follow-up Data Collection Methods

Changes to the follow-up questionnaire

While the vast majority of the baseline questionnaire was repeated for follow-up, a number of noteworthy changes were made to the questionnaire prior to beginning follow-up surveys.

- In order to shorten the questionnaire and make it less burdensome, the 20-item depression section was removed.
- Reported sexual behaviour questions asking about the last 12 months were modified to ask about the last 6 months, since some schools had only 8-10 months in between completion of the Generation Skillz intervention and the follow-up survey.
- 10 items were added to the questionnaire completed by intervention participants, asking about their experience and perceptions of the intervention (if they remembered it) and the SMS's (if they received and remembered them).

- The Asset Index and questions about the participants' households were removed, as it was assumed that answers to these questions were unlikely to have changed notably between 2012 and 2013.
- As a result of these changes (and perhaps also because participants had familiarity with the phones), survey completion time at follow-up was substantially shorter (approximately 15-25 minutes) than at baseline (approximately 25-35 minutes).

Follow-up strategy and tracing

In order to minimize loss-to-follow-up and reach as many participants as possible at 12-month follow-up, the study adopted a multi-pronged follow-up strategy. Figure 1 presents a flowchart of the GOAL follow-up tracing process.

First, repeat visits were made to each school to conduct follow-up questionnaires with participants now in Grade 10 as well as those repeating Grade 9. The survey teams liaised with Life Orientation teachers to identify which students were in Grade 10, still in Grade 9 or had dropped out. Efforts then were made to trace participants who could not be located at their trial school (i.e. those who had dropped out, moved to another school, etc). Each survey team had at least 1 survey administrator who served as point person for tracing, with the entire team helping with tracing during school holidays.

If information had been obtained about a participant, the survey teams would first follow that lead. For instance, in Khayelitsha, the team learned that a number of trial participants had left their high school and enrolled in False Bay College, so they visited the college several times and found roughly a dozen participants there. If no information

Figure 1: Diagram showing GOAL Trial tracing process
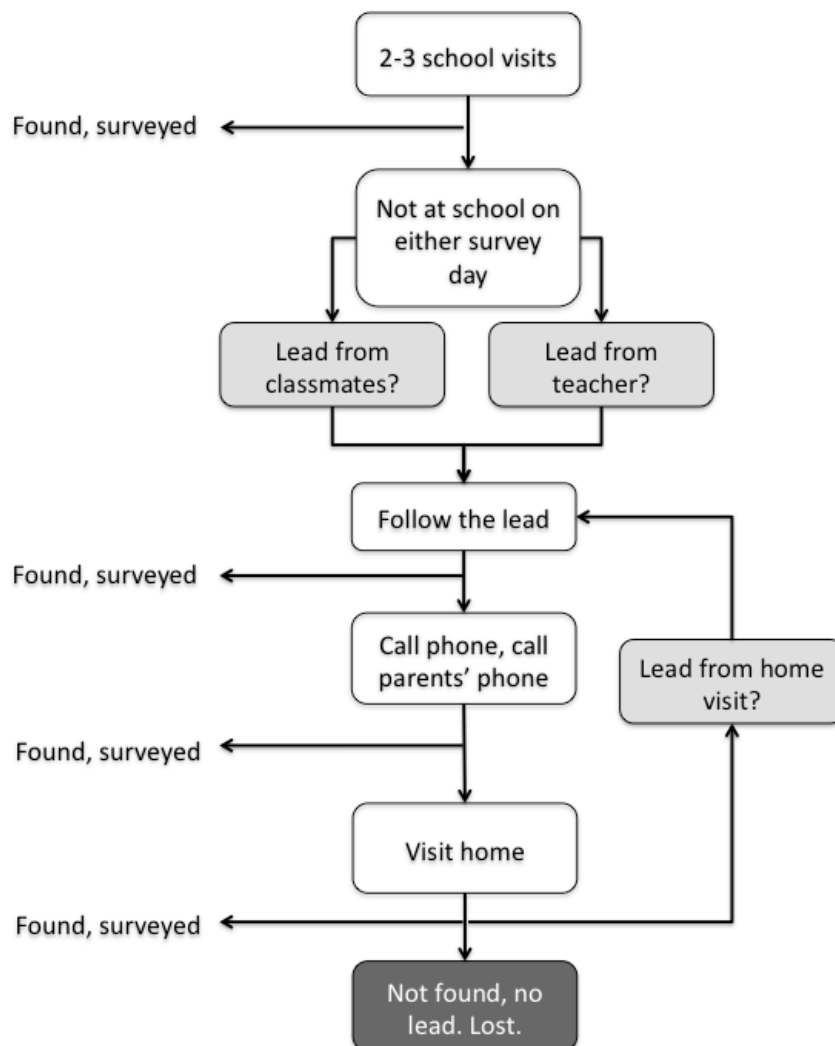
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Midline results of the GOAL Trial: a cluster-randomised trial of a sport-based HIV prevention intervention and associated SMS campaign in South African schools

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Abstract

Purpose: The need for effective interventions to reduce sexual risk behaviour among adolescents remains critical. Previous evaluations of sport-based HIV prevention (SBHP) interventions have shown promise but lacked rigour, and a growing body of research suggests SMS messaging may be an effective tool for promoting sexual health.

Methods: A cluster-randomised trial was carried out in forty-six schools in informal settlements in Cape Town and Port Elizabeth, South Africa to assess the effectiveness of an eleven-session SBHP intervention and an associated 12-month, biweekly SMS campaign in reducing reported age-disparate sex, multiple partnerships, and rape perpetration. The primary trial results will be based on a 2014 endline survey, but in 2013, midline questionnaires were completed by 3442 participants 8-11 months post-intervention delivery (median age: 16 years). Random-effects logistic and linear regressions were used to assess differences between study groups, adjusting for age group, site, school-level clustering, and baseline outcomes.

Results: There was very strong evidence that the SBHP intervention increased HIV-related knowledge for both males and females (β=0.39, 95%CI=0.25-0.53), reported ever testing for HIV among males (OR=1.38, 95%CI=1.11-1.72), and reported testing for HIV in the last year among males (OR=1.47, 95%CI=1.13-1.90). On the other hand, there was strong evidence that the intervention increased reported multiple partnerships in the last six months among males (OR=1.34, 95%CI=1.08-1.66). Within the intervention arm, there was strong evidence that the SMS campaign reduced reported multiple partnerships in the last six months among males and females combined (OR=0.75, 95%CI=0.58-0.96), but no evidence that it improved knowledge or attitudes.

Conclusions: The trial's midline results suggest the SBHP intervention was not effective in achieving its primary behavioural objectives in the first year, despite increases in knowledge and self-reported HIV testing. Our findings provide further evidence that targeted SMS's may be an effective tool for sexual health promotion.

Keywords: HIV, sexual behaviour, sport, SMS, adolescents

Introduction

The need for effective adolescent-targeted interventions to reduce sexual risk behaviour remains critical. South Africa is enduring the world's most severe HIV epidemic, with more than 6.4 million people living with HIV and approximately 469,000 new infections per year.[1,2] Roughly 30% of these new infections occur among 15-24 year-old youth, corresponding to approximately 1.5% HIV incidence per year.[1]

Interest is growing internationally in the use of sport in interventions to change behaviour and improve health, with numerous sport-based HIV prevention (SBHP) interventions currently being delivered across Sub-Saharan Africa, for example[3]. A recent systematic review showed that while results of observational and quasi-experimental studies of SBHP interventions have been promising, no RCTs had been reported.[4]

In its 2012-2016 strategic plan, the South African government identified young women and people living in informal settlements as key target populations for HIV prevention, also stating that curricular and co-curricular sexuality education and life skills programs must be provided in all schools "to build skills, increase knowledge and shift attitudes, change harmful social norms and risky behaviour" (p41).[5] While there is strong evidence supporting the effect of well-designed school-based HIV prevention interventions on knowledge and self-reported behavioural outcomes,[6] no trials have yet compared sport-based interventions with traditional teacher-led interventions in schools.

The use of short messaging service (SMS) messages is becoming increasingly common in health promotion programmes—including sexual health—around the world, including in sub-Saharan Africa.[7,8] This is particularly relevant in South Africa, which has the highest mobile phone penetration in Africa.[9] Evidence of the potential positive health effects of SMS-based interventions has come from a trial of smoking cessation SMS's in the UK [10] and two trials of ART-adherence SMS's in Kenya.[11,12] Reviewing the literature on the use of SMS's specifically for sexual health, Lim and

Colleagues[8] highlighted the growing use of SMS's by clinics for partner notification, contact tracing, and sexual health education, finding some evidence of effectiveness but an overall need for further evaluation of these interventions. Outside of an intervention context, however, use of instant-message-based social media may increase sexual risk-taking, as suggested by a cross-sectional study among South African adolescents.[13]

This paper presents midline results from the GOAL Trial, assessing the effect on reported sexual behaviour, HIV-related knowledge and HIV-related attitudes of (i) the first year of the Generation Skillz intervention, and (ii) the additional effect of sending biweekly SMS messages.

Methods

Trial Design

Schools were the unit of randomisation in this cluster-randomised trial. Detailed aspects of the trial design have been documented previously.[14] Ethics approval for the trial was obtained from the University of the Witwatersrand's Human Research Ethics Committee and the London School of Hygiene and Tropical Medicine Ethics Committee. The trial is registered with the Pan-African Clinical Trials Registry (ID number: PACTR201402000767141).

Participants

The study enrolled male and female Grade 9 learners at 46 public secondary schools in informal settlements in Cape Town (n=16 school) and Port Elizabeth (n=30 schools). Port Elizabeth was divided into two sites: Port Elizabeth 1 (urban townships in the city – Zwide, New Brighton, Kwazakhele, n=15 schools) and Port Elizabeth 2 (peri-urban townships to the east of the city – Motherwell and Uitenhage, n=15 schools). Participating schools in Cape Town (n=16) were located in the communities of Khayelitsha, Gugulethu, and Langa. A youth advisory committee was formed with adolescents from participating schools, advising on questionnaire content, recruitment procedures, and ways to make the trial's data collection as youth-friendly as possible.

The trial's baseline results[15] showed that the vast majority of trial participants spoke Xhosa at home (96%) and self-identified as black (92%). It also showed that groups were well matched in terms of socio-economic status (as measured via a five-item asset index), telecommunications access, and baseline knowledge and reported attitudes, though control group males were slightly older at baseline and a slightly higher proportion of females in the control group reported having ever had sex.

Interventions

The Generation Skillz core curriculum was designed and delivered by Grassroot Soccer (GRS), an international NGO with its headquarters in Cape Town, South Africa. Generation Skillz consists of eleven 45-minute activity- and discussion-based sessions, delivered during life-orientation school periods by trained "Coaches" (see below). The curriculum is primarily focused on reducing multiple partnerships, age-disparate sex, and gender-based violence, but also addresses male circumcision, condom use, and HIV counselling and testing. The core curriculum was delivered between March and October 2012 in the 23 intervention schools. In addition, approximately 10-12 months after the core intervention, Generation Skillz Coaches delivered a further seven 'booster' sessions (known as Generation Skillz Utshintsho) between March and September 2013 (the midline survey was conducted prior to delivery of Generation Skillz Utshintsho interventions). The intervention and its development process are described in detail elsewhere.[16] Both intervention and control schools also received standard Department of Education life orientation classes related to HIV. At the time of implementation within the GOAL Trial, the 97-page Generation Skillz curriculum [17] was in its fourth version. [16]

Generation Skillz 'Coaches' are young community role models from the informal settlements where the interventions are delivered. Most are between 18 and 25 years and have completed secondary school. Coaches receive a 5-day pre-service training, additional on-the-job training and support from certified "Master Coaches" with at least one visit per month per coach, and weekly development sessions led by Master Coaches. In addition to curriculum content, Coach training courses teach facilitation skills, HIV and AIDS epidemiology, and how to make referrals.

Between May 2012 and March 2013, biweekly SMS messages were sent to all youth in 12 (of the 23) randomly chosen intervention schools. The SMS messages were developed to reinforce key messages in the Generation Skillz curriculum and encourage participants to share their knowledge with their peers. For example, one SMS reads: "WOW! In SA, 20% of people 20-34 years old have HIV! Only 5% of people your age have HIV. Which partner puts you more at risk?" A total of 35 different SMS messages sent out over 12 months. SMS's were sent from the online trial database to participants' phone numbers that had been collected at the beginning of the study on assent forms.

Control schools received standard, teacher-led Department of Education (DoE) life orientation classes, which vary in nature site-to-site and school-to-school. Of relevance to Generation Skillz, the DoE's curriculum statement states that Grade 9 learners should spend a total of four hours learning about 'sexual behaviour and sexual health' during the year, and an additional four hours learning about 'goal-setting: personal lifestyle choices'.[18]

Outcomes

The trial had three primary, predefined behavioural outcomes:

- Age-disparate sex (defined as reporting having had a sexual partner who was five or more years older or younger) in the last six months. Participants were asked "How old was the oldest sexual partner you had sex with in the last 6 months?" and "How old was the youngest sexual partner you had sex with in the last 6 months?"
- Multiple partners (defined as reporting two or more sexual partners) in the last six months
- Reported rape perpetration ever among males (defined as responding affirmatively to a question about having forced unwanted sex with a partner/girlfriend and/or a question about having forced unwanted sex with a non-partner)

Secondary outcomes for the trial include:

- Reported hazardous alcohol use (measured via the AUDIT scale[19]; a score of 8 or higher is considered hazardous. This cut-off also includes those who screen positive for harmful drinking);

- Belief in male-dominant gender norms (measured via an adapted 10-item GEM scale[20], divided into three equal score ranges: low, medium, and high);

- HIV-related stigma (adapted from the Measure DHS AIDS Indicator Survey (AIS)[21], divided into three equal score ranges: low, medium, and high); and

- HIV-related knowledge (measured on a 10-item scale, including items from AIS[21] and UNGASS[22] as well as others related to circumcision, prevention of mother to child transmission, and ADS; divided into three equal score ranges: low, medium, and high).

Originally, we had planned to use a recall period of the last twelve months for these outcomes. However, since some schools had only 9 to 11 months in between the end of intervention delivery and the follow-up survey, the outcome period was shortened to six months for all participants.

Sample Size

The trial design assumed an average of 100 learners per school, 9% attrition per year, 15% end-line period prevalence of ADS, 25% end-line period prevalence of recent multiple partners, and 15% end-line period prevalence of reported rape perpetration in the control group, and a k of 0.25. Using the Hayes and Bennett [23] method for assessing sample size for cluster randomised trials, we determined that a sample size of 46 schools and 4600 participants would give the trial an 80% chance of detecting a true 27% effect of the Generation Skillz intervention on the period prevalence of ADS (p=0.05), a true 24% effect on multiple partners in the last 6 months, and a true 29.5% effect on reported rape perpetration.

Randomisation

Stratified randomisation was used to determine each school's group allocation. Schools were stratified first by site, then by size (large vs. small, based on whether they fell into the upper or lower 50% of schools based on enrolment numbers) and then by estimated attrition (high or low, based on the expected percentage of school dropouts between Grade 9 and Grade 12, approximated using 2012 cross-sectional enrolment numbers provided by schools). This gave a total of 12 strata. To ensure transparency, public randomisation events were held in each site approximately 3-4 weeks prior to the start of data collection, with life-orientation teachers, school administrators, and GRS staff and volunteers in attendance. After the main allocation, intervention schools were re-randomised using the same stratified approach to determine which schools would receive the SMS booster. All schools had agreed to participate in the trial before the randomisation events were held. Due to the logistical need to disclose whether a school would receive the intervention (after randomisation), it was not possible to mask a school's allocation from school administrators, teachers, study participants, or survey administrators.

Data Collection

A 146-item questionnaire was developed to assess participants' demographic status, HIV-related knowledge, reported attitudes, reported gender norms, reported alcohol use, reported experience or perpetration of IPV, and reported sexual behavior at baseline. Most demographic questions were removed from follow-up questionnaires, shortening them to 109 items plus an additional 12 questions assessing the intervention group's perceptions of the Generation Skillz intervention. Participants had the option to select "I don't want to answer" on each question.

Baseline and midline surveys was carried out using Open Data Kit (ODK) Collect (version 1.2) on Android mobile phones provided temporarily by the study to the respondents for questionnaire completion.[24] ODK has been pilot tested successfully in numerous resource-limited settings in Africa and Latin America.[25] We have observed high participant acceptability for a similar ODK-based sexual behaviour survey in Zimbabwe.[26] Similar, more expensive technologies—such as Audio Computer Assisted Self-Interview (ACASI)—for collection of data on sexual behaviour

have been shown to be more valid in cross-sectional surveys than self-administered questionnaires on pen and paper or face-to-face interviews [27]. Questionnaires took participants, on average, approximately 25-30 minutes to complete. When completing a questionnaire, participants had the option to read and select options written in English or isiXhosa, with optional audio assistance also available in isiXhosa. All GOAL surveys were confidential; participants were identified only with a six-digit study ID, and no personal identifying information is entered into the mobile phones. Data were transmitted daily through a secure wifi connection to an online database.

Statistical methods

A pre-hoc analysis plan was developed and approved by the trial's Data Safety and Monitoring Board prior to data analysis being carried out. Cluster-level summary statistics for primary and secondary outcomes from baseline surveys were computed by sex for each school. For the primary trial results presented here, an intention-to-treat analysis was conducted. Random-effects logistic regression was used to assess differences between groups on behavioural outcomes, adjusting for age group, school-level clustering and cluster-level baseline summaries of each outcome. Differences between groups in continuous outcomes (knowledge, reported self-efficacy, reported stigma, reported gender-equitable norms) were assessed using random-effects linear regression, adjusting for age group, school-level clustering, and cluster-level baseline summaries of each outcome. For example, the assessment of knowledge differences at follow-up between males receiving Generation Skillz and those in the control group was adjusted for age group, school-level clustering and school-level mean baseline knowledge scores among males. This approach was favoured over a cohort-style analysis based on imperfections in study ID linkage between baseline and follow-up surveys.

Results

Recruitment

At baseline, 4485 participants were enrolled and completed questionnaires (2173 interventions; 2312 control). The results of the baseline survey, including sample characteristics and descriptive statistics for the trial's primary and secondary outcomes have been documented in a separate paper.[14] In the 2013 midline follow-up, 3442 surveys were completed (1607 intervention, 74.0% follow-up; 1835 control, 79.4% follow-up) for an overall follow-up rate of 76.7%. The follow-up rate for females (77.8%) was slightly higher than the follow-up rate for males (75.4%). Figure 1 shows the flow of participants in the trial by group.

[INSERT FIGURE 1 NEAR HERE]

Table 1 presents sample characteristics by group and by sex. The median age at follow-up was 16 years for female participants (IQR: 15-17 years) and 17 years for male participants (IQR: 16-18 years). Control males (mean age=16.9 years, SD=1.4 years) were slightly older, on average, than intervention males (mean age=16.6 years, SD=1.3 years). Across sexes, the intervention group had a slightly lower proportion of participants from Port Elizabeth 1 (25.3% vs 29.1%) and a slightly higher proportion of participants from Port Elizabeth 2 (33.1% vs 30.8%). A slightly higher proportion of intervention participants reported living with both parents (33.0% vs 29.2%) and a slightly lower proportion reported living with neither of their parents (21.8% vs 24.4%).

[INSERT TABLE 1 NEAR HERE]

Effects of Generation Skillz on reported sexual behaviour

Table 2 presents differences between groups by sex in reported sexual behaviour. After adjusting for age group, site, school-level clustering and baseline prevalence, males in the intervention group had 34% higher odds of reporting more than one partner in the last six months than males in the control group (OR=1.34, 95%CI=1.08-1.66). Females in the intervention group had higher odds of reporting an age-disparate partner in the last six months than females in the control group (5.2% vs 3.4%, OR=1.65, 95%CI=1.03-2.63) and there was a similar, but non-significant tendency for them to report age-disparate older partners (4.1% vs 2.9%, OR=1.65, 95%CI=0.90-3.01, p=0.10). Relative to males in the control group, males in the intervention group had higher odds of reporting having ever tested for HIV

(OR=1.38, 95%CI=1.11-1.72) and of having tested for HIV in the last 12 months (OR=1.47, 95%CI=1.13-1.90). On the other hand, males in the intervention group also had higher odds of reporting having ever perpetrated physical intimate-partner violence (OR=1.27, 95%CI=1.00-1.60).

[INSERT TABLE 2 NEAR HERE]

Effects of Generation Skillz on HIV-related knowledge and reported attitudes

Table 3 presents differences overall and by sex between groups in HIV-related knowledge, reported attitudes, and reported gender norms. After adjusting for age group, site, school-level clustering and baseline knowledge scores, there was very strong evidence at midline that participants in intervention schools (μ=6.40, SD=2.04) had higher HIV-related knowledge than participants in control schools (μ=5.96, SD=2.12) (β=0.39, 95%CI=0.25-0.53. This effect was consistent for both males (β=0.44, 95%CI=0.22-0.66, p<0.001) and females (β=0.35, 95%CI=0.17-0.53). No evidence of effect was observed on HIV stigma, self-efficacy to prevent HIV, or gender-equitable norms.

[INSERT TABLE 3 NEAR HERE]

Table 4 presents knowledge differences between groups question-by-question. Specifically, the intervention group scored higher than the control group on knowledge of older partners as a risk factor (OR=1.87, 95%CI=1.46-2.41), having other STIs as a risk factor (OR=1.30, 95%CI=1.07-1.56), alcohol as a risk factor (OR=1.47, 95%CI=1.19-1.80), and the increased risk of HIV transmission during the first 6-8 weeks of infection (OR=1.25, 95%CI=1.07-1.46).

[INSERT TABLE 4 NEAR HERE]

Effects of Generation Skillz SMS campaign

Table 5 presents differences in reported behavioural outcomes between the intervention sub-groups (SMS and non-SMS). Across sexes, after adjusting for age group, site, sim card ownership, school-level clustering and baseline prevalence, there was strong evidence that participants at schools receiving the SMS campaign had roughly 25% lower odds of reporting multiple partners in the last six months, compared to participants at schools receiving only Generation Skillz without the SMS

campaign (OR=0.75, 95%CI=0.58-0.96). There was strong evidence that girls at the SMS schools had nearly 2-times lower odds of reporting having had sex while drunk in the last six months (OR=0.54, 95%CI=0.32-0.92) and weak evidence that they had nearly twice the odds of reporting having ever used a condom (OR=1.94, 95%CI=0.99-3.78). On the other hand, males at SMS schools had roughly 1.6-times higher odds of reporting more than two lifetime partners (OR=1.59, 95%CI=1.07-2.37), but there was no significant difference in their odds of reporting recent or current multiple partnerships. No evidence of an effect of the SMS campaign on age-disparate sex in the last six months was observed, though responses trended towards lower odds for both sexes (Combined OR=0.72, 95%CI=0.42-1.22). Similarly, there was no significant effect of the SMS campaign on reported rape perpetration but a trend towards lower odds in the group receiving SMS's (OR=0.65, 95%CI=0.33-1.29).

[INSERT TABLE 5 NEAR HERE]

Table 6 presents differences in knowledge, reported attitudes and reported gender norms between participants from intervention schools receiving SMS's and those from schools not receiving SMS's. After adjusting for age group, site, sim card ownership, school-level clustering, and baseline scores, there was no evidence that the SMS campaign had an effect on HIV-related knowledge, stigma, self-efficacy or gender-equitable norms. Sex-specific analyses did not reveal evidence of any differences in this lack of an effect for males or females.

[INSERT TABLE 6 NEAR HERE]

Table 7 presents differences in the three primary behavioural outcomes between schools receiving Generation Skillz and the SMS campaign (n=12) and control schools (n=23). No evidence of difference was observed on reported age-disparate sex in the last six months (OR=1.04, 95%CI=0.64-1.71), multiple partners in the last six months (OR=0.98, 95%CI=0.74-1.29) or rape perpetration (OR=0.74, 95%CI=0.47-1.15).

[INSERT TABLE 7 NEAR HERE]

Loss-to-follow-up analysis

The loss-to-follow-up (LTFU) analysis revealed 1309 participants (29.5% of the baseline sample) who were surveyed at baseline and did not have midline surveys

matching their study ID. Of these, 677 were intervention participants (31.6% LTFU) and 632 were control participants (27.6% LTFU). There was no evidence of differential loss-to-follow-up rates by study group (aOR=1.03, 95%CI = 0.69-1.55). Table 8 summarizes the sample characteristics of participants lost-to-follow-up by group. There was very strong evidence of lower LTFU in the Port Elizabeth 1 site, compared to Cape Town (20.9% vs 35.1%, OR=0.46, 95%CI=0.30-0.71) and to Motherwell/Uitenhage (20.9% vs 33.1% LTFU, OR=0.47, 95%CI=0.30-0.73). There was very strong evidence that the odds of LTFU increased linearly with baseline age (OR=1.27, 95%CI=1.20-1.35). Compared to participants living with both parents at baseline, there was very strong evidence of increased odds of LTFU among participants living with neither parent at baseline (OR=1.30, 95%CI=1.08-1.58) and among participants living with only their father at baseline (OR=1.55, 95%CI=1.15-2.09). However, there was no evidence of higher odds of LTFU among participants who had lost one or both parents. There was weak evidence of an association between increased LTFU and having fewer baseline household residents (coef=-0.36, 95%CI=-0.72 to 0.01, p=0.06) and between increased LTFU and having a lower baseline asset index (coef=-0.01, 95%CI=-0.03 to 0.00, p=0.06).

Overall, LTFU was more common among those participants who reported more sexual risk behaviour, alcohol consumption and partner violence at baseline. Specifically, there was very strong evidence that participants who reported already having ever had sex at baseline had higher odds of LTFU (OR=1.60, 95%CI=1.38-1.84). There was also very strong evidence of higher odds of LTFU among participants reporting multiple partners in the past year at baseline (OR=1.36, 95%CI=1.15-1.60), weak evidence of increased odds of LTFU among those reporting ADS in the last year at baseline (OR=1.26, 95%CI=0.96-1.65), strong evidence of increased odds of LTFU among those reporting have ever perpetrated rape (OR=1.33, 95%CI=1.02-1.72), strong evidence of increased odds of LTFU among males reporting having ever perpetrated IPV (OR=1.27, 95%CI=1.03-1.56), and very strong evidence that odds of LTFU increased linearly with increased hazardous drinking (OR=1.15, 95%CI=1.04-1.27).

[INSERT TABLE 8 NEAR HERE]

Within groups, LTFU varied by site. Among the intervention group, the highest proportion of participants lost-to-follow-up came from Cape Town (38.6%), whereas in the control group, the highest proportion of participants lost-to-follow-up came from Motherwell/Uitenhage (32.1%). Notably, there was differential LTFU between groups in terms of reported multiple partnerships. In the control group, there was very strong evidence of higher odds of LTFU among males reporting more than one partner in the last year at baseline (OR=1.61, 95%CI=1.20-2.16) whereas there was no such evidence in the intervention group (OR=1.23, 95%CI=0.90-1.68). The opposite was true for females, with very strong evidence of higher odds of LTFU among intervention females reporting multiple partners in the last year (OR=1.69, 95%CI=1.11-2.55) but not among control females (OR=1.04, 95%CI=0.70-1.56). Similarly, while there was strong evidence of increased odds of LTFU among control participants reporting ADS at baseline (OR=1.42, 95%CI=1.00-2.02), there was no such evidence among intervention participants (OR=1.07, 95%CI=0.70-1.65).

Discussion

Very strong evidence was observed of a positive effect of the Generation Skillz intervention on HIV-related knowledge for both sexes and on reported HIV testing among males, while strong evidence of a negative effect was observed on reported multiple partners in the last six months among males, age-disparate sex (with a younger or older partner) in the last six months among females, and intimate-partner violence perpetration among males. Given that these latter three behaviours were the primary focus of the intervention, which was designed in accordance with the 17 characteristics of effective sex and HIV education programmes reported by Kirby and colleagues,[6] and given previous findings on SBHP interventions' effectiveness[28], these results are both surprising and discouraging.

The on-going process evaluation may help to answer questions of why these negative effects have been observed, and it will be important to see whether they persist, attenuate, or are reversed after the second year of the intervention through

the survey that is being conducted between February and August 2014. We have hypothesized three potential explanations. First, a partial explanation could be that the intervention increases use of Mxit, a South African social network which works on mobile phones and tablet computers, among males (81.2% in the intervention group compared to 72.5% in the control group, p=0.006) and this has been documented as a risk factor for multiple partnerships.[13] Second, there may have been one or more "coaches" who promoted negative behaviours or potentially even engaged in sexual relationships with participants. Indeed, the intervention, by its delivery mechanism, does facilitate contacts between teenage girls and young adult male coaches, many of who are 5-10 years older than the participants. Thirdly, it may be possible that increasing adolescents' awareness of certain risk factors like ADS and multiple partners might lead them to over-report these risky behaviours, as was suggested by investigators in a previous trial of an IPV reduction intervention in South Africa.[29]

On the other hand, comparing participants from intervention schools receiving the SMS campaign to those from intervention schools not receiving it, we observed strong evidence that the SMS campaign was associated with a decrease in reported multiple partners in the last six months (OR=0.75, 95%CI 0.58-0.96), despite seeing no evidence of an effect on knowledge, reported attitudes, reported gender norms or other reported behaviours. This observed effect supports previous findings in the literature that suggest that SMS campaigns can positively influence behaviour.[10,11] However, comparing the schools receiving SMS's to control schools, no evidence of difference was observed on any of the three primary behavioural outcomes. This suggests that the intervention combined with SMS's still did not produce the desired outcomes at midline.

The LTFU analysis revealed that riskier participants, older participants, and Cape Town participants had higher odds of attrition, and that the profiles of participants lost differed between the intervention and control groups. Importantly, control males reporting multiple partners at baseline had higher odds of being lost (compared to males not reporting multiple partners at baseline), while the same was

not true for intervention males reporting multiple partners at baseline. This may partly explain the observed midline difference between intervention and control groups in reported multiple partnerships and reported ADS, as the midline analysis was adjusted for baseline differences and the control group had higher odds than the intervention group of losing participants who had reported multiple partners and/or ADS at baseline. Further investigation in the process evaluation should look into reasons why the groups may have lost participants with different risk profiles.

The study had several limitations. First, self-reported data on sexual behaviour is prone to social desirability bias, which may reduce study validity,[30] and the intervention may have also influenced what participants view as socially desirable responses. The mobile-phone-based questionnaire was designed to maximize confidentiality and minimize social desirability bias, but it is possible that some participants felt that they should give answers they deemed to be socially desirable rather than truthful answers. Additionally, selection bias may have played an important role in the trial, both in terms of enrolment into the study (with nearly half of learners not participating) and in terms of follow-up. Since a higher proportion of intervention participants than control participants were lost-to-follow-up, it is possible that selection bias may have been differential. This could have led to an under-estimate of the effects (i.e., if riskier adolescents were more likely to be lost-to-follow-up) or an over-estimate of the effects (i.e., if riskier adolescents were more likely to participate at follow-up). There was a small risk of contamination between study groups, as it is possible that intervention and control participants may have interacted outside of the school context (e.g. in other community settings or activities, such as sports teams or youth groups). We expect that minimal contamination occurred, however, since no study school was within close proximity (<1km) to another school in the opposite group. Lastly, there is a possibility of recall bias, as two of the primary outcomes depend on a recall period of six months, and it is possible some participants misremembered the ages of their recent partners or the number of recent partners.

The study's findings may be generalizable to secondary schools in informal settlements in the Eastern and Western Cape (and perhaps more broadly in South Africa) but should not be generalized to all sport-based HIV prevention interventions. Indeed, many such interventions target younger participants than Generation Skillz.

In sum, while the SMS campaign has shown promise, the Generation Skillz intervention, while improving knowledge, had no significant impact on HIV stigma, self-efficacy to prevent HIV, gender-equitable norms, self-reported rape perpetration among males, self-reported age-disparate sex in the last 6 months among males, or self-reported multiple partners in the last 6 months among females, and resulted in an increase in self-reported age-disparate sex in the last 6 months among females, and an increase in self-reported multiple partners in the last 6 months among males. If the two-year follow-up survey confirms these findings, the Generation Skillz intervention or aspects of the staff delivering it will need to be modified in order to achieve its desired objectives of reducing age-disparate sex, multiple partnerships, and rape perpetration. In the meantime, based on the midline results alone, we cannot recommend implementation of Generation Skillz over standard DoE Life Orientation education. Further research will explore the GOAL Trial's qualitative process evaluation findings and the 2014 follow-up survey results.

Contributions of authors

ZK served as Trial Director, leading trial design, management, analysis and write-up. EBK and JD led intervention design and contributed to study design and preparation. RH and SD led data collection teams and contributed to study management. HW served as statistical advisor for the trial. CF advised on the nested SMS trial and the design of the SMS campaign. DR and SDM served as co-Principal Investigators, overseeing study design and write-up. All authors reviewed drafts of the manuscript.

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Figure 1: GOAL Trial flow of participants from enrolment through 2013 follow-up

46 schools
8225 Grade 9 learners

Intervention

Control

23 schools
4154 Grade 9 learners

23 schools
4071 Grade 9 learners

1981 no consent received

1759 no consent received

2173 participants
939 males; 1234 females

2012 baseline

2312 participants
1052 males; 1260 females

566 no follow-up (26.0%)

477 no follow-up (20.6%)

1607 participants
687 males; 920 females

2013 Follow-up

1835 participants
814 males; 1021 females

24 month survey

2014 Follow-up

24 month survey

Table 1: Sample characteristics in 2013 follow-up survey (n=3442)

Characteristics	All (n=3442)				Females (n=1692)				Males (n=1302)			
	Intervention		Control		Intervention		Control		Intervention		Control	
	n	%	n	%	n	%	n	%	n	%	n	%
Baseline surveys completed	2173		2312		1234		1260		939		1052	
Follow-up surveys completed	1607	74.0	1835	79.4	920	74.6	1021	81.0	687	73.2	814	77.4
Site												
Cape Town	668	41.6	736	40.1	350	38.0	384	37.6	318	46.3	352	43.2
Port Elizabeth 1	407	25.3	533	29.1	236	25.7	291	28.5	171	24.9	242	29.7
Port Elizabeth 2	532	33.1	566	30.8	334	36.3	346	33.9	198	28.8	220	27.0
Age												
12-14 years	48	3.0	32	1.7	28	3.0	22	2.2	20	2.9	10	1.2
15 years	357	22.2	349	19.0	255	27.7	246	24.1	102	14.9	103	12.7
16 years	543	33.8	627	34.2	319	34.7	375	36.7	224	32.6	252	31.0
17 years	355	22.1	417	22.7	192	20.9	217	21.3	163	23.7	200	24.6
18-20 years	304	18.9	410	22.3	126	13.7	161	15.8	178	25.9	249	30.6
Live with parents												
Live with both parents	530	33.0	535	29.2	301	32.7	301	29.5	229	21.5	234	22.4
Live with mother only	641	39.9	736	40.1	368	40.0	402	39.4	273	5.4	334	7.9
Live with father only	86	5.4	117	6.4	49	5.3	53	5.2	37	39.7	64	41.0
Live with neither parent	350	21.8	447	24.4	202	22.0	265	26.0	148	33.3	182	28.8
Orphan Status*												
Both parents alive	1090	67.8	1258	68.6	615	66.9	709	69.4	475	69.1	549	67.4
Single Orphan	418	26.0	445	24.3	244	26.5	235	23.0	174	25.3	210	25.8
Double Orphan	98	6.1	129	7.0	60	6.5	74	7.3	38	5.5	55	6.8
Telecomms and Social Media												
Own a sim card	1138	70.8	1267	69.1	664	72.2	729	71.4	474	69.0	538	66.1
Own a cell phone	1058	65.8	1105	60.2	604	65.7	621	60.8	454	66.1	484	59.5
Have a Mxit account	1248	77.7	1343	73.2	690	75	753	73.8	558	81.2	590	72.5
Have a Facebook account	413	25.7	505	27.5	240	26.1	275	26.9	173	25.2	230	28.3

Table 2: Intention-to-treat analysis of effect of Generation Skillz on reported behaviour (n=3442)

	All (n=3442)						Females (n=1941)						Males (n=1501)					
	Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*	
	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)
Primary Behavioral Outcomes																		
Age-disparate sex last 6 months	103	6.4	96	5.2	1.40	0.99-1.98	48	5.2	35	3.4	**1.65**	**1.03-2.63**	55	8.0	61	7.5	1.19	0.79-1.78
Older partner (5+ years) last 6 months	53	3.6	46	2.7	1.45	0.90-2.35	35	4.1	27	2.9	1.65	0.90-3.01	18	2.9	19	2.6	1.17	0.60-2.28
Younger partner (5+ years) last 6 months	50	5.5	51	5.0	1.24	0.78-1.97	13	2.6	8	1.4	N/A		37	9.1	43	9.4	1.10	0.64-1.88
More than 1 partner last 6 months	363	22.6	364	19.8	**1.32**	**1.08-1.63**	92	10.0	94	9.2	1.15	0.85-1.57	271	39.5	270	33.2	**1.34**	**1.08-1.66**
Reported rape perpetration ever													87	12.8	104	12.7	1.07	0.71-1.62
Secondary Behavioral Outcomes																		
Ever had sex	971	60.4	1086	59.2	1.21	1.00-1.47	461	50.1	506	49.6	1.15	0.91-1.44	510	74.2	580	71.3	1.22	0.95-1.57
More than 2 lifetime partners	420	43.3	447	41.2	1.19	0.93-1.52	120	26.0	111	21.9	1.29	0.95-1.76	300	58.8	336	57.9	1.00	0.78-1.29
Currently have >1 partner	174	11.4	220	12.6	0.88	0.71-1.09	85	9.7	103	10.5	0.91	0.67-1.23	89	13.7	117	15.2	0.89	0.65-1.21
Ever tested for HIV	892	55.5	995	54.2	1.16	0.95-1.41	533	57.9	611	59.8	0.97	0.76-1.24	359	52.3	384	47.2	**1.38**	**1.11-1.72**
Tested for HIV last 12 months	538	34.1	545	30.4	1.21	0.98-1.49	332	36.4	356	35.4	1.08	0.82-1.40	206	31.0	189	24.0	**1.47**	**1.13-1.90**
Circumcised													59	8.6	77	9.5	1.16	0.73-1.84
Ever used a condom*	734	75.6	816	75.1	1.02	0.80-1.29	375	813	410	81.0	0.98	0.66-1.45	359	70.4	406	70.0	1.03	0.78-1.38
Used a condom at last sex*	592	61.0	656	60.4	1.04	0.86-1.25	293	63.4	318	62.9	1.04	0.79-1.36	299	58.6	338	58.3	1.07	0.83-1.37
Sex while drunk last 6 months	197	12.9	269	15.4	0.97	0.76-1.25	92	9.4	72	8.2	0.97	0.68-1.39	125	19.3	177	23.1	0.84	0.62-1.14
Transactional sex last 6 months	58	3.8	82	4.7	0.93	0.61-1.40	16	1.8	24	2.5	0.75	0.39-1.42	42	6.5	58	7.6	0.92	0.57-1.48
Perpetration of physical intimate-partner violence ever													244	35.5	266	32.7	**1.27**	**1.00-1.60**
Hazardous alcohol use (8+ points)†	297	18.5	331	18.0	1.12	0.92-1.36	118	12.9	116	11.4	1.16	0.88-1.54	179	26.1	215	26.5	1.01	0.80-1.28

*Via random-effects logistic regression comparing intervention vs control, adjusted for age group, school-level clustering, and baseline prevalence

†Also includes harmful and high-risk alcohol use   NA = Not enough events to carry out the regression

Table 3: Intention-to-treat analysis of effect of Generation Skillz on HIV-related knowledge, reported attitudes and reported gender norms (n=3442)

Scale	All (n=3442)						Females (n=1941)						Males (n=1502)					
	Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*	
	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI
HIV Knowledge (out of 10)	6.40	2.04	5.96	2.12	**0.39**	**0.25 to 0.53**	6.37	2.02	5.97	2.15	**0.35**	**0.17 to 0.53**	6.45	2.07	5.96	2.08	**0.44**	**0.22-0.66**
HIV Stigma (out of 3)^	2.26	0.54	2.22	0.58	0.01	-0.03 to 0.04	2.28	0.54	2.25	0.58	0.02	-0.03 to 0.07	2.22	0.54	2.18	0.58	-0.02	-0.07 to 0.04
HIV Prevention Self-Efficacy (out of 3)	2.03	0.49	2.01	0.51	-0.01	-0.05 to 0.02	2.08	0.51	2.05	0.54	0.00	-0.05 to 0.04	1.97	0.44	1.96	0.46	-0.03	-0.08 to 0.03
Gender-Equitable Norms (out of 3)	1.71	0.35	1.69	0.35	0.00	-0.02 to 0.03	1.76	0.36	1.74	0.37	0.02	-0.01 to 0.05	1.65	0.33	1.64	0.33	-0.01	-0.04 to 0.02

*Via random-effects linear regression comparing intervention to control, adjusted for school-level clustering, age group, site, and baseline scores

^Higher scores indicate more favorable attitudes towards people living with HIV   β = Coefficient for linear regression, positive numbers indicate a positive correlation

Table 4: Question-by-question analysis of differences in HIV-related knowledge between the intervention and control group (n=3442)

Question	All (n=3442)					
	Intervention		Control		Intention To Treat*	
	n	%	n	%	OR	95% CI
I can tell if someone has HIV by looking at him or her	1271	79.1	1399	76.2	1.09	0.86-1.38
Having an older sexual partner increases your risk of getting HIV	1234	76.8	1166	63.5	**1.87**	**1.46-2.41**
Using condoms during sex reduces your risk of getting HIV	943	58.7	1011	55.1	1.09	0.91-1.31
An HIV-positive mother would never give birth to an HIV-negative baby. ^	1095	68.1	1241	67.6	1.04	0.89-1.22
You are more likely to get HIV if you already have an STI	930	57.9	947	51.6	**1.30**	**1.07-1.56**
Having only one mutually faithful partner reduces your risk of getting HIV	883	55.0	954	52.0	1.04	0.86-1.25
Male circumcision reduces a man's risk of getting HIV	681	42.4	758	41.3	1.11	0.96-1.28
Legally, men are allowed to beat their wives.^	1320	82.1	1506	82.1	0.93	0.74-1.17
Drinking alcohol can increase your risk of getting HIV	1041	64.8	1007	54.9	**1.47**	**1.19-1.80**
Someone is most likely to spread HIV during the first 6-8 weeks after they get infected	888	55.3	955	52.0	**1.25**	**1.07-1.46**

Numbers and percentages shown indicate those of favourable responses

^ For these questions, false was the favourable response

*Via random-effects logistic regression, adjusted for age group, site, school-level clustering and baseline knowledge

Table 5: Intention-to-treat analysis of effect of Generation Skillz SMS campaign on reported behaviour (n=1690)

	All (n=1690)						Females (n=967)						Males (n=723)					
	SMS		No SMS		Intention To Treat*		SMS		No SMS		Intention To Treat*		SMS		No SMS		Intention To Treat*	
	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)
Primary Behavioral Outcomes																		
Age-disparate sex last 6 months	42	5.3	63	7.1	0.72	0.42-1.22	21	4.4	28	5.8	0.74	0.38-1.44	21	6.6	35	8.7	0.78	0.43-1.41
Older partner (5+ years) last 6 months	20	2.7	33	4.1	0.62	0.26-1.46	15	3.4	20	4.4	0.77	0.31-1.89	5	1.7	13	3.6	0.47	0.15-1.43
Younger partner (5+ years) last 6 months	22	4.9	30	5.9	0.84	0.42-1.70	6	2.3	8	3.0	N/A		16	8.4	22	9.3	N/A	
More than 1 partner last 6 months	160	20.0	221	24.8	**0.75**	**0.58-0.96**	43	8.9	56	11.5	0.83	0.53-1.31	117	36.7	165	40.8	0.78	0.55-1.09
Reported rape perpetration ever	33	14.4	58	19.0	0.65	0.33-1.29							33	14.4	58	19.0	0.65	0.33-1.29
Secondary Behavioral Outcomes																		
Ever had sex	465	58.1	558	62.7	0.76	0.54-1.07	236	49.1	253	52.1	0.88	0.62-1.26	229	71.8	305	75.5	0.64	0.43-0.95
More than 2 lifetime partners	206	44.3	238	42.7	1.22	0.92-1.63	63	26.7	65	25.7	1.31	0.83-2.05	47	10.2	40	8.6	**1.59**	**1.07-2.37**
Currently have >1 partner	88	11.6	91	10.8	1.11	0.80-1.54	47	10.2	40	8.6	N/A		41	13.5	51	13.6	1.14	0.71-1.82
Ever tested for HIV	429	53.6	522	58.7	0.79	0.59-1.05	267	55.5	302	62.1	0.70	0.48-1.02	162	50.8	220	54.5	0.90	0.65-1.25
Tested for HIV last 12 months	260	33.0	314	36.1	0.76	0.54-1.07	166	34.9	189	39.2	0.66	0.42-1.02	94	30.0	125	32.3	0.84	0.58-1.23
Circumcised													27	8.5	35	8.7	1.03	0.52-2.03
Ever used a condom*	358	77.0	418	74.9	1.21	0.87-1.69	200	84.8	199	78.7	1.94	0.99-3.78	158	69.0	219	71.8	1.00	0.66-1.51
Used a condom at last sex*	289	62.2	336	60.2	1.07	0.81-1.42	151	64.0	160	63.2	1.04	0.68-1.58	138	60.3	176	57.7	1.17	0.77-1.78
Sex while drunk last 6 months	94	12.3	121	14.3	0.84	0.60-1.18	30	6.5	51	10.9	**0.54**	**0.32-0.92**	64	21.1	70	18.6	1.06	0.60-1.90
Transactional sex last 6 months	31	4.1	31	3.7	1.23	0.62-2.46	13	2.8	5	1.1	N/A		18	5.9	26	6.9	N/A	
Perpetration of physical intimate-partner violence ever													114	35.7	144	35.6	0.96	0.69-1.33
Hazardous alcohol use (8+ points)†	157	19.6	162	18.2	1.21	0.91-1.61	68	14.1	60	12.4	1.30	0.86-1.96	89	27.9	102	25.3	1.27	0.89-1.81

*Via random-effects logistic regression comparing Generation Skill + SMS vs just Generation Skillz, adjusted for age group, school-level clustering, sim card ownership, and baseline prevalence

†Also includes harmful and high-risk alcohol use   NA = Not enough events to carry out the regression

Table 6: Intention-to-treat analysis of effect of Generation Skillz SMS campaign on knowledge, reported attitudes and reported gender norms (n=1690)

	All Intervention (n=1690)						Females (n=967)						Males (n=723)					
	SMS		No SMS		Intention To Treat		SMS		No SMS		Intention To Treat		SMS		No SMS		Intention To Treat	
Scale	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI
HIV Knowledge (out of 10)	6.36	2.09	6.35	2.01	-0.06	-0.34 to 0.22	6.35	2.04	6.34	2.00	-0.03	-0.30 to 0.23	6.37	2.17	6.37	2.03	-0.03	-0.49 to 0.43
HIV Stigma (out of 3)^	2.25	0.55	2.26	0.54	-0.02	-0.08 to 0.03	2.30	0.55	2.27	0.53	-0.01	-0.08 to 0.06	2.17	0.53	2.25	0.54	-0.04	-0.12 to 0.04
HIV Prevention Self-Efficacy (out of 3)	2.04	0.50	2.02	0.48	0.01	0.04 to 0.05	2.09	0.52	2.06	0.51	-0.03	-0.10 to 0.03	1.96	0.45	1.97	0.43	0.01	-0.06 to 0.08
Gender-Equitable Norms (out of 3)	1.71	0.34	1.70	0.36	-0.01	-0.06 to 0.04	1.77	0.35	1.73	0.36	-0.01	-0.08 to 0.06	1.63	0.30	1.65	0.35	-0.01	-0.06 to 0.04

β = coefficient from random-effects linear regression comparing intervention to control, adjusted for school-level clustering, age group, site, sim card ownership and baseline scores

^Higher scores indicate more favorable attitudes towards people living with HIV

Table 7: Intention-to-treat analysis of schools receiving Generation Skillz plus SMS's vs control schools (n=2552)

	All (n=2552)						Females (n=1455)						Males (n=1097)					
	GS + SMS		Control		Intention To Treat*		GS + SMS		Control		Intention To Treat*		GS + SMS		Control		Intention To Treat*	
	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)
Primary Behavioral Outcomes																		
Age-disparate sex last 6 months	42	5.3	94	5.4	1.04	0.64-1.71	21	4.4	34	3.5	1.26	0.64-2.48	21	6.6	60	7.7	0.85	0.48-1.48
Older partner (5+ years) last 6 months	20	2.7	46	2.9	1.01	0.55-1.87	15	3.4	27	3.0	1.15	0.52-2.53	5	1.7	19	2.7	NA	
Younger partner (5+ years) last 6 months	22	4.9	49	5.0	1.01	0.54-1.88	6	2.3	7	1.3	1.75	0.38-7.96	16	8.4	42	9.6	0.90	0.48-1.69
More than 1 partner last 6 months	160	20.0	346	19.8	0.98	0.74-1.29	43	8.9	87	8.9	0.93	0.62-1.39	117	36.7	259	33.3	1.13	0.85-1.50
Reported rape perpetration ever													33	10.3	100	12.9	0.74	0.47-1.15

*Via random-effects logistic regression comparing Generation Skillz + SMS vs Control, adjusted for age group, school-level clustering, and baseline prevalence

NA = Not enough events to carry out the regression

Table 8: Loss-to-follow-up by study group and baseline characteristics (n=4435)

Baseline Characteristics	All baseline participants, unique IDs (n=4435)						Intervention (n=2142)						Control (n=2293)					
	Not Lost		Lost		Difference*		Not Lost		Lost		Difference*		Not Lost		Lost		Difference*	
	n	%	n	%	OR	95% CI	n	%	n	%	OR	95% CI	n	%	n	%	OR	95% CI
Group																		
Control	1661	72.4	632	27.6	1.00													
Intervention	1465	68.4	677	31.6	1.03	0.69-1.55												
Sex																		
Male	1373	69.6	600	30.4	1.00		631	67.9	298	32.1	1.00		743	71.2	301	28.8	1.00	
Female	1753	71.2	709	28.8	1.10	0.96-1.26	834	68.8	379	31.2	1.07	0.88-1.30	918	73.5	331	26.5	1.12	0.93-1.36
Site																		
Cape Town	1022	64.9	552	35.1	1.00		502	61.4	316	38.6	1.00		520	68.8	236	31.2	1.00	
Port Elizabeth 1	1230	79.1	325	20.9	0.46	0.30-0.71	600	77.9	170	22.1	0.37	0.18-0.77	630	80.3	155	19.8	0.56	0.34-0.90
Port Elizabeth 2	874	66.9	432	33.1	0.98	0.64-1.50	363	65.5	191	34.5	0.82	0.41-1.66	511	68.0	241	32.1	1.15	0.71-1.85
Baseline age																		
12-14 years	696	77.8	199	22.2	1.00		363	75.6	117	24.4	1.00		333	80.2	82	19.8	1.00	
15 years	1028	74.8	346	25.2	1.16	0.94-1.42	486	70.0	208	30.0	1.30	0.99-1.72	542	79.7	138	20.3	1.01	0.74-1.37
16 years	720	69.0	323	31.0	**1.50**	**1.21-1.87**	331	67.0	163	33.0	1.49	1.11-2.01	389	70.9	160	29.1	1.52	1.11-2.07
17 years	388	62.8	230	37.2	**2.05**	**1.61-2.61**	176	61.1	112	38.9	1.99	1.42-2.78	212	64.2	118	35.8	2.10	1.49-2.96
18-20 years	294	58.2	211	41.8	**2.48**	**1.92-3.20**	109	58.6	77	41.4	2.32	1.57-3.43	185	58.0	134	42.0	2.58	1.82-3.65
Live with parents																		
Live with both parents	1072	71.8	421	28.2	1.00		525	69.0	236	31.0	1.00		547	74.7	185	25.3	1.00	
Live with mother only	1259	71.6	499	34.8	1.03	0.88-1.21	594	71.0	243	29.0	0.94	0.75-1.18	665	72.2	256	27.8	1.13	0.90-1.42
Live with father only	163	65.2	87	28.4	**1.55**	**1.15-2.09**	69	62.7	41	37.3	**1.59**	**1.02-2.47**	94	67.1	46	32.9	**1.53**	**1.02-2.29**
Live with neither parent	601	67.8	285	32.2	**1.30**	**1.08-1.58**	263	63.8	149	36.2	**1.39**	**1.06-1.82**	338	71.3	136	28.7	1.24	0.95-1.62
Orphan status																		
Both parents alive	2233	70.7	924	29.3	1.00		1038	67.5	499	32.5	1.00		1195	73.8	425	67.3	1.00	
Single Orphan	719	70.2	305	29.8	1.06	0.91-1.25	351	71.2	142	28.8	0.88	0.70-1.12	368	69.3	163	25.8	**1.27**	**1.02-1.59**
Double Orphan	174	68.5	80	31.5	1.15	0.86-1.53	76	67.9	36	32.1	0.95	0.62-1.47	98	69.0	44	7.0	1.35	0.91-1.98
Ever had sex																		
No	1463	76.0	462	24.0	1.00		707	73.6	254	26.4	1.00		756	78.4	208	21.6	1.00	
Yes	1513	66.2	772	33.8	**1.60**	**1.38-1.84**	688	64.2	384	35.8	**1.59**	**1.29-1.95**	825	68.0	388	32.0	**1.62**	**1.32-1.98**

Partners in last 12 months (all)																	
None or one	2220	72.2	853	27.8	1.00		1064	70.0	456	30.0	1.00		1156	74.4	397	25.6	1.00	
Two or more	649	66.0	335	34.0	**1.36**	**1.15-1.60**	293	64.5	161	35.5	**1.36**	**1.07-1.72**	356	67.2	174	32.8	**1.37**	**1.09-1.70**
Partners in last 12 months (males)																	
None or one	796	72.6	300	27.4	1.00		367	69.5	161	30.5	1.00		429	75.5	139	24.5	1.00	
Two or more	476	66.2	243	33.8	**1.42**	**1.14-1.75**	223	67.0	110	33.0	1.23	0.90-1.68	253	65.5	133	35.5	**1.61**	**1.20-2.16**
Partners in last 12 months (females)																	
None or one	1424	72.0	553	28.0	1.00		697	70.3	295	29.7	1.00		727	73.8	258	26.2	1.00	
Two or more	173	65.3	92	34.7	1.30	0.97-1.73	70	57.9	51	42.2	**1.68**	**1.11-2.55**	103	71.5	41	28.5	1.04	0.70-1.56
Age-disparate sex in last 12 months																	
No	2796	71.0	1140	29.0	1.00		1316	68.7	601	31.4	1.00		1480	73.3	539	26.7	1.00	
Yes	180	65.7	94	34.3	1.26	0.96-1.65	79	68.1	37	31.9	1.07	0.70-1.65	101	63.9	57	36.1	**1.42**	**1.00-2.02**
Alcohol use (AUDIT)																	
Normal (<8)	2618	71.5	1044	28.5	1.00		1238	69.3	549	30.7	1.00		1380	73.6	495	26.4	1.00	
Hazardous (8-15)	341	68.2	159	31.8	1.07	0.87-1.32	156	66.7	78	33.3	0.97	0.71-1.32	185	69.6	81	30.5	1.17	0.88-1.56
Harmful (16-19)	96	62.8	57	27.3	1.38	0.97-1.97	40	59.7	27	40.3	1.28	0.75-2.17	56	65.1	30	34.9	1.47	0.92-2.36
Dependent (20+)	71	59.2	49	40.8	**1.61**	**1.09-2.37**	31	57.4	23	42.6	1.52	0.85-2.73	40	60.6	26	39.4	**1.69**	**1.00-2.85**
Ever perpetrated rape																	
No	1082	71.1	439	28.9	1.00		504	68.8	229	31.2	1.00		578	73.4	210	26.7	1.00	
Yes	219	64.8	119	35.2	1.33	1.02-1.72	95	66.9	47	33.1	1.19	0.79-1.79	124	63.3	72	36.7	**1.47**	**1.04-2.06**
Physical IPV ever (males)																	
No	913	71.7	361	28.3	1.00		422	68.1	198	31.9	1.00		491	75.1	229	24.9	1.00	
Yes	461	66.0	238	34.1	1.27	1.03-1.56	209	67.6	100	32.4	1.00	0.73-1.36	252	64.6	47	35.4	**1.56**	**1.18-2.08**
Baseline Characteristics	mean	SD	mean	SD	Coef	95%CI	mean	SD	mean	SD			mean	SD	mean	SD		
# of people in household	5.45	5.70	5.09	5.60	-0.36	-0.72 to 0.01	5.45	5.34	4.84	2.10	**-0.56**	**-0.99 to -0.13**	5.44	6.00	5.37	7.75	-0.08	-0.68 to 0.52
Asset index	0.71	0.20	0.69	0.21	-0.01	-0.03 to 0.00	0.71	0.21	0.70	0.20	-0.01	-0.03 to 0.01	0.71	0.20	0.69	0.22	**-0.02**	**-0.04 to 0.00**

*Assessed via random-effects logistic regression adjusted for school-level clustering

Overall discussion and conclusions

The GOAL Trial is the first randomised controlled trial (RCT) of a sport-based HIV prevention (SBHP) intervention to be carried out, and one of the first RCTs carried out in the growing Sport-for-Development (SFD) sector. Prior to the trial, evidence on the effective of SBHP interventions had come only from observational and quasi-experimental studies, many only assessing effects on HIV-related knowledge and reported attitudes over a short period of follow-up. With a cluster-randomised design, two years of follow-up, an innovative mobile-phone-assisted methodology for conducting self-administered questionnaires, and primary behavioural outcomes that are closely linked to South Africa's HIV epidemic, the GOAL Trial represents an important step forward for evaluation of SBHP interventions and for the SFD sector in general. Given the lack of scientific evidence in the sector, researchers have called for more rigorous evaluations and openly questioned whether the 'impact' rhetoric of practitioners, policymakers, and funders focused on SFD has been overly optimistic.[1]

Summary of findings by research question

Globally, what is the evidence of effectiveness for sport-based HIV prevention interventions, particularly for young people?

Prior to the GOAL Trial, no randomised controlled trials of sport-based HIV prevention interventions had been carried out. The systematic review provided strong evidence that SBHP interventions have at least a short-term effect on HIV-related knowledge, stigma, self-efficacy, reported communication, and reported recent condom use. There was no overall evidence of effects on uptake of HCT or other HIV-related services, but few studies had assessed this. Limited follow-up data suggested that intervention effectiveness on knowledge, attitudes, and communication may diminish over time. There was no evidence either way, however, on whether they can reduce HIV, STI or unintended pregnancy rates. There was also no evidence to suggest that these interventions have had negative effects. More rigorous intervention studies are needed to determine

whether these effects are consistent across multiple settings and whether SBHP interventions have an effect on biological outcomes, such as HIV incidence and STI incidence.

What are the patterns of reported sexual risk behaviour among male and female adolescents in informal settlements in Cape Town and Port Elizabeth, South Africa?

High prevalence of reported risk behaviour was observed, in particular among males, with 20.5% reporting three or more partners in the last year, 22.5% reported currently having more than one sexual partner, 23.5% screening positive for hazardous or harmful alcohol use, 18.2% reporting having ever perpetrated rape, and 35.7% reporting having ever perpetrated physical intimate-partner violence. Important sex differences were observed in reported sexual behavior and alcohol use. After adjusting for age and site, males had roughly 2.5-times higher odds of reporting having ever had sex, roughly 4.5-times higher odds of reporting having three or more sexual partners in the last 12 months, roughly 4-times higher odds of reporting currently having multiple sexual partners, and 2-times higher odds of screening positive for hazardous alcohol use. Females, however, had 2-times higher odds of reporting having had an age-disparate older partner in the last year (11.0% vs 2.4%).

Is social media use associated with reported multiple partnerships in the last year, age-disparate sex in the last year, and/or reported hazardous alcohol use among this population?

Among females, having a Facebook account was associated with reported multiple partnerships in the last year (AOR=1.81, 95%CI=1.19-2.74), age-disparate sex in the last year (AOR=1.96, 95%CI=1.16-3.32) and hazardous alcohol use (AOR=1.97, 95%CI=1.41-2.74). Using Mxit—a popular mobile instant messaging application—was associated with higher odds of reported multiple partnerships in the last year among both males (AOR=1.70, 95%CI=1.35-2.14) and females (AOR=1.45, 95%CI=1.07-1.96) and with hazardous alcohol use

among both males (AOR=1.47, 95%CI=1.14-1.90) and females (AOR=1.50, 95%CI=1.18-1.90).

Over one year, does the Generation Skillz intervention reduce reported age-disparate sex, multiple partnerships, and/or rape perpetration among this population?

The midline GOAL Trial results were mixed and surprisingly disappointing in terms of the Generation Skillz intervention's effect on reported sexual risk behaviour. While there was very strong evidence of an increase in HIV-related knowledge for both sexes (p<0.001) and on reported HIV testing ever (p=0.004) and in the past 12 months (p=0.004) among males, there was also strong evidence of an increase in reported multiple partners in the last six months among males (p=0.007), reported age-disparate sex (with a younger or older partner) in the last six months among females (p=0.037), and intimate-partner violence perpetration among males (p=0.047). Given that these latter three behaviours were the primary focus of the intervention, which was designed in accordance with the 17 characteristics of effective sex and HIV education programmes,[2] these results are both surprising and discouraging. That said, the LTFU analysis suggested that the intervention group had lower attrition than the control group of participants who were already sexual-risk-takers at baseline, perhaps providing a partial explanation of the observed midline differences. It may be that this type of sport-based, behavioural intervention can be effective in changing peer supported positive behaviours—such as HIV testing and male circumcision—but are less effective or ineffective in influencing more deeply seated norms surrounding sexual relationships, such as age-disparate sex and multiple partnerships.

Generation Skillz Utshintsho interventions were delivered shortly after each school completed its midline survey and well before the results were analysed, so it was not possible to consider the midline results in deciding whether to go ahead with the booster sessions. Had the booster been scheduled for later on,

the DSMB may have decided to terminate the trial on the basis of the negative effects on certain reported behavioural outcomes observed at midline. On the other hand, it may be that the Generation Skillz Utshintsho intervention will mitigate or reverse the observed negative effects.

Does sending biweekly SMS messages to participants for one year enhance the effectiveness of Generation Skillz in improving HIV-related knowledge, reported attitudes, and/or reported behaviour over one year?

Comparing participants from intervention schools receiving the SMS campaign to those from schools not receiving it, we observed strong evidence of a positive effect of the SMS campaign on reported multiple partners in the last six months (OR=0.75, 95%CI=0.58-0.96). There was strong evidence of a positive effect of the SMS campaign on reported sex while drunk in the last six months among females (OR=0.54, 95%CI=0.34-0.92). There was no evidence of an effect on knowledge, reported attitudes, reported gender norms or other primary behavioural outcomes. Comparing the schools receiving the SMS's to control schools, there was no evidence of difference in any of the three primary behavioural outcomes.

Strengths

This was a relatively large RCT with a rich baseline and midline data set containing reported data on a wide range of outcomes of public health importance in a population with one of the highest HIV prevalences in the world. The data collection approach ensured strict confidentiality, minimizing potential observer/interviewer bias and maximizing the amount of usable data, through validation rules and complex skip patterns. The study's use of mobile phones for confidential, self-administered data collection was commended by peer reviewers as 'novel' and 'innovative'. Robust statistical methods were used, adjusting for school-level clustering, age and site differences between groups, and cluster-level baseline outcomes (to ensure that any observed effects were not merely products of baseline differences). The follow-up rate, while lower

than expected and hoped, was understandable, given the mobility of the study population.

Limitations

There are several important limitations in the GOAL Trial. First, due to the smaller-than-anticipated sample size and the Trial Advisory Committee's decision to forego biomarker data collection at follow-up, the trial's primary outcomes rely on self-reported behavioural data. Concerns about the validity of self-reported sexual behaviour data have been well documented, with males commonly over-reporting and females commonly under-reporting the number of partners and sexual activity.[3-5] The use of confidential mobile-phone-based, self-administered questionnaires (rather than face-to-face interviews or written self-administered questionnaires) may have helped to reduce social desirability bias in the GOAL Trial.[6] Nevertheless, it is possible that social desirability bias may have influenced participants' responses and/or that the intervention may have influenced perceptions of socially desirable answers rather than truly influencing behaviour. One would not expect this to explain the observed harmful effects of Generation Skillz in increasing self-reported behavioural outcomes, though it is possible that the intervention may have increased participants' awareness of risky behaviours and that this increased their likelihood of disclosing multiple sexual partners, age-disparate partners, or intimate-partner violence. There is precedent for this from a previous HIV prevention and IPV trial in South Africa.[7]

Selection bias—often a challenge in cluster-randomised trials[8]—presents another limitation. Importantly, a large proportion of the registered students did not enrol in the trial at baseline, primarily due to lack of having obtained written parental consent. Since youth who are able to obtain a parental signature may be systematically different from youth who are not able to obtain a parental signature (i.e. they might have a stronger relationship with their parents or a more supportive household), this may have resulted in the GOAL Trial sample having a less risky behavioural profile than the population of Grade 9 learners as a whole. Further selection bias may have arisen through loss-to-follow-up,[9]

which was differential between study groups (20.6% in the control group; 26.0% in the intervention group). Again, this would not seem to explain the observed negative behavioural effects. Indeed, since one would expect those lost-to-follow-up (e.g., school dropouts) to tend to be riskier than those followed-up, the differential loss-to-follow-up observed in the GOAL Trial would be expected to influence the effect in favour of the intervention group (which lost a larger proportion of participants from baseline to midline) rather than the control group. This said, some studies, for example a cohort study of commercial sex workers in Kenya,[10] have found the opposite – that more risk behaviour is associated with lower odds of loss-to-follow-up. Thus, it is plausible that both the negative and the positive effects observed in the GOAL Trial were influenced by loss-to-follow-up. Subsequent analysis should assess baseline differences between those were and were not lost-to-follow-up.

Generalizability

The loss of Soweto as a trial site limited the GOAL Trial's generalizability. The results should not be generalized to secondary schools in South Africa as a whole for several reasons. First, informal urban settlements differ economically and socially from rural settings as well as from formal urban settings. They tend to have higher HIV prevalence, higher unemployment, and higher rates of violence and crime.[11] Secondly, Xhosa culture differs from other cultures around South Africa, in terms of traditions, gender norms, and perceptions of male circumcision.[12,13] Including Soweto in the trial would have provided a much more diverse and culturally representative sample. The findings may be able to be generalized—taking into consideration the aforementioned selection bias caveats—to informal settlement schools in Cape Town, Port Elizabeth, and perhaps other predominantly Xhosa informal urban communities in the Eastern and Western Cape.

The results should likewise neither be generalized to all of Grassroot Soccer's interventions nor all SBHP interventions. As the systematic review identified, many previously evaluated SBHP interventions (including those of Grassroot

Soccer) work with younger adolescents than Generation Skillz. Additionally, other SBHP interventions use quite different approaches, some quite curriculum-based and others less structured.

On-going work and next steps

Endline GOAL Trial surveys began in February 2014 and will continue through August 2014. As of 10 April 2014, 1205 endline surveys had been completed in Cape Town and Port Elizabeth. The same analysis and deduplication approach used with the midline data will be used with the endline data. The endline analysis will help us to understand (a) whether the positive and negative effects observed at midline remain consistent after two years of follow-up and (b) whether the Generation Skillz Utshintsho sessions influence the intervention's effects positively, negatively or neutrally. As the SMS campaign was not continued into the second year of follow-up, the endline survey will only be able to tell whether the effect of the previous SMS's sent in 2012-2013 persisted into 2014. One would anticipate that the effect of the SMS's would diminish over time, as has been observed with other short-term HIV prevention interventions followed over long-term studies.[14]

A process evaluation of Generation Skillz and the GOAL Trial began in 2013 and is the subject of another doctoral candidate's research. Using primarily qualitative methods (in-depth interviews, focus group discussions, observation of trainings and interventions) in addition to attendance and 'coach support visit' data collected by Grassroot Soccer, the process evaluation should help to answer questions of why the Generation Skillz intervention was not successful in achieving its objectives in 2012-2013 and how the organisation might modify either the content, format, or delivery of the intervention to increase its effectiveness. We expect findings from the process evaluation to begin emerging in 2014, with the analysis and write-up finishing in 2015.

Further analysis of the quantitative GOAL midline results could explore:

A. Whether there is any evidence of dose-response (i.e. is the number of sessions attended associated with gains in knowledge and/or with any of the negative behavioural effects observed?);

B. Whether and, if so, how participants lost-to-follow-up differ from those who completed midline questionnaires;

C. Whether there is evidence of effect modification of the SMS campaign by sim card, mobile phone ownership, and/or Mxit use;

D. Whether traced participants (i.e. those followed up outside of school) exhibited different patterns of reported behaviour and how this compared between groups;

E. Risk factors (apart from Generation Skillz participation) for reported multiple partners in the last six months;

F. Risk factors for reported rape and intimate-partner violence perpetration (note: this is the topic of another paper not presented in this thesis);

G. Whether adjusting for survey date or month affects the observed effects (since the recall period was only six months, some participants' recall period would have included the holidays, while others would have only included term time. Sexual behaviour may differ during different times of the year);

Several researchers on the GOAL Trial (Kaufman, DeCelles, Weiss and Ross) led another cluster-randomised trial in 2013-2014, assessing the effectiveness of a single-session SBHP intervention developed and implemented by Grassroot Soccer in increasing uptake of voluntary medical male circumcision among adult male soccer players in Bulawayo, Zimbabwe.[15] The trial enrolled 47 teams and 735 men aged 18-50 years. The findings, which will be presented at the 20th International AIDS Conference in Melbourne, Australia, present promising evidence that the 'Make The Cut' intervention increases the odds of VMMC uptake by nearly 10-fold or, in absolute terms, by roughly 4 percent over four months of follow-up, compared to a control group receiving no intervention.[16] A further trial of Make The Cut is being carried out in Bulawayo in 2015 to assess

whether a modified version of the intervention is effective in increasing uptake among adolescent males. Together with the positive effect of Generation Skillz on reported HIV testing uptake among males and previous evidence of effects of the HoMBReS intervention on HCT uptake in the US,[17] there is now growing evidence of the effectiveness of SBHP interventions in increasing uptake of HIV-related services among males. Given the urgent need for and potential of public health impact of scaling up VMMC coverage in Southern Africa[18,19] as well as the consistently lower HCT uptake rates among men relative to women in the region,[20,21] policymakers and practitioners should still consider sport-based interventions in designing programmes to increase demand for HIV-related services among young and adult men, despite the findings of the GOAL Trial reported here.

Final Thoughts

As the first RCT of a sport-based HIV prevention intervention and one of the first RCTs in the Sport-for-Development sector, the GOAL Trial marks an important step forward in advancing evaluation of a programming area that, despite growing funding streams, has lacked high-quality evidence. The trial's midline results raise important questions for GRS and its peer organisations working in SBHP. What about the intervention led male participants to be more likely to take up HCT? Why was the same effect not observed for females? Why might an SBHP intervention focused on reducing multiple partnerships, age-disparate sex, and intimate partner violence actually increase reports of these three outcomes, at least by some groups of participants?

The mobile and online technology tools used in the GOAL Trial (discussed in Linking Section 1) may be of interest to trialists currently using paper and/or spreadsheets or other electronic ways of collecting data. Overall, ODK and Force.com combined for a powerful and cost-effective trial operations suite. Building on the experience in the GOAL Trial, the MCUTS Trials, and consulting work with other research organizations, the doctoral candidate and colleagues are working to develop a Force.com-based application for use in trial

management, tracking research sites, staff, participants, survey completion, equipment, and more. Since the start of the GOAL Trial, several projects connected to LSHTM have begun using ODK for mobile data collection in Zimbabwe, Malawi, and India.

Our study team encountered numerous operational challenges during the GOAL Trial. First and foremost, there were regulatory challenges, such as longer than expected delays in local ethics approval, the lack of approval from the Gauteng Department of Education, and the requirement to use written (opt-in) rather than passive (opt-out) parental consent. There were—as is the norm in research studies in resource-limited settings—significant logistical challenges, including coordinating schedules with dozens of teachers and school administrators, dealing with poor and inconsistent Internet access (particularly in Port Elizabeth), and frequent teacher and student absenteeism. Additionally, there were safety-related challenges, with cases of students or gangsters attempting to steal the study phones, notable bouts of gang violence occurring in at least two schools, and tracing of participants who did not attend the midline follow-up survey requiring requiring that staff visit notoriously unsafe neighbourhoods. These challenges explain the basis of some of the aforementioned study limitations, particularly those related to selection bias.

It is important to consider that the GOAL Trial was carried out in a real-world programmatic context, rather than a carefully controlled clinical context. Singal and colleagues recently highlighted some of the key differences between this type of 'effectiveness' trial and more clinical 'efficacy' trials, noting that the former tend to have stronger external validity while the latter have stronger internal validity.[22] Indeed, many of the challenges encountered in implementation of Generation Skillz in the context of the GOAL Trial have also been encountered by GRS in delivery of its interventions outside of a trial context. For example, while schools were willing to cooperate, on the whole, neither the survey teams nor the GRS Coaches had full control of the study or intervention environment. Young people's attendance in the intervention was

imperfect and unpredictable. Occasionally, schools or teachers would change the schedule without notifying GRS. The intervention or survey team ran into periodic car and transport problems, such as cars being double-booked or under maintenance during a scheduled survey or intervention session. Two schools had outbursts of gang violence that resulted in temporary shut downs and changes of timelines for both data collection and intervention delivery. Participants in both groups may have had exposure to other HIV prevention programmes. These are all challenges that an organisation implementing HIV prevention education in informal settlements in South Africa might indeed run into. Hence, while the trial lacked a tightly controlled clinical environment, it approximated the real-world delivery of a sport-based HIV prevention intervention in informal settlement schools.

Conclusion

Prior to the GOAL Trial, the observational and quasi-experimental research on sport-based HIV prevention (including a preliminary pre/post evaluation of Generation Skillz in South Africa) provided promising evidence of effects on knowledge and reported attitudes, with a potential effect on reported condom use. No studies had found any evidence of negative effects. The baseline results provided insight into the high prevalence of certain reported risk behaviours in this population of informal settlement adolescents in Cape Town and Port Elizabeth, in particular reported recent multiple partners, age-disparate sex, hazardous alcohol use, and rape perpetration. Noteworthy associations emerged from the baseline, some of which were consistent with previous literature (i.e. sexual risk behaviour with alcohol use) and some of which were novel (i.e. social media use with reported multiple partners, age-disparate sex, and alcohol use).

The GOAL Trial midline results were consistent with the previous literature in terms of finding very strong evidence of a positive effect on knowledge and partially consistent in terms of finding a positive effect on reported HIV testing uptake among males. They were inconsistent, however, in not finding an effect on reported attitudes and in finding evidence of negative effects on reported

multiple partners in the last six months and reported intimate-partner violence perpetration among males and reported age-disparate sex in the last six months among females. The midline findings thus proved surprising and disappointing, raising questions of why the intervention might have a negative effect on reported behaviour. Meanwhile, the trial found encouragingly strong evidence that participants at schools receiving the Generation Skillz SMS Campaign had lower odds of reporting multiple partners in the last six months. In sum, the findings suggest that SMS's should be included in the Generation Skillz intervention, that the intervention was effective in improving knowledge among boys and girls and uptake of HCT among boys, but that the intervention was ineffective in reducing reported multiple partnerships in the last six months, age-disparate sex in the last six months, and rape perpetration, and may even have led to an increase in each of these reported outcomes.

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