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**WORLD BANK GROUP**  
Health, Nutrition & Population

# SMART LINKAGE TO CARE EVALUATION REPORT

April 2018



In collaboration with:



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Department:  
Health  
**REPUBLIC OF SOUTH AFRICA**



**NATIONAL HEALTH  
LABORATORY SERVICE**



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April 2018

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# ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral treatment
CD4	Cluster of differentiation/classification determinant
HIV	Human Immunodeficiency Virus
HJH	Helen Joseph Hospital
IP	Internet protocol address
KB	Kilobyte
MB	Megabyte
NGO	Non-Governmental Organization
NHLS	South African National Health Laboratory Services
HREC	Witwatersrand Human Research Ethics Committee
MAMA	Maternal m-Health Programme
NPP	National Priority Programme
PIN	Personal identification number
RAM	Random access memory
SMS	Smart message service
TB	Tuberculosis
UNAIDS	United Nations AIDS
VL	Viral load
WHO	World Health Organisation

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# EXECUTIVE SUMMARY

South Africa has both the world's largest HIV epidemic and the largest antiretroviral treatment (ART) programme. Loss to follow-up at the various stages of HIV care is a major operational challenge, with unnecessary morbidity, mortality and further HIV transmission as a result of delayed ART initiation. Interventions to address this loss have had limited success in clinical trials. Cell phones are commonly used in South Africa, with a steadily growing number of users migrating to smart phones, representing an opportunity to engage patients with chronic diseases such as HIV, and potentially reduce loss to follow up.

We conducted a prospective randomised controlled trial assessing a smartphone application (app) that provided laboratory results to patients in an urban South African setting, as a means to improve the initial linkage to care after HIV diagnosis.

The study, done in partnership with the South African National Health Laboratory Services (NHLS) and World Bank Group, utilised routinely collected laboratory results from the NHLS database, which were then sent to study participant smartphones, with tracking of subsequent linkage to care for a minimum of 8 and a maximum of 16 months till February 2017. Linkage to care was defined as the existence of a HIV-related laboratory test (CD4 count, viral load test, creatinine) during patient follow-up. The time window considered was 2 weeks to 8 months after randomisation. Of the 4,537 clients screened, 353 clients were recruited and randomised to either the intervention group or control group. Of these, 122 (34.6%) were male, 157 (44.5%) were aged 18-30, and 92 (26.1%) were unemployed.

The study had multiple implementation challenges that meant that it had delayed initiation, and did not recruit the initially projected number of participants (Venter et al. 2018). Challenges included regulatory delays, changes in HIV facility testing patterns prior to initiation, and major technological design issues with installing the app on smartphones.

Only a minority of patients qualified for entry into the trial due to the strict eligibility criteria, ownership of suitable smart phones and app installation requirements. In terms of the trial's primary endpoint of linkage to care, only 48% of the participants in the study linked to care after eight months (Venter et al, submitted). The linkage to care rates by sub-group were: 52% for males, 46% for females, 45% for 18-30 year olds, and



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51% for >30 year olds. Extending the time interval for assessment of linkage to care suggested that some trial participants returned to care sometime after the 8 month mark (by February 2017, 53% of 18–30 year olds and 69% of 31+ year olds had laboratory evidence of linkage to care).

The As-treated analysis of app effectiveness was based on 345 trial participants randomized to either the app arm or the control arm. Of these, 65% were female and 44% were under 30 years of age. 47% were employed full-time, 95.9% had at least secondary school education, and just over one third (35.9%) were from Zimbabwe. Several patients in the control arm had been sent SMS notices by error and were excluded from the As-treated analysis (leaving 345 trial participants for analysis).

Linkage to care between two weeks and eight months was 48.6% in the intervention arm versus 45.1% in the control ( $P=0.52$ ) and increased to 64.1% and 61.0% ( $P=0.55$ ), respectively, after the initial eight-month period (Venter et al. submitted). 18-30 years old showed a statistically significant 20% increase in linkage to care for the intervention group. Youth under 30 years of age have been historically difficult to reach with traditional interventions, and the SmartLink app provides a proof of concept that this population reacts to mHealth interventions that engage patients in HIV care.

There were several implementation lessons learned during the study. The intervention we tested was not accessible to 90% of participants, meaning that finding ways to either expanding access to the app, or finding alternatives that fulfill similar functions, will need to be tested, if this approach is pursued in future. In this trial, app uptake of those randomised to the intervention arm suggested that HIV clients are keen to digitally access personal health information, possibly based on experiences of hard-to-obtain laboratory test results and perceived disconnect from the health care providers. Over 4,500 SmartLink app opening events were registered on Google Analytics during the impact evaluation.

## SECTION 1

# INTRODUCTION

South Africa has the largest number of people with HIV in any country. In addition, it has the largest absolute number of people on ART in the world, with an estimated 4.36 million on treatment in 2017 (UNAIDS, 2018). The expansion of the South African ART programme has been a remarkable public health success, with life expectancy jumping by a decade almost entirely due to increased ART coverage across the country (Statistics SA, 2016).

The impact of suppressive ART on sexual infection risk has been comprehensively demonstrated, supporting the expansion of ART as a major HIV preventive intervention (Cohen et al, 2016; Rodger et al, 2016). Evidence from the last few years has demonstrated clinical benefit with starting modern ART immediately, irrespective of immunological status, leading to a widespread recommendation for a “test and treat” approach (Cohen et al., 2016; TEMPRANO ANRS 12136 Study Group et al., 2015; The INSIGHT START Study Group, 2016; World Health Organization, 2015). This approach was adopted by South Africa in September 2016. Test and treat has further enjoyed support from mathematical models and observational studies, demonstrating public health benefit in that increasing ART coverage may substantially impact on new infections (Granich et al, 2009 Tanser et al, 2011).



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UNAIDS and WHO have driven the “90-90-90” initiative since 2015, as a mechanism to maximise the impact of expanded ART coverage for both individual health as well as decreasing new infections. The initiative calls for 90% of HIV-positive people to know their status, 90% eligible for therapy to be initiated on ART and 90% maintaining viral suppression (UNAIDS, 2016; WHO, 2015).

However, this approach has not shown anticipated impact on new infections in a well-conducted recent clinical trial (Iwuji et al, 2016), probably because of inadequate and late engagement with care. 90-90-90 relies on effective, timeous case finding and successful referral for ART initiation, as well as retention, a problem across the world documented widely in the so-called “care cascade” (Rosen et al, 2017, Hill, 2015). The cascade shows substantial loss to follow-up at every step along the diagnosis, staging, ART initiation and maintenance continuum, especially after HIV diagnosis. The resources being directed at the South African ART programme will exceed \$450 million a year for ART drug cost alone, a significant percentage of the health budget (Venter et



al, 2017). Extracting the most benefit from this large investment is important to continue to justify expenditure.

## 1.1 THE IDEA BEING TESTED

The significant patient attrition between HIV diagnosis and entry into HIV care means delayed access to ART, with avoidable illness and mortality, as well as unnecessary transmission of the virus (Hill, 2015). Interventions have been tested to decrease this attrition, most involving facilitation of HIV or CD4 staging results, with variable, largely modest results (Fox et al, 2016). New innovative approaches to address the cascade and track diagnosis, linkage to services and maintaining people with HIV on ART, are needed.

mHealth (the practice of medicine and public health, supported by mobile devices) has been identified as a potential tool to support the steps along the HIV treatment cascade. Interest in using cell phones to facilitate health care has increased in recent years in Africa, due to high levels of cell phone ownership. Recent evidence using short-message-

 *The goal of this project was to acquire an understanding of the implementation and impact of a smartphone-based app on the steps between HIV diagnosis and linkage to care programmes.*

services (SMS) showed reported self-adherence benefits or allowed for feedback regarding services (Mbuagbaw et al, 2015, Barron et al, 2016). Mobile applications (or "apps"), programmes that allow engagement on "smart" cell phones, have become a major part of people's lives, allowing for simple access to information (Google), to GPS tracking and engagement with services (Uber), to banking (most South African banks), social media (Facebook) and instant messaging (WhatsApp). We are unaware of any study that looked at using smartphones or apps to link patients to care.

The goal of this project was to acquire an understanding of the implementation and impact of a smartphone-based app on the steps between HIV diagnosis and linkage to care programmes. We conducted a prospective randomised controlled study to test whether providing newly diagnosed HIV patients with secure laboratory results and supporting information on their cell phones, would improve linkage from the point of diagnosis to attendance at an HIV care and ART initiation site. We hypothesised that patients would be more likely to engage with care after HIV diagnosis, if they were given rapid and personalised communications on their cell phones about their blood results, with supportive prompts on what to do with this information.

## SECTION 2

# BACKGROUND

## 2.1 SETTING

### 2.1.1 The South African health system and HIV

South Africa has a two-tier health system, public and private, with approximately 80% of the population using the largely free government-run public system, which is funded from the country's tax base. There are over 4,300 public health care facilities across the country, which provide comprehensive health services from primary to tertiary level, including HIV care. Provision of health services is the responsibility of provincial and local governments. The National Department of Health provides policy on minimum standards and standardised protocols, and assists the Department of Treasury in setting budgets, but implementation of these are left to the provincial and local governments.

With national HIV prevalence rates in South Africa at 12.7% (Statistics South Africa, 2016), a large portion of government health care funding goes to supporting HIV-positive patients. Antiretroviral treatment has been offered to HIV-positive patients since 2004 if they meet a certain CD4-count threshold; this threshold was originally set at 200 cells/mm<sup>3</sup> in 2004, raised to 350 cells/mm<sup>3</sup> in 2010, 500 cells/mm<sup>3</sup> in 2013, and with the introduction of test and treat, the threshold was removed completely in 2016. The HIV programme, largely thanks to accurate forecast costing, has enjoyed Department of Treasury support as it has expanded over the last 13 years. In addition, the programme has been expanded within the private medical market through managed care programmes.



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### 2.1.2 South Africa HIV testing and linkage

South African HIV testing rates are relatively high, with over 65% of adults knowing their status (Shisana, et al, 2012). However, immediate linkage to the next levels of care of newly diagnosed HIV-positive individuals is low throughout the region (Fox et al, 2017). Improved access to point-of-care CD4 diagnosis, widely anticipated to improve linkage to care, has yielded disappointingly limited success, suggesting other interventions are required (Faal et al, 2011; Fox et al, 2016, Larson et al, 2013). Supporting patients within the cascade of care may require multiple very different but complementary interventions (Fox et al, 2016). HIV diagnosis is usually performed by



lay counsellors in South Africa, sometimes outside of clinical flow of patient care within facilities or away from conventional clinical environments. This means that a substantial number get lost in the initial referral process, and before the patient receives their CD4 result.

Simplification of this step has been implemented as policy in South Africa, with an immediate CD4 count drawn and sent to the laboratory after HIV diagnosis; however, this still requires the newly diagnosed person to return to the clinic for the result and assessment for ART. Test and treat approaches that remove the CD4 count as a criteria for initiation, do not remove the step from diagnosis to referral into formal nurse or doctor-based clinical services, as the CD4 is used for assessing requirements for opportunistic infection screening and prophylaxis, as well as the speed of ART initiation. Very few programmes have implemented prompting or reminders of appointments, or tracking of defaulters, relying rather on passive entry to the assessment site.

South Africa has severe gender disparity in terms of access to HIV testing and care services (Shisana 2012 et al, UNAIDS 2016). Men remain under-tested, are less likely to

 *Epidemiology, including recent phylogenetic data suggest that infection risk is concentrated in their 20s, in both men and women (although with an 8-year age difference between genders), suggesting that earlier linkage to care at a younger age is needed.*

link to care, access antiretrovirals at lower CD4 levels, and appear to be more prone to loss to follow-up (Shisana et al, 2012; Takarinda et al, 2015, Rosen et al, 2016, Maheu-Giroux M et al, 2017, Reniers G, 2017). Finally, the initiation of ART occurs in South Africans usually during their 30s and 40s, due to late testing. Epidemiology, including recent phylogenetic data suggest that infection risk is concentrated in their 20s, in both men and women (although with an 8-year age difference between genders), suggesting that earlier linkage to care at a younger age is needed (UNAIDS, 2016; Grabowski MK et al, 2017).

Linkage to care and adherence to medication is higher in HIV than in most other chronic illnesses, and this is widely ascribed to widespread HIV patient education programmes within communities and facilities, with a term “the activated patient”

referring to someone knowledgeable about their condition and ways to negotiate the health system to access required care (Torjesen, 2011). Facilitating this engagement at the initial step after HIV diagnosis may assist in mitigating the loss to follow-up experienced within HIV testing and treatment programmes.

### 2.1.3 Demographics and site of project

Gauteng is the smallest but richest and most populated province in South Africa. It is home to around 12 million inhabitants, which make up approximately 25% of the country’s total population, and has an estimated HIV prevalence rate of 12% (Shishana et al, 2012; Statistics South Africa, 2016). Approximately 50% of all deaths in Gauteng were thought to be HIV-related, before the implementation of widespread treatment programmes. Almost one million people in the province are now receiving ART. The inner city area of Johannesburg, has an estimated 1 million residents making it one of



southern Africa's most densely populated area, with overcrowding, poverty, crime, substance abuse, sex work and unemployment rendering residents particularly vulnerable to HIV. The area has a well-established HIV testing and antiretroviral access programme, although actual testing levels, linkage to care and retention is difficult to measure, due to the transient nature of the community.

Hillbrow, a residential suburb in the heart of inner city Johannesburg, has 16 primary-level HIV clinics which provide antiretroviral care. The largest, Hillbrow Community Health Centre (HCHC) is estimated to have over 20 000 patients on ART, as well as a busy HIV testing centre, and was the principal site for this trial. The clinic is a provincial primary health care facility including 24-hour emergency room care, family planning, maternal health, HIV and TB care and treatment services. Other trial sites were nearby clinics (80 Albert, Yeoville and Jeppestown), all significantly smaller and also providing primary care such as family planning, maternal health and HIV care and support. Wits RHI has worked in the inner city since its inception in 1994 and has been supporting public health facilities, since 2002, with direct clinical help, technical assistance and training.

Helen Joseph Hospital (HJH), just to the west of Johannesburg's inner city, was the second large site selected for the trial. HJH is a provincially-run tertiary-level health care service facility which has 21 in-patient wards in addition to a number of out-patient services including the Themba Lethu HIV clinic, one of the largest ART sites in the country.



*Multiple systems are used to collect and record patient clinical and other data, for HIV and other conditions.*

#### 2.1.4 HIV monitoring, tracking and laboratory systems

Multiple systems are used to collect and record patient clinical and other data, for HIV and other conditions. Tier.net is a national HIV patient monitoring tool developed by the University of Cape Town and supported by the Department of Health, and is used in most public clinics in South Africa. All HIV-positive patient data is regularly recorded in Tier.net, and used for reporting against Department of Health indicators. However, this system has many challenges, and while it has the potential to be used for communicating with patients, was not designed for this in mind nor used as such.

South Africa has a well-established laboratory provision system through the National Health Laboratory Service (NHLS) that provides comprehensive services for state patients (several private country-wide laboratories service the medical aid and private industry). The NHLS has a sophisticated information infrastructure that can link patient laboratory results across health facilities and provinces. TrakCare is a consolidated laboratory database system, with results added from each of the more than 250 NHLS laboratories across the country, and which can be accessed by any authorised medical practitioner for immediate results. Access is currently largely internet-based, with terminals confined to selected hospitals and large clinics. TrakCare utilises a composite of first name, last name, date of birth, health care site and occasionally national identity



number. Currently, the NHLS provides diagnostic, staging, monitoring and toxicity detection for the HIV treatment programme in all clinics nationally.

In 2013, the National Department of Health agreed to use a single patient identifier across the country for clinical records and laboratory results, meaning that longitudinal monitoring of patients will be made easier in future, and theoretically tracked between facilities and across the country. Implementation, even within the NHLS, has been very slow, but implementation of the single patient identifier promises to be a powerful tool to allow for future programme monitoring, using routine diagnostic and investigative results at facility, district and provincial levels to monitor adherence to national algorithms, as well as quality of care.

### 2.1.5 NHLS HIV testing and CD4 staging information pathway

Upon testing HIV positive using the Department of Health's testing algorithm, a blood sample is drawn from the patient by a health care worker and sent to a designated

nearby NHLS lab for routine analysis of CD4 count, which guides whether to initiate ART (until recent test and treat policy), the speed of initiation, and the implementation of opportunistic infection prophylaxis. Samples are barcoded with a unique NHLS sample number and recorded on the patient's file, and taken to the nearest NHLS lab. CD4 count analysis is usually done within one to five hours after reaching the lab, and the result is automatically entered into TrakCare immediately.

Laboratory results from HIV-positive patients are sent to the health facility in two ways; formal paper reports and via an SMS printer. The South African HIV care and support protocol states that health care workers must be able to verify a laboratory result prior to providing treatment; most health care workers interpret this to mean that they need paper, computer database or telephonic confirmation of the laboratory results.



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Paper results are printed in the lab and sent to the facility. SMS-based results are sent automatically, as well as on request, to a clinic-based SMS printer available in most clinics across South Africa. The SMS printer receives the results through the cell phone network and prints the results as they are received. The facility staff are expected to add the printed results to patient files on a regular basis. A benefit of the SMS printer is that it is two-way; health care workers can submit a request for results to be (re-)sent through the printer by entering the unique NHLS blood sample identification number into the SMS printer, with a result within two-to-five minutes. In almost all cases, requests for CD4 and viral load information by health workers occur once a patient is within the facility environment for a routine appointment or if ill, rather than when they are performed by the laboratory (and may require action). Currently, patients cannot access their own results through any mechanism other than facility attendance and a request to the health worker.



One example where mHealth is already being used for communication of lab results to mobile devices in the South African public healthcare context is the TreatTB app. This NHLS tablet-based TB database app monitors existing TB-positive patients and their drug regime, and notifies TB physicians, health care workers and other health professionals when a new TB case has been identified. New specimen results are sent via the app to the mobile devices of all health care workers in the referring facility.

## 2.2 IMPLEMENTING PARTNERS

The Wits Reproductive Health and HIV Institute (Wits RHI) has been a leading reproductive health innovator, programme implementer and research organisation since 1994, and combines a unique mix of extensive frontline experience with public health programme implementation and evaluation expertise, with strong research collaborations with the NHLS. RHI staff were instrumental in supporting the development of the Department of Health HIV testing guidelines (National Department of Health, 2015) and the HIV testing consensus statement from the NGO sector (Southern African HIV Clinicians Society, et al, 2012), as well as the WHO testing and treatment guideline (WHO, 2015).

The NHLS is a parastatal, with direct accountability to the Department of Health, and is responsible for implementation of all laboratory projects within the Department. It has an oversight board appointed by the Minister, and funding is provided through the Department of Health. The research and development section of the NHLS has been instrumental in identifying high quality, low cost alternatives to conventional CD4 monitoring, HIV resistance testing, and viral load monitoring. More recently, the National Priority Programme (NPP) within the NHLS has assessed multiple point of care instruments, including for CD4 and viral loads, and was responsible for the successful rollout of the tuberculosis (TB) GeneXpert programme, which has largely replaced conventional sputum microscopy across the country, and resulted in the identification of large numbers of patients with multi-drug resistant TB. The mHealth department of the NHLS looks at using mobile technology to support the priority areas of HIV and TB, and was responsible for developing the TreatTB intervention.



*The research and development section of the NHLS has been instrumental in identifying high quality, low cost alternatives to conventional CD4 monitoring, HIV resistance testing, and viral load monitoring.*

## 2.3 SMARTPHONE OWNERSHIP AND USAGE IN SOUTH AFRICA

### 2.3.1 Historical and current smartphone sales

South Africa is a middle-income country that has seen a large increase in mobile phone ownership over the past few years, with significant growth in smartphone ownership, which stood at 37% of the adult population in 2015 (Poushter, 2016). Since early 2014,



most phones sold every month in South Africa have been smartphones, due in large part to price drops with smartphones selling for under R500 (Techcentral, 2014). This proliferation of smartphones in South Africa provides an excellent opportunity for testing new mHealth interventions.

### 2.3.2 Market research at Hillbrow CHC and in Eastern Cape

In early, 2015, prior to starting the study, the project team conducted market research on patients undergoing HIV testing at the Hillbrow CHC facility. Results from the research showed that of 373 individuals with phones, just under half (43%) had smartphones with data packages allowing a constant connection to the internet through the mobile phone network. Of those with smartphones, approximately 42% had Android phones, with the bulk of the remainder being Nokia (22%) or Blackberry (20%). Therefore, in this small sample of patients, 18% of individuals with a phone had an Android smartphone with data. A similar market research study was conducted one year later (March 2016) in three urban health care facilities, one in Port Elizabeth and two in East London in Eastern Cape Province of South Africa. The results from the Eastern Cape survey showed that of 1486 individuals with phones, almost two-thirds (62%) had smartphones with data. Of those with smartphones with data, 68% had Android, which equates to 43% of all phones of patients surveyed. These results show a



*Android was also the only operating system that a patient laboratory result system could be developed for, as neither Blackberry nor Nokia devices have the necessary security systems in place to ensure secure transmission and viewing of personal health data.*

higher Android ownership rate in Eastern Cape; this can be understood by the fact that both Nokia and Blackberry had stopped making inexpensive smartphones at that time; in addition, both had begun migrating to an Android platform. For this reason, since late 2015 anyone wanting to buy a new smartphone in South Africa for under R2,500 is limited to Android devices.

Android was therefore assessed as being the best smartphone operating system to develop the app for, as it would be accessible to the largest number of patients. Android was also the only operating system that a patient laboratory result system could be developed for, as neither Blackberry nor Nokia devices have the necessary security systems in place to ensure secure transmission and viewing of personal health data.

## 2.4 MHEALTH RELEVANT LITERATURE REVIEW

Previous research has suggested that mobile phones (mHealth) can improve antiretroviral (ART) adherence rates in low-resource settings, largely using SMS systems as adherence reminders (Lester et al, 2010; Pop-Eleches et al, 2011, Finitis et al 2014, Mathes et al 2014, Mugo et al, 2016, Kanters S et al, 2017). A small randomised controlled trial from New Zealand (Perera et al, 2014) showed that a smartphone app that supported HIV-positive patients by providing relevant information improved viral suppression rates. Testing levels can be improved with combinations of SMS and phone



calls. However, we are unaware of any study using mHealth to encourage patient retention before initiation of ART.

## 2.5 MHEALTH AT RHI

Wits RHI's mHealth department started in 2011. Past projects include the Vodacom HIV and MAMA South Africa projects. These projects implemented SMS-based interventions for pregnant women. In 2016 each of these projects had over 35,000 individuals receiving ongoing support messages. The MAMA project has successfully been taken to scale and a version has been adopted by the National Department of Health (Barron et al, 2016). The RHI staff have gained significant experience with all aspects of mHealth project implementation including project design, content creation, user testing, staff training, patient recruitment and follow-up, monitoring and evaluation, status/final report creation and project analysis.

This trial was done in close collaboration with the NHLS NPP division who facilitated access to patient laboratory data. The NPP team also provided app design advice and ongoing support throughout the project.

## 2.6 STUDY PURPOSE

We wanted to improve linkage to care of newly diagnosed HIV patients; specifically we wanted to rapidly demonstrate the effectiveness of a patient-controlled, smartphone-based HIV linkage-to-care app using existing NHLS infrastructure and data systems, from the point of HIV diagnosis to linkage to care (either for ART or for access to then non-ART "wellness packages"; the study commenced prior to CD4 thresholds being relaxed altogether), that engages patients in their own healthcare. Widespread smartphone usage amongst the population coupled with Wits RHI's partnerships with NHLS, allowed for implementation and evaluation of the application, called 'SmartLink', on linkage to care and retention outcomes. If successful, this approach could potentially be expanded to support other aspects of the HIV care cascade, and may even be expanded to other chronic diseases, allowing for patients to routinely engage with their laboratory results, link to information and support services, and receive prompts if they fall out of care.

## 2.7 KEY LEARNINGS FROM PRE-STUDY DATA

Preliminary research by the project team regarding implementation yielded a number of key insights.

### 2.7.1 Create and test Android app (as opposed to other platforms)

Developing an Android app was identified as a priority, for several reasons. Firstly, this is due to Android functionality and communication systems built into the operating system. Nokia and Blackberry operating systems did not offer a method of 'push'



communication from the study team to a phone. Push notifications are alerts that are automatically sent to a phone based on availability of information (i.e.: WhatsApp message, weather alert, sport scores, etc.). As Nokia and Blackberry do not allow for third party push communication, it would have meant that users/patients would have to manually check for their own results or learn when their next appointment should be, rather than having it 'pushed' to their phone when it was available. Secondly, Android functionality allows for easier programming, saving both time and cost when compared to the development of Blackberry or Nokia-based apps. Lastly, as detailed above, Android had the largest market share of all smartphone operating systems in South Africa, is a popular device within our target population, and given cost and availability, is likely to remain so for some time into the future.

### 2.7.2 Limiting cost of data usage for patients

Previous mHealth projects at Wits RHI showed that the target patient population had low incomes and were very cost sensitive with regards to mHealth support, especially

 ...having study staff install the app on participant smartphones using files available through study-supplied wireless connection devices, was the most practical and cost effective solution, providing the following advantages; there was a once-off cost to the study team with no cost to participants..

as access to data on phones is relatively expensive in South Africa. In 2012 MAMA South Africa, a maternal mHealth project run by Wits RHI's mHealth team found that 66% of women that were interested in participating in the project did not have the required R1 (approximately \$0.10 at 2012 exchange rates) airtime credit on their phone to sign up to the service (Coleman et al, unpublished data). Patients used up their data limits rapidly, and had no phone credit for the majority of the week because they could not afford it. If they needed to speak with someone, they would send a free 'please call me' notification to the person they needed to speak with.

Three options were considered regarding offering a smartphone app to participants while limiting their costs; 1) providing prepaid mobile data to users, 2) offering on-site free Wi-Fi to download the app, or 3) installing the app on participant phones directly and limiting data requirements to the bare minimum. Providing mobile

data to users, while theoretically possible, was a logistical challenge; buying data packages only works for prepaid (not post-paid contract-based) mobile phone accounts, and each of South Africa's three main and five 'virtual' mobile phone networks use different systems to purchase data. Offering free Wi-Fi to download the app would be a solution, but upon investigation the team found that there would have been complex to install, with significant maintenance costs for installation and maintenance of internet connectivity at the recruitment sites.

It was assessed that a third option, having study staff install the app on participant smartphones using files available through study-supplied wireless connection devices, was the most practical and cost effective solution, providing the following advantages; there was a once-off cost to the study team with no cost to participants, it could be done



from any location within the recruitment site (or any site), the identification check could occur at the same time, the staff could provide a brief training session on the app to check participants knew how to use it, and the process would be logistically simple as no refunds for data usage or Wi-Fi installation was required.

There are three disadvantages to this approach. Firstly, the app would not be available on the Google Play store for download, which automatically checks the phone for compatibility with the app and allows future app updates to be easily installed (free on Wi-Fi, but for a charge using mobile data). Secondly, to implement this solution, the team would need to train the recruitment staff to understand privacy issues and install the app (rather than have users download and install themselves). Lastly, the app cannot be easily updated, to fix bugs or add in more features, without incurring significant data costs or a repeat visit to the study site.

### 2.7.3 Ensure app uses minimal data

The app would have to use minimal data once it was installed to contain costs to the end user. All static information in the app (including reference material, result colour coding logic, and images) had to be built into the app when it was installed. This was to ensure that these items were not downloaded later at participant expense. The only information sent to the participant's phone would be values of the blood sample results which use up minimal data. During testing of the app, the study team confirmed that this amount of data transmitted when receiving a result was less than 2 KB (0.002 MB). This would cost approximately 0.002 Rands per result, calculated at the most expensive pay-as-you-go rate for data in South Africa (Vodacom - R2 per MB). Additionally, accessing (i.e., logging-in) the app is equivalent to one-third of the data transmission of one WhatsApp message.

### 2.7.4 Verifying participant identity

Privacy and security of participant data are important, especially in the context of a stigmatised illness such as HIV. The app required verification of identity by an independent health employee, to ensure that the correct person was receiving confidential laboratory results, by using photo ID (without this step, a person could simply claim to be someone else, and have access to that person's laboratory information). However, this requirement meant that all participants were required to carry photo identification at recruitment. This was not an unreasonable assumption, as many processes for citizens in both public health, and other services require production of ID or quoting of an ID number. Once the study team had access to the NHLS TrakCare system this requirement could be relaxed as the study team could verify names and identity in the TrakCare system, although implementation of the single patient identifier was yet to be widely adhered to.



*The app required verification of identity by an independent health employee, to ensure that the correct person was receiving confidential laboratory results, by using photo ID.*



### 2.7.5 Need to measure feasibility, acceptability and impact

This intervention, if successful and rolled out, would require committed resources to assist participants install the app, as well as continued maintenance of the information systems to support it. Robust evidence that supports this, in the context of routine clinical care, is required to motivate for these resources. As a proof-of-concept study, the study team therefore collected data on multiple aspects of the participant experience. This included:

- *Feasibility*; would it be realistic to offer an app like SmartLink in the South African public healthcare system.
- *Acceptability*; do participants feel that SmartLink is useful and/or appropriate for them?
- *Impact*; does SmartLink have an effect on those who use it, and what is that impact?

Together, these would assist to guide policy decisions around a recommendation of implementation and/or expansion of SmartLink as a patient support tool.

### 2.7.6 Measuring representativeness/homogeneity

Socio-demographic data was collected on all participants invited to the study, including those who did not have an Android smartphone, or who did not meet other inclusion criteria. This was to enable the study team to identify how these populations could be accessed in future.

### 2.7.7 Plan to over-sample for two high-risk for loss to follow-up groups

Two groups that are underserved in current treatment programmes leading to delayed presentation are younger people and men, and they may benefit from the smartphone intervention. Based on this, the research team planned to over-sample these two groups, allowing for a sub-group analysis with a large enough sample size to be confident that any differences identified were not by chance.

## SECTION 3

# METHODOLOGY

### 3.1 STUDY HYPOTHESIS

The hypothesis for the study was that providing smartphone-owners with their laboratory results immediately and securely through a smartphone app from the moment of HIV diagnosis, with linked explanatory information about what the results mean, along with prompts to link and relink with care, will lead to:

- improved *linkage to care* (defined as attending for a CD4 count or viral load or creatinine clearance measurement at least 2 weeks after the HIV testing date),
- better *retention in care* (defined as attending for a CD4 count measurement PLUS two other NHLS test within 12 months of HIV diagnosis),

Although we did not measure this directly in the study time frame in the end, we anticipated better knowledge of CD4 and viral load results, improved healthcare worker requests for results, decreased additional blood tests, clinic decongestion, and higher long term rates of viral suppression, as a result of improved communication with participants.

### 3.2 PRIMARY OUTCOME

The primary outcome of the study was routine linkage to HIV care within state HIV services after a diagnosis of HIV within 8 months post-diagnosis, comparing the app intervention and the standard of care control arm.

### 3.3 SECONDARY OUTCOMES

Secondary outcomes for the study were:

- Antiretroviral initiation rates between intervention and control arms.
- The feasibility and acceptability of receiving laboratory results to a personal smartphone application.
- Secondary effects from improved participant information, including return rates after falling out of care, participant satisfaction, and rates of repeat blood tests.
- Linkage to care in men and young people under 30 years.



## 3.4 RECRUITMENT, INTERVENTION AND FOLLOW-UP METHODS

The study was set up as a multi-site randomised controlled trial which recruited from HIV counselling and testing sites at the time of blood sample collection for CD4 staging. Newly diagnosed HIV-positive people fulfilling all inclusion criteria, and who routinely have a blood sample drawn for CD4 count immediately afterwards (as per SA guidelines; and this occurs in >90% of newly diagnosed people in the study sites), were randomised to either receive the intervention (installation of a password-protected laboratory result and HIV-information app on their smartphone) or receive standard of care (routine referral to the nearest clinic for a health care assessment of the participant in conjunction with their CD4 result, with no prompting with results or to remind them to attend the facility). In both cases, participants were recruited to the study by trained study fieldworkers, provided with their unique laboratory sample identifier, told to attend the nearest treatment clinic, and asked for permission for the research team to

 *Notifications of results and appointments were automated using algorithms based on national guidelines.*

phone them and ask them about their experience of HIV care and to verify their clinic attendance at the end of the study (this was not done, eventually, due to limited funding for the study). When a participant was randomised to the intervention arm, a study staff member assisted them with installing the application on their phone, setting a user name, password and secure PIN code, and explain how to access the data and supporting information on the

app. All participants were recruited immediately after HIV diagnosis and provided R50 in airtime credit after recruitment was completed.

There was no individualised or real time care other than at the installation of the app and call backs if the participant required help accessing the app; the goal was to demonstrate the performance of the app in as 'real-world' an environment as possible, with a view to generating evidence which is directly relevant to a programme context. Notifications of results and appointments were automated using algorithms based on national guidelines. If visits were missed, as registered by TrakCare, or monitoring protocols (as designated by Department of Health guidelines that suggest clinic attendance and blood draws at regular intervals) not followed, this was noted in the data set at the study conclusion.

### 3.4.1 Intervention arm

We built on the existing NHLS TB-app (TreatTB) experience by creating a personalised Android smartphone app that allows participants to view their secure and password-protected laboratory results. This included all prior and new NHLS CD4 count and viral load laboratory results. Previously, all new CD4 and viral load results were available to patients only by returning to the same clinic several days later, and requesting the information directly from the health care worker. The intervention allowed laboratory results to be seen on the participant's smartphone as soon as the results were available.



Access to all medical data was limited by a username/password and PIN-code authorisation (using similar security as local mobile banking apps). The laboratory results were presented in simple language so that they were easy to interpret, showing the results with date, a visual scale based on a red-yellow-green traffic light system and showing the actual laboratory result and 'normal' values with a short explanation of what the result means and what action, if any, should be taken (See appendix I). Additionally, the app included a link for participants to access more information about HIV, antiretroviral adherence, and laboratory tests in two different major South African languages, English and isiZulu. Lastly, automated appointment reminders and notification of new results were available through the app, which were secured on the smartphone with a unique username/password and PIN code to ensure privacy and security. The automated appointment reminders were set to notify participants, through SmartLink, two weeks before and one day before their 6-month and 12-months follow-up visit, as monitored using TrakCare. If a participant was found to have a CD4 count or VL result before their originally scheduled test, timing for the notification would be reset based on the date of the new result so notifications were sent 5.5 and 6 months (minus one day) after their most recent laboratory CD4 or VL result.



*The laboratory results were presented in simple language so that they were easy to interpret, showing the results with date, a visual scale based on a red-yellow-green traffic light system and showing the actual laboratory result and 'normal' values with a short explanation of what the result means and what action, if any, should be taken.*

### 3.4.2 Control arm

Participants randomised to the control arm received the standard of care which included counselling and referral to local state HIV clinics that provided care, if the site did not do so itself, or within-facility if ART was available.

### 3.4.3 Data collection

Baseline data collection at recruitment included socio-demographics. Participants were to be followed up for one year. The primary outcomes included an eight-month follow-up, as measured by repeat laboratory sampling, while secondary outcomes were followed up at 12 months post-recruitment. During the study, we measured the number of times the app was opened and the amount of time spent in the app to view laboratory results, and/or support information by the user.

## 3.5 STATISTICAL ASSUMPTIONS

### 3.5.1 Sample size calculation

Based on a primary endpoint of a second HIV-linked laboratory test (CD4, viral load, creatinine clearance) being performed at a clinical facility, within 8 months after the baseline CD4 test, suggesting successful attendance and entry into HIV care, we anticipated at least 1000 participants in each arm would be needed (and, as discussed



later in this report, was revised downwards). The study team expected to see a 20% difference in linkage to care levels through the app (using a second HIV-linked laboratory test as an indicator for linkage to care). The sample size was calculated based on 80% power, 0.05 significance with a loss-to-follow-up rate of approximately 27% (Hillbrow CHC data). Both ART and pre-ART participants were expected to return for a follow-up laboratory test around 6 months after diagnosis; ART participants for a viral load and creatinine clearance, and pre-ART for a follow-up CD4 count.

### 3.5.2 Database construction and access permissions

Prior to launching, the study created the database using the electronic REDCap clinical research database, and trained the clinic-based recruitment staff who were to be based at the recruitment sites. The recruitment team conducted a number of 'dry run' recruitments with study staff, and then with potential participants at Hillbrow CHC.

### 3.5.3 Permissions

The study team worked with the necessary authorities to receive ethics permission and permission from the Gauteng Province and City of Johannesburg research teams, and met with the site managers to get their authorisation and buy-in. Ethics committee submissions and amendments were done through the University of the Witwatersrand's Human Research Ethics Committee (Medical). The protocol was discussed internally and with the World Bank team before any changes were made. Formal Wits RHI organisational SOP's were adapted and used to train staff implementing the study, so as to comply with the protocol and Ethics Committee requirement, including Good Clinical Practice (GCP) training. The trial protocol was registered with the ClinicalTrials.gov Protocol Registration and Results System (Protocol ID: 7173708).

## SECTION 4

# IMPLEMENTATION

## 4.1 IMPLEMENTATION OVERVIEW

The study was launched on 12 October, 2015 at HCHC which also saw the first participant recruited. The other recruitment facilities were brought on-line with a staggered methodology to identify issues immediately. The first date of recruitment for the remaining sites were: Yeoville Clinic on 20 October, 80 Albert Street Clinic on 27 October, Jeppe on 3 November, followed by HJH on 24 November.

The steps to the recruitment process were as follows:

1. HIV-positive individuals were identified by clinic or facility staff and introduced to the recruitment team
2. The recruitment team introduced the participant to the study and invited them to participate. If the individual was not interested, they were asked to provide a reason.
3. Basic socio-demographic questions were asked, followed by screening questions to ensure eligibility.

Eligible participants were recruited after they had blood drawn for CD4 count measuring. The recruitment process consisted of providing informed consent, and being randomised to either the control or intervention arm. Participants randomised to the intervention arm were aided in installing SmartLink, selecting account details, and shown how to use the app.

## 4.2 IMPLEMENTATION CHALLENGES

The project and study met a number of challenges which resulted in significant issues due to administrative approval, recruitment, app installation, app compatibility and data management. These challenges, and mitigation where appropriate are discussed below:

1. Implementation delays due to Ethics & Health Department approval processes

All research studies conducted at Wits RHI must be approved by the University of Witwatersrand Human Research Ethics Committee (HREC), followed by the Gauteng and Johannesburg Departments of Health. The committee meets once per month and approval normally takes approximately four to six weeks between submissions and response, with most prospective studies requiring



amendments, which then requires 2-4 weeks on average for final written approval. For this study, the submission was made on the 6th of March, 2015, with a response coming back seven weeks later, on the 24th of April with minor feedback and a comment stating that the application could not be read due to illegibility of several copies of the submitted document due to the photocopier that was used, with a request for a full resubmission. With the committee only meeting once a month, the study team was only able to make the recommended changes and re-submit for the following meeting, which was in June 2015. The City of Johannesburg submission, which can only occur after HREC approval is given, occurred while the city was changing and updating their approval process which meant that City of Johannesburg approval was only given on the 25th of September 2015. The study team had expected to be able to start recruitment in late April 2015, but the various approval delays resulted in the first participant recruitment occurring over five months later.

## 2. HIV positivity

The study team expected to have a much larger number of newly diagnosed HIV positive people to draw from for recruitment than were available. The team conducted both fieldwork and desk research to work out the expected numbers of HIV positive participants at the facilities. Fieldwork consisted of speaking with the HIV Testing Nurse in Charge at HCHC. She stated that approximately 250 people were tested and between 40 and 80 new HIV-positive cases were identified by her team each day. Desk research, consisting of checking the District Health Information System (DHIS) database, the official South African routine health information system for managing aggregated data, confirmed this number. Newly identified HIV cases in HCHC, as reported in DHIS between July to December 2015 were listed at between 800 to 1800 per month (30-70 per day). When recruitment started in mid-October 2015, new HIV-positive cases at Hillbrow CHC were found to be approximately 200-300 per month (8-12 per day).

A similar situation was identified at HJH once the team was allowed access; the number of newly diagnosed HIV positive participants that could be identified on-site were significantly lower than had been reported in the DHIS. During site identification in late 2014 and early 2015 DHIS figures showed that HJH was the only health care facility north of Johannesburg City Centre to diagnose more than 1000 new HIV positive participants per month. After arriving on-site at HJH in late 2015, only around 70 HIV-positive individuals were identified (and thus pre-screened) per month. It is unclear why the positivity numbers at both Hillbrow CHC and HJH had dropped so dramatically, in the space of less than a year, but may have been due to decentralised testing at numerous surrounding facilities.



The three additional sites were much smaller primary health care clinics, and were selected as they were the local sites which had the highest numbers of monthly new HIV-positive patients according to DHIS. Each of these sites was reported to have 80-120 new HIV cases per month. During the recruitment process, the pre-screening data showed that the DHIS data for these smaller sites was correct. Due to the smaller size, fewer recruitment staff were based at each of them, with most of the recruitment team based at Hillbrow CHC and HJH.

### 3. Recruitment Constraints due to Smartphone Version Limitations

Having an Android phone was an anticipated limiting factor for recruitment to the study. The team's market research on phone ownership and type projected that approximately 20% of HIV-positive patients would have Android smartphones (40% of all patients having a smartphone and 40% of those using Android). This was an accurate projection. Furthermore, in order for all SmartLink features to work, the software developers had based their app on Android version 4.2. At the time, in mid-2015, Android 4.2 was over two years old, and with over 75% of all active Android devices compatible globally. During the recruitment phase it quickly became obvious that a large portion of participant-held Android phones were over two years old, and therefore not operating on version 4.2 or higher, severely limiting recruitment.

The Android version compatibility issue had been unexpected for the research team; the preliminary data collection on smartphone ownership did not include identification of the Android version number, in retrospect, a significant omission by the team investigating cell phone and platforms during the preliminary phase. Additionally, the research team was only informed about the version 4.2 requirement by the SmartLink developers just prior to its release. Given the other delays in starting recruitment the study team decided to go ahead with the Android 4.2 requirement, excluding patients with the earlier version. To do otherwise would have required the team to remove the automated laboratory result notification and appointment notification features, both of which are key features to allow automation of processes within SmartLink.

### 4. Recruitment Constraints due to Difficulties with App Installation on Participant Devices

The project team had requested that the software development team create SmartLink so that it could work on all Android devices, including smartphones and tablets. During recruitment the research team quickly found that in addition to the Android version requirement (described above) there were two other unanticipated requirements that caused significant implementation challenges.

First, a number of potential participants who were randomised to the intervention arm with Android smartphones Version 4.2 or newer, were unable



to install SmartLink on their devices. It became clear that these devices tended to be the more inexpensive smartphones that had very small amounts of Random Access Memory (RAM). RAM is one of the most expensive aspects of a Smartphone, and in order to reduce cost and market price, a number of smaller smartphone manufacturers were selling smartphone models with small amounts of RAM. After further investigation by the developer, it was determined that 350 megabytes (MB) was the minimum amount of RAM that was required for successful installation and running of SmartLink on a smartphone. This was also added to SOP as the minimum requirement for participation in the study.

Secondly, despite being told that SmartLink would work on tablet devices, and the software developers successfully installing and testing it on tablets, not all participants that had tablets could complete the installation. The developer cannot explain why it would not install as required. The lack of tablet compatibility was unfortunate, since around the time of first recruitment (late 2015), tablet-phones were becoming popular among patients due to the fact that they cost no more than a smartphone, but had a larger screen, so were seen as a better value. Attempting to install SmartLink on tablets, and being unable to complete the installation, took so much time that the study team had to revise the study protocol to exclude the recruitment of patients who had a tablet-phone. Exact numbers were not collected by the recruiting staff, but the study team estimate we could have recruited 5-10% more participants if this had not occurred.

#### 5. Data Issues due to a lack of unique patient ID and database access

The lack of a unique patient identifier in South Africa meant that the study team had to create a method to keep track of participants across multiple databases that did not communicate directly with each other. This meant that any single error in participant information collection and transcription during recruitment, clinic blood specimen collection or blood analysis lead to difficulties identifying that participant in the other databases.

The electronic REDCap clinical research database provided a unique participant identifier for the study. This unique number, created only for the study, was the only truly unique identifier that could be used to link the data that was received to the study database from the multiple data systems, including TrakCare, SmartLink and the software developer's project database. Throughout the study, data quality processes were hampered because of the manual process of having to search for participant information in TrakCare's user interface, rather than accessing the database directly.

Data analysis for the project was further hampered due to the above issues; many participant records could not be identified in the NHLS database due to data transcription errors, identified during manual checks. Participant follow-up data (CD4 and viral load records) was automatically identified in the NHLS



database by participant first name, last name and date of birth. For example, the study team found that 15% of participants who had been identified as lost to follow-up (i.e.: no follow-up CD4 or viral load) through the automatic data process were actually linked to care when a manual search was conducted that included variations of names and dates of births compared against dates and clinic sites of the tests. These data issues contributed to the delay in project completion as such a large number of data-related issues were not expected.

#### 6. Recruitment completion

Due to the challenges mentioned above, the original end-date for recruitment, three months after recruitment started, was pushed back multiple times. The last participant was recruited on 17 June, 2016.

*This page is for collation purposes.*

## SECTION 5

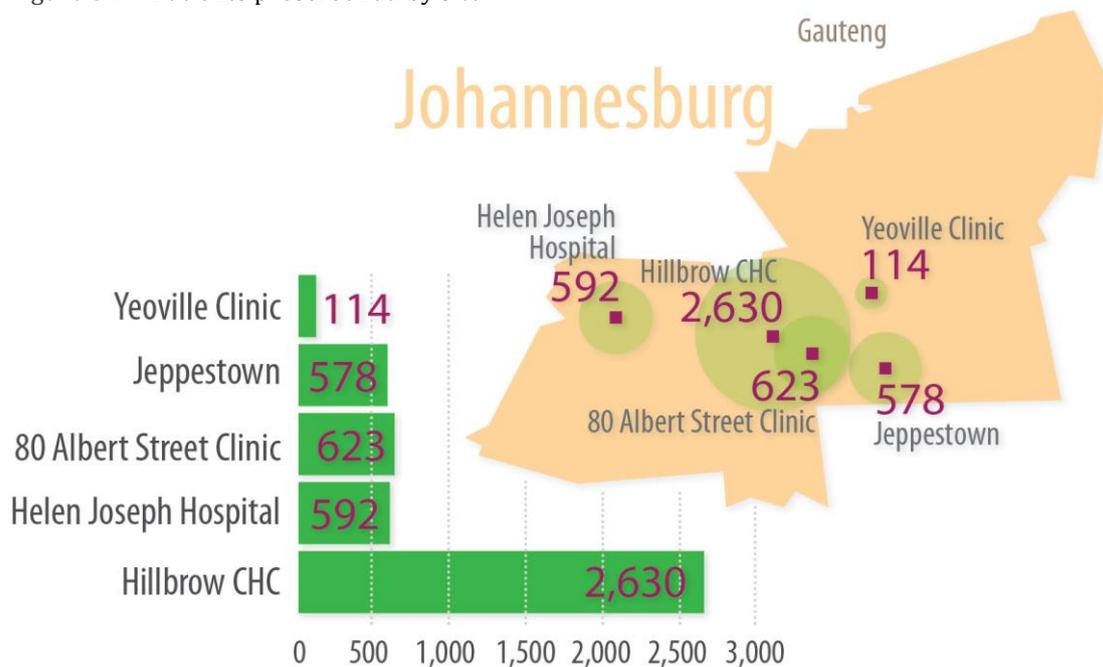
# RESULTS

### 5.1 IDENTIFICATION & PRE-SCREENING

Over the course of the study, 4537 HIV-positive individuals were identified across the five recruitment sites and pre-screened (fig. 1). Of these, 90 declined to participate and 907 individuals were identified as ineligible during pre-screening (fig. 2). Reasons for and exact numbers of ineligibility during pre-screening are as follows:

- Total identified ineligible at pre-screening stage: 997
- Reasons:
  - ▶ Refusal: 90
  - ▶ Under 18 years: 12
  - ▶ Pregnant: 269
  - ▶ Could not read English or isiZulu: 87
  - ▶ No photo ID (a requirement from 12 October - 17 December 2016): 539

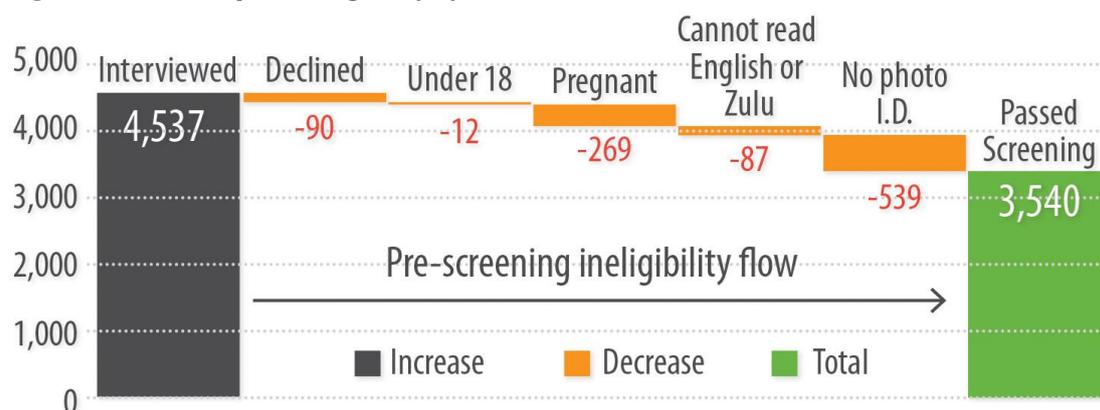
Figure 5.1 Patients prescreened by site



Source: Authors.



Figure 5.2 Participant ineligibility by reason



Source: Authors.

Table 5.1 Profile of pre-screened participants

	Passed pre-screening (N=3540)		Did not pass pre-screening (N=997)		Total (N=4537)	
	N	%	N	%	N	%
<b>Sex</b>	<b>3538</b>		<b>921</b>		<b>4459</b>	
Male	1588	(44.9)	344	(37.4)	1932	(43.3)
Female	1950	(55.1)	577	(62.7)	2527	(56.7)
Missing	2	(0)	76	(7.6)	78	(1.7)
<b>Age</b>	<b>3540</b>		<b>986</b>		<b>4526</b>	
18-30	1350	(38.1)	394	(40)	1744	(38.5)
31-40	1454	(41.1)	330	(33.5)	1784	(39.4)
41-50	535	(15.1)	115	(11.7)	650	(14.4)
51+	201	(5.7)	147	(14.9)	348	(7.7)
Missing	0	(0)	11	(1.1)	11	(0.2)

Source: Authors.

## 5.2 SCREENING & SOCIO-DEMOGRAPHIC DATA COLLECTION

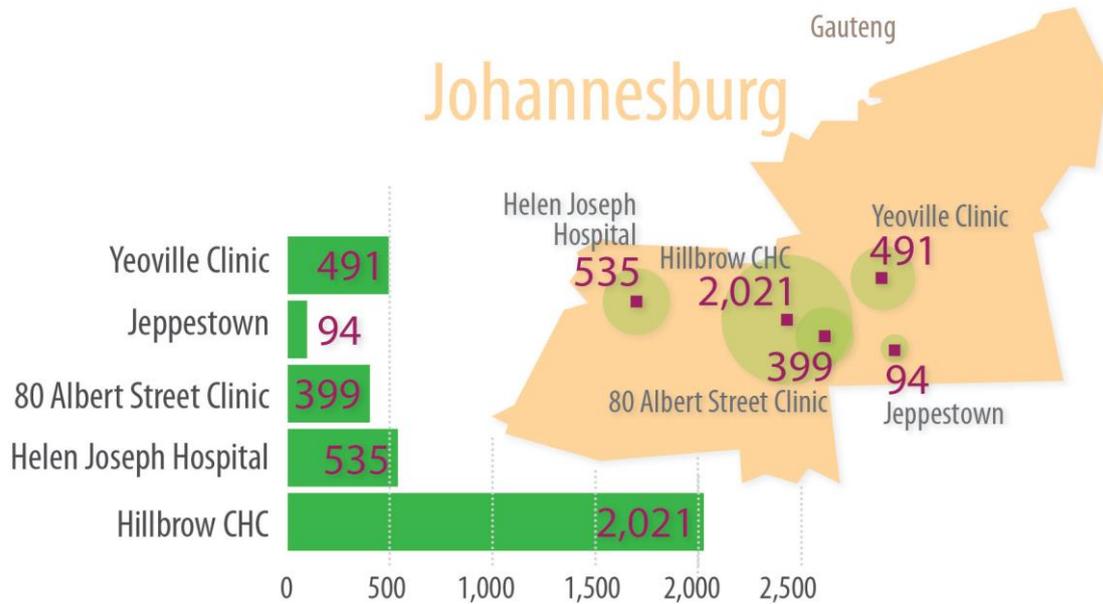
Socio-demographic data from the 3540 individuals passing the pre-screening step was collected at the final eligibility screening. During the screening process 3187 individuals were found to be ineligible (fig. 3). The reasons for ineligibility, and number of individuals, in the order they were asked is as follows:

- Total ineligible: 3187
- Reasons:
  - ▶ No phone: 498
  - ▶ No active SIM card in phone: 8



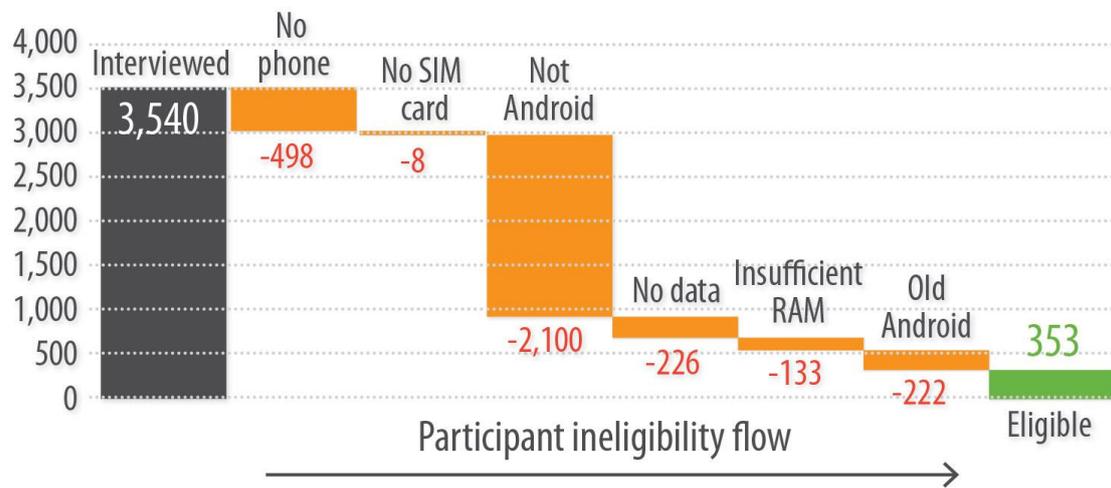
- ▶ No Android smartphone: 2100
- ▶ No data on phone: 226
- ▶ Insufficient RAM on phone: 133
- ▶ Android version too old (i.e., pre Version 4.2): 222

Figure 5.3 Patients screened by site



Source: Authors.

Figure 5.4 Screened participant ineligibility by reason



Source: authors.



Table 5.2 Profile of screened participants

	<b>N=3540</b>	<b>%</b>
<b>Sex</b>		
Male	1588	(44.9)
Female	1950	(55.1)
<b>Age</b>		
18-30	1350	(38.1)
31-40	1454	(41.1)
41-50	535	(15.1)
51+	201	(5.7)
<b>Country of Birth</b>		
South Africa	2006	(56.7)
Zimbabwe	1288	(36.4)
Other	246	(6.9)
<b>Education</b>		
Primary only	341	(9.6)
Some secondary school	1426	(40.3)
Completed secondary school	1443	(40.8)
Attended some or completed tertiary	326	(9.2)
<b>Employment status</b>		
Employed full time	1465	(41.4)
Employed part time	470	(13.3)
Unemployed	1279	(36.1)
Self employed	254	(7.2)
Student	67	(1.9)

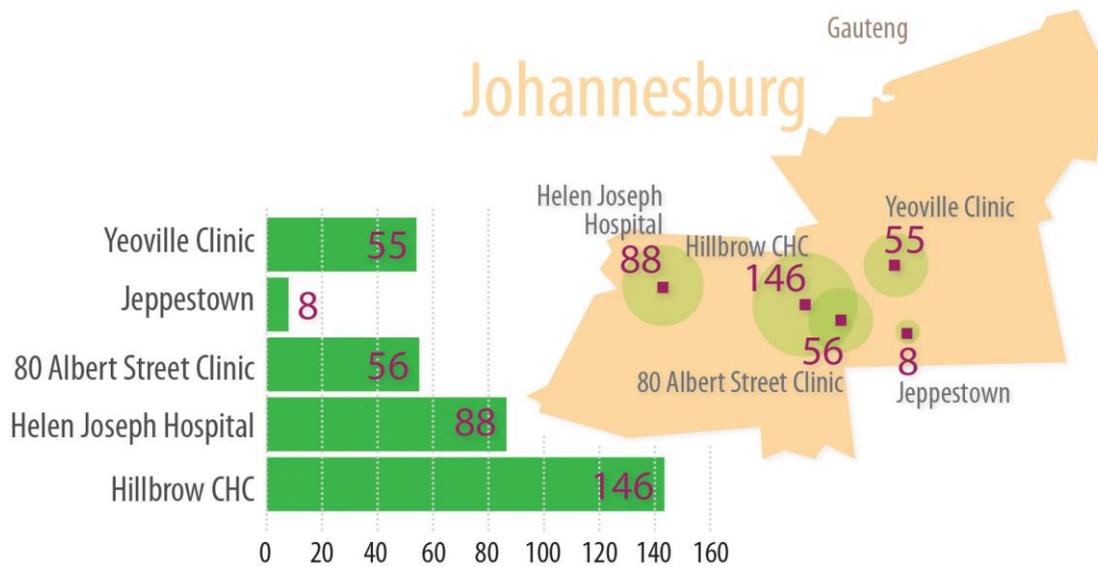
Source: Authors.

## 5.3 PASSED SCREENING & RECRUITED

Upon consent, 353 individuals were recruited into the study and randomised (fig. 4), 172 to the control arm, while 181 were allocated to the intervention arm.



Figure 5.5 Patients recruited by site



Source: Authors.

Table 5.3 Profile of participants

	N=353	%
<b>Sex</b>		
Male	122	(34.6)
Female	231	(65.4)
<b>Age</b>		
18-30	157	(44.5)
31-40	155	(43.9)
41-50	39	(11.0)
51+	2	(0.6)
<b>Country of Birth</b>		
South Africa	204	(57.8)
Zimbabwe	126	(35.7)
Other	23	(6.5)
<b>Education</b>		
Primary only	15	(4.2)
Some secondary school	96	(27.2)
Completed secondary school	185	(52.4)
Attended some or completed tertiary	57	(16.1)

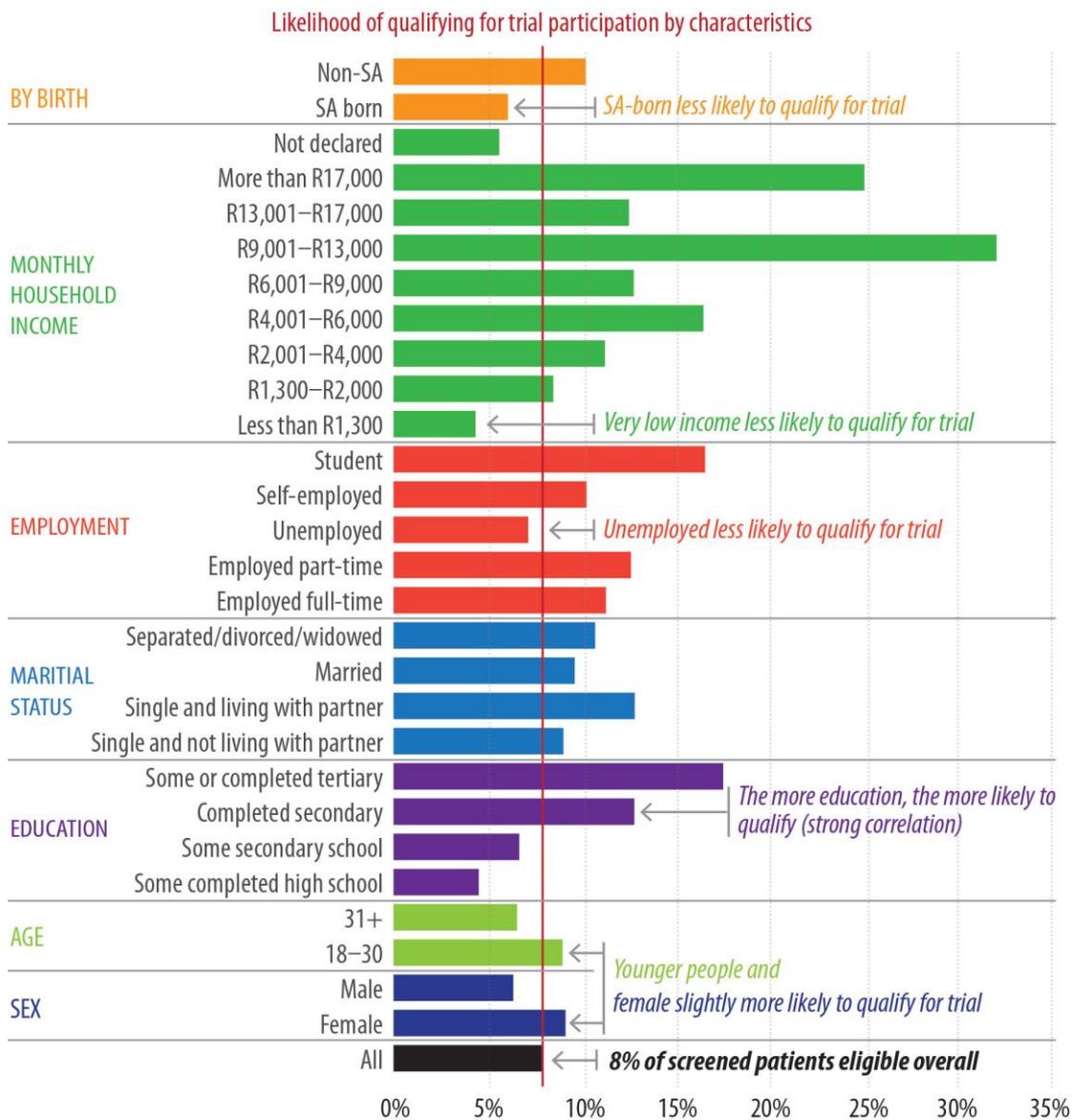


**Table 5.3 Profile of participants (continued)**

	N=353	%
<b>Employment status</b>		
Employed full time	165	(46.7)
Employed part time	59	(16.7)
Unemployed	92	(26.1)
Self employed	26	(7.4)
Student	11	(3.1)

Source: Authors.

Figure 5.6 Analysis of the likelihood of screened individuals to join the trial, by socio-economic characteristics



Source: Authors.

Figure 5.6 shows that South-African born participants were less likely to be eligible; this may reflect the demographics of central Johannesburg, where many Zimbabwean



migrants live, and who are often relatively well educated (and possibly more likely to be employed, better paid and with more advanced smartphones) when compared to the South Africans living there. Those earning less, those who are unemployed, and those with less education were similarly less likely to have eligible smartphones.

## 5.4 LINKAGE TO CARE

Only half the participants were found to link to care, overall, within 8 months of recruitment (having evidence of a second HIV-related laboratory test result of CD4, viral load, or creatinine clearance in the NHLS system).

Table 5.4 All randomised

	Linked to Care	Not Linked to Care	Total randomised
<b>SOC</b>	81 (47.1%)	91 (52.9%)	172
<b>App</b>	88 (48.6%)	93 (51.4%)	181
<b>All</b>	169 (47.9%)	184 (52.1%)	353

Source: Authors.

Note:  $\chi^2 = 0.0823$ ,  $p = 0.774$  SOC – standard of care.

After recruitment, it was found that a number of the SOC care arm (n=8) had mistakenly received SMS reminders concerning their 6-month clinic attendance. As they did not receive the app intervention (and hence do not qualify being included in the “app” group), we have removed them from the next tabled evaluation, and the amended results are shown below, showing little difference.

Table 5.5 All randomised - SMS contamination removed

	Linked to Care	Not Linked to Care	Total randomised
<b>SOC</b>	74 (45.1%)	90 (54.9%)	164
<b>App</b>	88 (48.6%)	93 (51.4%)	181
<b>All</b>	162 (47.0%)	183 (53.0%)	345

Source: Authors.

Note:  $\chi^2 = 0.4224$ ,  $p = 0.516$  SOC – standard of care.

Originally, the study was designed to see whether the intervention would have an impact on groups that traditionally have not linked to care, specifically men and young people. As recruitment numbers were far lower than anticipated, the numbers in these sub groups are low, but the results point to important app effects especially in younger HIV clients.

Table 5.6 As treated - Males only

	Linked to Care	Not Linked to Care	Total randomised
<b>SOC</b>	29 (47.5%)	32 (52.5%)	61
<b>App</b>	33 (55.0%)	27 (45.0%)	60
<b>Combined</b>	63 (51.6%)	59 (48.4%)	121

Source: Authors

Note:  $\chi^2 = 0.6736$ ,  $P = 0.412$ .



Table 5.7 As treated - Females only

	Linked to Care	Not Linked to Care	Total randomised
<b>SOC</b>	45 (43.7%)	58 (56.3%)	103
<b>App</b>	55 (45.5%)	66 (54.6%)	121
<b>Combined</b>	100 (44.6%)	124 (55.4%)	224

Source: Authors

Note:  $\chi^2 = 0.0702$ ,  $P = 0.791$ .

Table 5.8 As treated - 18-30 only

	Linked to Care	Not Linked to Care	Total randomised
<b>SOC</b>	22 (31.9%)	47 (68.1%)	69
<b>App</b>	44 (53.0%)	39 (47.0%)	83
<b>Combined</b>	66 (43.4%)	86 (56.6%)	152

Source: Authors

Note:  $\chi^2 = 6.8461$ ,  $P = 0.009$

Table 5.9 As treated - 31+ only

	Linked to Care	Not Linked to Care	Total randomised
<b>SOC</b>	52 (54.7)	43 (45.3%)	95
<b>App</b>	44 (44.9%)	54 (55.1%)	98
<b>Combined</b>	96 (49.7%)	97 (50.3%)	193

Source: Authors.

Notes:  $\chi^2 = 1.8679$ ,  $P = 0.172$ .

## 5.5 MONITORING USAGE OF INTERVENTION PARTICIPANTS

A benefit of a smartphone-based laboratory results system such as SmartLink is that it works across national borders. Patients can both read their own results when travelling abroad, and they can make their own laboratory results accessible to health care workers in other countries. For example, the study team was able to identify when SmartLink was opened and where users were when it was opened (down to the city level). One example is that during the Christmas period in late 2015 SmartLink was opened by a user while they were in Zimbabwe. This makes sense as many patients in Johannesburg's inner-city are Zimbabwean, and many Zimbabweans return to Zimbabwe around Christmas. This is likely the first instance of a patient of the South African public healthcare system receiving their blood results on a smartphone while they were out of the country, an important component as large numbers of foreigners, especially Zimbabweans, access care through the state system.

## SECTION 6

# DISCUSSION

This study was probably the first of its kind in Africa. South Africa, which boasts the highest average per capita income in Africa, has a higher usage of smartphones than elsewhere on the continent. However, with smartphone (and data) prices falling, it is expected that smartphone ownership will continue to increase throughout the globe. During the project we demonstrated that we could install SmartLink on participant smartphones and provide them with their NHLS laboratory data.

Formal conventional scientific studies that evaluate mHealth interventions looking at improving health outcomes suffer from the fact that the design and execution of these studies often takes years, in an environment where changes in technology, social media and cultural engagement is often measured in months. This study was unique as it attempted to engage participants in their own health care, by allowing access to their laboratory data, using technology they already owned in the form of their cell phones. We were able to design and execute the study fairly rapidly and within budget, despite major and complex delays, and learn from the process of implementation.

However, the study had severe technological, logistical and implementation challenges, that have several hard lessons for future similar projects (Venter et al. 2018). As a proof-of-concept, the SmartLink app worked as it should for the cell phones with the specifications allowing for installation, but could only be used for a small minority of people newly diagnosed with HIV. It was only used correctly when SmartLink was successfully installed, the user logged into SmartLink correctly, and a laboratory result for the participant was identified on the NHLS servers. When each of these requirements were met, notifications and blood results were securely sent to the participant. Unfortunately, this did not occur as frequently as expected and more work needs to be done to improve the installation, login and data linking process.

Importantly, we were not successful in several key areas:

- The project had several regulatory delays, that meant that implementation did not occur as rapidly as hoped, limiting the number of participants reached.
- We did not recruit anywhere near the number our sample size required. The reasons are outlined above, and some were out of our control, but this limited our ability to test the power of the intervention. Given the challenges to recruit patients into the trial, remedial strategies were implemented, including expanding the number of recruitment sites (from one to five), revising enrollment targets, dropping the ID document criteria in favour of other



identification criteria, and working very actively with individual health care staff within the recruitment sites to optimize flow and recruitment.

- Linked to this, we will unlikely be able to test whether the intervention would address the two groups that have historically not linked as well to care, namely young people and men. Again, our study confirmed that men are difficult to recruit, a recurrent theme when dealing with male engagement in HIV care.
- We did not develop an approach that would cover the participants with all Android cell phones receiving a new HIV diagnosis, as both older versions (older than version 4.2) and RAM limitations (less than 350MB available) meant even those with Android phones could not have the app installed; again, the reasons are complex and multifold, and largely related to software development.

However, the experience of implementing this app has resulted in several useful and practical recommendations going forward, and detailed below.

## SECTION 7

# CONCLUSIONS AND RECOMMENDATIONS

This project was far more complex than we expected, with multiple unanticipated challenges. mHealth approaches are exciting, perhaps tapping into patient engagement in a way we have never been able to before, but there is substantial work to be done on how to do this most effectively, and expertise in multiple areas of implementation are required.

## 7.1 ADDITIONAL INTERVENTIONS MAY BE REQUIRED TO COVER ALL POPULATIONS

Our app, in the end, was only able to be used by a small percentage of the population it was intended for. While acknowledging the growth of smartphones within the population, it is likely that we will still require other interventions to address the cascade of care.

**Recommendation:** Field testing prior to any intervention is important, to test assumptions about prevalence of technology penetration and routine use of smartphones. The vast majority of patients getting an HIV result had a phone during screening, but 90% lacked either the technical or data requirements of the app. Having an additional, automated SMS or telephone system to complement any app system may be necessary, during the transition to smartphone use.

## 7.2 WORKING WITH NHLS WAS CRUCIAL

The National Health Laboratory Service fulfills over 90% of laboratory analysis within the public health system in South Africa. Partnering with the NHLS ensured that study participant laboratory results could be transmitted to participant smartphones that had SmartLink immediately; there were no additional steps required. Without the NHLS as a partner, the process of identifying results would be either a manual process, or result in identifying another NHLS partner to work with, bringing in the possibility of connectivity and/or further data issues.

**Recommendation:** Where possible, having the data sent directly from the NHLS source, would simplify and make the process of engagement more reliable.



## 7.3 CREATING SOFTWARE APPLICATIONS

Creating apps is complex and requires attention to an evolving technological environment. Despite the fact that a number of the project team members were technologically savvy and had experience in working in mHealth, only one person on the team had experience creating an app previously, the NHLS TreatTB app that the NHLS had developed. TreatTB was different in many ways, and hadn't yet been finalised when SmartLink development started. As an app, TreatTB was created for healthcare workers to use to monitor patients using a project-relevant unique patient identifier. It also was designed for tablet devices, and was used as a link to an existing database. SmartLink, on the other hand, was designed for patients, on phones and tablets, and involved allowing for dynamic notifications, scheduling future notifications and matching patient data from two databases without a unique identifier. Additionally, the software development company that was hired to create SmartLink had much experience with databases, but very limited experience creating Android apps; TreatTB was their first. This lack of experience from the project and Android software development teams contributed to the app-creation challenges (described above) that were encountered.

The size of the app was limited, to make installation cheap and easy; however, other issues, such as the size of RAM, remained important. Security issues were relatively easy to solve, as the development team elected to use a system used by local banks than include formal registration followed by a simple password system for future access.

**Recommendation:** The technology and/or SMS-based mHealth experience or knowledge is not the same as software development experience. If members of the project team do not have experience with the software development/creation process, it is recommended to hire a software development company that has a significant amount of experience in developing in the same programming language, the same operating system that you will be using and the same field of work (i.e. health care, finance, agriculture etc.). If a developer is hired without having relevant experience, they will be learning as they work on the project which is likely to result in both delays and mistakes.

- Where possible, an open call for proposals, allowing bidding from multiple organisations so they can show their experience is strongly recommended. Even with an open process such as this, there is no guarantee that the successful bidder is able to complete the project on time or on budget. Regular or even constant communication with the developer can assist, while ensuring the project has sufficient human resources to enable such communication.
- Furthermore, more extensive field testing prior to recruitment initiation, with a large number of patient phones, might have identified the app-related issues (Android version 4.2 and RAM requirements, non-compatibility with tablet devices, etc.). Unfortunately, SmartLink was only ready for use at the same time as the regulatory issues were resolved and the study team was eager to start



recruitment without further delays. A week or two of intensive piloting/field-testing would likely have minimised the number of issues that were experienced.

## 7.4 HOW TO DISSEMINATE AN APP IF FOUND EFFECTIVE AND APPROVED FOR SCALE-UP

A decision was made not to make the app available through Google Play Store, to protect patient confidentiality (the app was only available to HIV-positive participants for the study, and we have no control over Google data on downloads, meaning we could not assure confidentiality). The decision to install SmartLink onto participants' phones manually was the best choice based on the information that the team had at the time (ie: before recruitment started), and the budget available. As the study progressed from concept to active recruitment, unexpected issues around installation of SmartLink on patient phones emerged. A benefit of installation directly off the Google Play Store is that it conducts an immediate analysis on the potential installation device to ensure it is compatible with different Android devices. It also provides the developer with information about how to make the application more compatible, and allows for users to be notified of newer/updated versions of the application (however, with additional cost to download the update).

**Recommendation:** Based on this experience and how smartphone technology and ownership has progressed, the study team strongly recommends that future research projects involving smartphone apps use an authorised application store wherever possible. If a similar app is available that is not disease-specific (as ours was for HIV), issues such as confidentiality may not be as much of an issue, as all patients could have access to laboratory results, not only if they are HIV-positive. For Android devices, that is the Google Play store or the Amazon Marketplace (Note: At this point, only a very small percentage of phones are sold with the Amazon Marketplace, but may grow in size in the future). The majority of phones in our study, as well as prior surveys, suggest the Android devices are the current and near-future platforms South Africans use. For iOS/Apple devices the only authorised application store is the App Store. For Blackberry OS devices the only authorised application store is Blackberry World (previously Blackberry App World), however as of late 2016, new Blackberry devices run Android, so can use Google Play or Amazon Marketplace. For Windows Phone devices, the Windows Store (previously Windows Phone Store) is the only authorised application store. Note: As of Q1 2016, iOS and Android contributed to 98.89% of all new smartphones sold across the globe (Gartner Inc., 2016).

## 7.5 INTEREST IN SMARTLINK ELSEWHERE IN SOUTH AFRICA

Providing laboratory results to patients is a very basic concept that health care providers and others working within public health can easily connect with. For that



reason, a number of internal and external projects have expressed interest in the SmartLink system. This has included the Wits RHI Health Systems Strengthening programme, Beyond Zero, in Eastern Cape, and Spilhaus Clinic in Harare, Zimbabwe. South Africa is relatively unique in having a national laboratory service, meaning that implementation at a national level appears possible, especially with implementation of a single patient identifier. As an NHLS-owned app, SmartLink can be licensed to various organisations that work with the NHLS to support the South African public healthcare system, with World Bank permission. Normative frameworks exist within South Africa to guide implementation, but practical experience remains low.

**Recommendation:** During the execution of this project, we have been made aware of several apps tested in the field in South Africa, looking at a variety of interventions, from use as an electronic patient record, to communication of laboratory results and appointment times similar to our app. All have suffered from severe implementation challenges, and some have been discarded, despite significant financial and political support. We suspect that pooling this experience in some communal forum in future may assist with future development of app interventions, as it appears that implementation may be far more complex than project teams anticipate, yet interest in mHealth solutions is high.

## 7.6 SMARTLINK AS A PROOF OF CONCEPT FOR DECREASING LOSS-TO-FOLLOW UP

Despite the significant implementation challenges in this trial, we still believe that development of the app, or a similar intervention, is important. Successful novel linkage to care interventions are not apparent within the HIV cascade, (other than same-day ART initiation, which appears to somewhat address the drop-off between diagnosis and initiation (Rosen, 2016)). Same-day treatment requires adequate communication with the small number of patients who are subsequently found to have abnormal renal function, who will need their therapy adjusted; and CD4-guided opportunistic prophylaxis. Communicating results directly to patients would seem to be a positive patient empowerment exercise and a form of transfer of medical history between institutions if required. The possibility of communication in future over other significant laboratory results (such as detectable viral loads), and of clinic appointments, medicine appointments or even reporting of side effects (Venter et al, 2017) Interest within South Africa remains high, as pressure accumulates on the Department of Health to “track” patients within the cascade, as well as act on important results such as detectable viral loads more timeously.

We will continue to work within our programmes to test this approach, and using the experience from this project and with the NHLS, to test this approach.

## SECTION 8

# CONCLUSIONS FROM PROFILE OF PARTICIPANTS & NON-ELIGIBLE POPULATION

### 8.1 GENERALISABILITY

As detailed above, 90% of patients identified could not be enrolled in the study, mostly due to technological and data issues (Venter et al. 2018). It is possible we will be able to get past some of these issues, as smartphone penetration and access to data improves, and through making the app more compact and less data intensive. Notably, we had problems recruiting men; broader interventions are clearly required to engage men with HIV testing and care.

### 8.2 CAN SMARTLINK SUPPORT LINKAGE TO CARE?

Overall, only 48% of the 353 trial participants linked to HIV care during the 2 week to 8 month trial window (irrespective of trial arm) (Venter et al. submitted). The linkage to care rates by sub-group were: 52% for males, 46% for females, 45% for 18-30 year olds, and 51% for >30 year olds. The evaluation of the app impact showed a statistically significant benefit in younger HIV patients aged 18-30 ( $p=0.009$ ). Low study power may have affected the detection of app effects in the other sub-groups especially males. Providing patients within a public health system with their results is empowering, in and of itself. Access to health data, through the current "Fitbit" and similar fitness technological interventions, has proved very popular across the globe; in the UK patients increasingly have access to their laboratory results, and communicate with their health care workers through smartphones and computers. Reminders concerning appointments (from private dental to car maintenance appointments) have become ubiquitous.

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## SECTION 9

# POSTSCRIPT: SMARTLINK AND THE INTRODUCTION OF TEST-AND-TREAT

In September 2016, South Africa removed the CD4 count threshold for ART initiation, in line with WHO recommendations of ‘test and treat’. However, the CD4 is still used for other treatment decisions, including opportunistic infection prophylaxis, and guides the speed of ART initiation, especially in the context of concomitant TB. The focus of future programmes, in the context of a burgeoning public sector programme, will shift to established patients and their viral load results, creating a further opportunity for rapid communication of results and implications of these tests, directly to patients. We think the role of an interactive information system for patients within the state sector will continue to be an opportunity, in the context of HIV becoming a chronic disease requiring decades of engagement with the health sector.

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## SECTION 10

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## APPENDIX 1

# SMARTLINK APP CONTENT (TEXT)

**BOLD** – TOPIC AREAS (CAN BE CLICKED ON IN APP)

### A1.1 LAB RESULTS

#### **</= CD4 OF 500**

It is best to start ARVs (medication) when you have a CD4 count that is less than or equal to 500. Even if you are feeling well, you have a virus in your blood, so you need to go back to your clinic. Speak to your nurse or doctor so they can start you on your ARV medication.

#### **> CD4 OF 500; AND NO OR MINOR SYMPTOMS:**

If your CD4 count is more than 500, you usually do not have any symptoms and you are generally feeling well. Your blood results are telling us, you have a virus, so it is important to test and check the level of CD4 every 6 months. If your CD4 count goes below 500, it is best to start ARVs. You can do practical things to help strengthen your body's health like doing exercise or eating healthy. If you are concerned about any health-related symptoms, please talk to your nurse or doctor as soon as possible.

#### **> CD4 OF 500; AND SERIOUS SYMPTOMS OR INFECTIONS:**

If your CD4 count is more than 500, but you have other symptoms, infections or clinical conditions, it is important for you to start your ARV medication. *Examples of infections or clinical conditions are:* TB; Oral thrush; Meningitis; Chronic genital herpes; severe loss of weight; some cancers like Kaposi sarcoma (mostly skin cancer but can also be in your mouth or lungs). Speak to your nurse or doctor. Please go back to the clinic as soon as possible. The nurse or doctor will be able to assess you and decide when you will start your ARV medication.

#### **IF YOU FALL PREGNANT:**

If you are pregnant, you need to start ARVs as soon as possible even when your CD4 count is above 500. This is important for you and your unborn baby as it will prevent transmission of HIV to your unborn baby. It is important for you to get counselling. You can sign up with your nurse or doctor for MomConnect, which provides information about pregnancy and looking after your baby.

#### **VL – LOWER THAN DETECTABLE LIMIT:**

This is a sign that your HIV virus is controlled. Continue taking your ARVs as directed.

#### **VL BETWEEN 400 AND 1000:**

This is the early sign that your ARVs are starting to fail working against controlling the HIV virus. Take your medication according to the correct direction of your nurse or doctor. The viral load should be taken again in the next 6 months. If you are



experiencing any challenges with treatment or in your life, please speak to your nurse, doctor or counsellor.

**VL >1000:**

This is a sign that your ARVs are failing to control the HIV virus and the common reason is that you might have not been taking your ARVs regularly and as advised by and agreed with your nurse or doctor. Please speak to your nurse, doctor or counsellor. You need to repeat the blood test in the next 2 months. If this high viral load continues to increase in the blood, your doctor might need to change your ARVs as the virus might have developed resistance (the virus continues to multiply), and no longer responds to the ARVs you have been taking. The higher the viral load the more the virus will destroy your soldier cells (CD4 cells) and you will be more likely to develop serious infections.

To avoid the virus continuing to multiply (this is known as resistance to your ARVs), you need to take your medication every day as agreed between you and the nurse or doctor.

## A1.2 HIV

**WHAT IS HIV?**

Our blood contains white and red blood cells. Normally the white blood cells (CD4s and others) fight off and kill any virus or bacteria which enters our bodies. In this way our bodies fight off many different viruses and the body is able to stay healthy.

HIV is a virus that attacks and destroys cells that fight infections and keep our body healthy – especially CD4 cells. The higher your CD4 soldier cell count is, the less likely you are to become ill from other serious infections. Because of ARVs, HIV is a manageable chronic disease.

If you test for HIV and the results are positive, then it means that you are infected with the HIV virus.

HIV is the virus that causes AIDS, but it can take years before you get sick from the virus if you take ARVs. With ARVs you can fight the HIV virus from developing and getting stronger. If untreated (no ARVs), HIV infection leads to a weakened immune system. This makes a person with HIV vulnerable to infections. AIDS results when HIV infection progresses to an advanced stage, damaging the immune system to a point at which the body can no longer fight illnesses.

By knowing what your CD4 cell count is, you can manage your health and strengthen your body's health.

**HOW IS THE HIV VIRUS SPREAD?**

The HIV virus is spread by having sexual intercourse (vaginal/anal/oral) without a condom; through sharing injection needles and syringes, and can spread from a pregnant mother to her baby. You cannot get HIV from touching, sharing eating utensils, coughing, sweat, or sharing bathroom facilities.



### **WHAT IS VIRAL LOAD?**

Viral load is the amount of HIV in the blood. The goal of taking your ARVs is to reduce the amount of HIV virus in your blood to such a low level that we cannot see it when we do a test (this is known as a viral load lower than detectable limit). Low level of HIV virus in the blood stops the HIV from destroying your CD4 soldier cells. This does not mean that you are cured of the HIV.

Every time you take your ARVs you boost the amount of ARV in your blood. Keep the level of ARV in your blood high so it can keep the HIV virus controlled.

Your nurse or doctor will take blood and check the viral load 6 months after you have ARVs to check if the virus is controlled. If the viral load is lower than detectable limit in the blood, then the second viral load will be checked after 6 months and then once a year thereafter. If your 12-month viral load is again undetectable, you are classified as “stable” and may be offered very convenient ways to get your ARVs. The lower the viral load, the less the chances of transmitting HIV to others; for example, to your sexual partner or your unborn child if you are pregnant.

## **A1.3 TB**

### **TUBERCULOSIS:**

TB is a disease caused by a germ (mycobacterium) and most often affects the lungs but can cause disease in any other part of the body like in the bones, the brain or the abdomen. TB is transmitted by inhaling it from the air. Each person with untreated TB can infect up to 15 others if not treated.

### **WHO IS AT RISK OF TB?**

People living in overcrowded places, who are smoking or have diabetes and people infected with HIV are more at risk of developing this disease. For every 100 people in South Africa, 1 has TB.

### **WHAT IS THE RELATIONSHIP BETWEEN TB AND HIV:**

If you are HIV infected your chances of developing TB disease are even higher. Seven in ten people with TB are also infected with HIV as well. TB makes HIV worse and HIV makes TB worse. All patients having HIV and TB at the same time must be started on ARVs regardless of how much their CD4 count is. So even if your CD4 count is above 500, you need to be started on ARVs, at least two weeks after TB treatment has been started.

Patients with both HIV and TB are more likely to develop complications if ARVs are not started early. TB treatment will be initiated first, followed by ARVs after a minimum of two weeks after starting TB treatment.



### **SIGNS AND SYMPTOMS OF TB:**

Common symptoms of TB are cough of any duration (if you are HIV positive), fever, night sweats and loss of weight, tiredness and generalised body weakness. Some symptoms can include abdominal pains, swollen glands. If you have any of these symptoms, please let your nurse or doctor know.

### **TB TREATMENT:**

Complete your TB treatment. Depending on what kind of TB you have – it will take 6 months usually to treat, but if you have other types of TB it might take longer than 6 months. If the TB is outside the lungs it can take from 9 to 12 months to treat.

## **A1.4 MEDICINES/ARVS**

### **WHAT ARE ARVS?**

ARVs are medications that stop the HIV virus from multiplying so it cannot attack or destroy your CD4 cells. ARVs do not cure you from HIV. It is important that the level of HIV (viral load) in your blood is low. This stops the HIV killing your CD4 soldier cells. Every time you take your ARVs you boost the amount of ARV in your blood. Keep the level of ARVs in your blood high so it can keep the HIV virus controlled.

There are different types of ARVs that you may be given. When you start medication, the doctor or nurse will take a sample of your blood to assess what ARV medication would work for you. In managing your health, you are in partnership with the nurse or doctor. Speak to them if you have any concerns or questions. If you are a truck driver, work night shifts and/or operate heavy machinery – please tell your doctor or nurse as this will help them decide which medication will work for you.

### **TYPES OF ARVS:**

- Fixed dose combination (FDC) – this is a combination of three different ARVs
- Other ARV treatments could be used, for example: Abacavir (ABC); Nevirapine (NVP); Stavudine (D4T); Lamivudine (3TC); Aluvia

***IMPORTANT MESSAGE:*** *initially you may have side effects, for example: tiredness; diarrhoea; nausea; dizziness; insomnia. DO NOT stop your ARVs! Your body will get used to the medication, and the side effects will disappear. Consult your doctor or nurse if you experience any symptoms.*

### **ARV TREATMENT**

Before ARVs are given you will be offered counselling to help you understand the treatment process and how to fit it into your daily life. When you start ARVs, the nurse or doctor will take a sample of your blood to assess which ARVs would work for you. You will go back to the clinic to collect your blood results and you will be told about how to take your ARVs. It is important to agree with the nurse or doctor when best it would be for you to take the ARVs. Remember, you need to take them daily.



Once you are on ARV treatment, your blood will be taken regularly. Ask your nurse or doctor on how often your bloods will be taken as it depends on what ARV treatment you are on. Your viral load will be taken after six months of starting ARVs. Viral load is the amount of HIV in the blood. The goal of taking your ARVs is to reduce the amount of HIV virus in your blood to such a low level that we cannot see it when we do a test (this is known as a viral load lower than detectable limit). That is a good sign, it means you are managing the HIV virus. This however does not mean that the HIV is cured. Note that HIV cannot be cured by ARVs, but it can be managed by correctly taking of your ARVs.

If the virus is lower than detectable limit, then your blood will be tested every year to check your HIV viral load. Missing your ARVs gives the HIV virus a chance to grow stronger. If you take your treatment every day your HIV viral load should be lower than detectable limit. If you forget to take your ARVs at your chosen time, it is better to take them late than to miss them completely. Taking (ARVs is lifelong – once you start treatment, you should not stop. If at any time you need to speak to a counsellor about anything you may do so.

Taking ARVs does not treat other infections like STIs and TB. If you are ill or have any questions about your medication or health, ask your nurse or doctor at your next clinic appointment.

Traditional or herbal medicine can affect the way your ARVs work. Speak to your doctor or nurse about your options. Remember: ARVs suppress the HIV virus.

### **ADHERENCE TO MEDICATION**

Taking ARVs is a lifelong commitment: once you start treatment, you should not stop. Adherence is about understanding and managing your medication. This can be understood as taking your ARV medication as the nurse or doctor suggested but it is important to know that you and your nurse, doctor and counsellor are part of the same team. You can talk together to decide when is the best time for you to take your medication and to agree a treatment plan that will fit into your life context (including the type of work that you do as well as being aware of what else is happening in your life at this time).

Adherence to taking the medication affects how well the ARVs work in our bodies. If adherence to medication is very good (that means you take your ARVs daily at the time(s) agreed with your nurse or doctor), the amount of HIV in your body will reduce very quickly after a few weeks or months. This allows for the immune system to start recovering, so that illness is reduced and health is regained. If adherence has been good, your viral load should be lower than the detectable limit within 6 months of starting ARVs. If the viral load does not drop, you need to speak to your nurse or doctor – there could be possible adherence or medication issues.



To take medication daily, it is helpful to have support. Firstly, it is important to speak with the nurse or doctor who gives you your treatment and to discuss how best to take your treatment every day.

#### **WHAT SHOULD YOU DO IF A DOSE OF YOUR ARVS IS MISSED?**

- Take it as soon as you realise and then return to your normal schedule.
- If you only remember when you get to the next dose, take the normal dose.
- It is better late than never.
- Do not take a double dose to make up for the one you have missed.

You could also speak to a trusted person (someone in your family or a friend) or join a support group. Once you have been on your ARVs for over a year and your viral load is below the detectable limit, then there may be opportunities for you to be part of an adherence club. This means that you only come to the clinic every second or third month to collect your medication, and you do not have to wait in the long queue. This can motivate you to keep taking your medication every day.

#### **TAKING MEDICATION EVERY DAY CAN BE DIFFICULT TO DO. HERE ARE SOME THINGS YOU CAN DO TO HELP YOU (SOME ARE MENTIONED ABOVE) REMEMBER TAKING THEM:**

- Talk to your doctor, nurse or counsellor to find out what time in the day would suit you best to take the medication.
- Tell someone that you trust (disclosure). You can then talk to this trusted support person that you can talk to when you are finding it difficult or someone who can check in with you or remind you to take your medication.
- Set an alarm on your phone (or an alarm clock) to remind you of the time to take your medication.
- You could use a pill box to help you remember to take your ARVs every day.
- If you are stressed, depressed or traumatised, get support to manage this.
- When going to holiday or visiting family, remember to get the medication that you need before you leave so that you do not run out.

#### **WHY IS IT IMPORTANT TO INFORM YOUR HEALTH CARE PROVIDER WHEN YOU ARE CHANGING HEALTH FACILITIES OR MOVING AWAY?**

- The health care worker will provide you with a referral letter that explains your condition and the ARVs that you are taking.
- The referral letter will save you time that you spent at the health facility.
- It will make it easier to access your ARVs.
- To avoid being classified as a defaulter.



## **WHAT ARE SEXUALLY TRANSMITTED INFECTIONS (STIs)?**

STIs are spread through having unprotected sex (sex without using a condom) with someone who has an STI.

### **HOW DO YOU GET STIs?**

- By having unprotected sex and coming into contact with sexual fluids (semen, pre-ejaculate and vaginal fluid) and the surfaces of the penis, vulva, rectum and mouth.
- Through all kinds of sexual contact (anal, oral and vaginal). All sexual contact that involves bodily fluids should be considered risky.
- The use of condoms does decrease your risk of getting STIs but is not 100% safe, because even with a condom you can still come into contact with infectious areas of the genitals.
- HIV, the virus that leads to AIDS, is also an STI but it can also be spread through blood and breast milk.

### **SIGNS AND SYMPTOMS OF STIS:**

If you have any of the following you should consult your doctor/nurse as soon as possible:

- Unusual discharge from vagina, penis or anus
- Itchy genitals
- Pain when urinating
- Pain during sexual intercourse
- Genital sores
- Swollen glands in the groin
- Lower abdominal pains
- Rashes or warts

### **STIS TREATMENT (OTHER THAN HIV)**

- Most STIs (other than HIV) can be cured with antibiotics.
- The earlier you go to the clinic and get treated the easier it will be to cure the infection.
- Always finish all the medicine you are given even if it looks like the infection has gone.
- If you stop taking your medicine before it is finished, the infection may come back.



- Never share your medicines as this will mean that neither you nor the other person will have enough in your system to cure the STI.
- As a male you might consult a traditional healer – you need to also visit your nurse or doctor.

### WHAT IS THE RELATIONSHIP BETWEEN STIS AND HIV?

- HIV, the virus that causes AIDS, is an STI.
- The biggest problem with STIs is that they increase the chances of you getting HIV.
- If you or your sexual partner has an STI and HIV, the chances of passing on or getting HIV increase dramatically.
- Many STIs make little cuts or tears or breaks in the skin. If your partner is HIV-positive, the HIV can enter your body through these breaks in the skin during sex.
- The discharges from any STI may contain a very high level (concentration) of HIV.

## A1.5 STAYING HEALTHY/HEALTHY LIFESTYLE/SRH

### A POSITIVE MENTAL ATTITUDE:

**Strengths and Resources:** Everyone has strengths and resources. The more resources and strengths that you recognize within yourself and within your support structure (e.g. clinic, family friends, counselors), the more you will be able to cope with good and challenging situations.

If you have just found out that you are HIV positive, you may feel many different feelings and emotions. These can include: shock, depression and anger. It may take some time before being able to accept what has happened and that life has changed. Remember, having HIV does not mean life has come to an end. Many illnesses (such as diabetes, asthma, epilepsy) are long – term but can be managed with a good attitude, external support and the right medication.

**Managing stress:** Free the mind of negative thoughts. This is easier said than done. Negative thoughts can weaken the immune system. Write down all the good reasons for living and staying healthy and focus on these when the negative thoughts come.

**Depression, Anxiety, Trauma:** these are the top three mental health challenges that people living in South Africa experience. If you are struggling with any of these, ask your trusted person or ask someone at the clinic to refer you to someone who can help you manage the difficult situation. If you don't get help, it could affect your adherence to your medication. Depression, anxiety and trauma symptoms are manageable when we get support for them.



## MAINTAINING HEALTHY LIFESTYLE CHOICES

**Exercise:** Being physically active helps the circulation of blood and makes the body stronger. It helps calm your mind (if you are worrying about things) and helps the body to heal quickly. It is important to always get enough rest when needed. Learn to listen to your body.

**Healthy eating and drinking:** A balanced diet is important for anyone as it can help to keep the immune system strong. Nutrients are the elements of food that the body uses to keep healthy, so it is important to eat enough of different kinds of food. Good nutrition helps to: Strengthen the body, especially when taking medications; Prevent weight loss and body weakness; Fight infections; Build energy to get through the day. In terms of drinking, it is necessary to drink lots of water and limit having large amounts of alcohol: both for physical health as well as for mental health. This helps us develop healthy relationships and make clear choices.

**Hygiene:** Use clean water and soap to avoid infection. Keep toilets clean to prevent germs and always wash hands with soap afterwards. Remember: you cannot get HIV from touching, sharing eating utensils, coughing, sweat, or sharing bathroom facilities.

Food should be cooked and clean. Always wash fruit and vegetables before eating them. Wash hands with soap before and after eating. Get lots of fresh air.

**Regular check-up and testing at the clinic:** physical health is important. Regular check-ups can pick up concerns and can manage them before you get too sick.

**Medical male circumcision (MMC):** This is a small operation involving the removal of the whole penile foreskin, performed under professional medical supervision. This includes a qualified surgeon, sterile equipment and immediate management of adverse effects (this includes management of pain and excessive bleeding). MMC services are aimed at males and offered routinely as part of the HIV counseling and testing (HCT). It can be used as an HIV preventative action and it can be used to reduce the risk of HIV re-infection. This means that if you are already HIV positive, MMC can reduce your risk at getting other types of HIV virus or infections. MMC is not a cure for HIV but it does reduce the transmission and contracting of STIs, other HIV strains and Human Papilloma Virus (which causes cancer). You still need to always use a condom to practice safe sex.

## PRACTICE SAFE SEX

Options include abstaining or using a condom (male or female) correctly every time one has sex to prevent transmission or re-infection with HIV and/or sexually transmitted infections (STIs).

**Negotiating safe sex:** You always have a right to decide whether you want sex or not – it is your decision. You cannot expect the other person to know what you're thinking – you need to say what you want or don't want. Sexual consent means that you agree to a specific sexual activity. So getting and giving consent is an on-going process. Just



because a person says yes to one type of sexual activity doesn't mean that they agree to everything. If someone shows a sexual interest one time it isn't an open invitation to have sex later. Consensual sex doesn't just happen – it's negotiated. Any sexual activity without consent is sexual assault and that's a crime. Being involved in a sexual relationship requires clear and direct communication.

### Using Condoms:

- storing condoms correctly (away from heat, not in a back trouser pocket)
- checking the expiry date
- opening the packaging and checking the condom is not damaged
- putting the condom on correctly (avoiding tearing it with sharp nails, not putting it on inside out)
- putting on the condom when the penis is fully hard
- using water-based lubricant such as KY gel or plain yoghurt, and avoiding oil-based lubricants such as hand cream and Vaseline
- withdrawing with the condom on while the penis is still hard
- ensure the condom is disposed of correctly (wrapped in tissue or paper and thrown into the rubbish bin, away from children.) It should not be flushed down a toilet
- using a new condom for each new act of sexual intercourse

### DISCLOSURE

Disclosure is a process of informing someone that you are HIV positive. It is useful for you to identify a *trusted person/persons* that you would feel comfortable to disclose your HIV status to.

When you disclose your status to others, it is helpful to have a good understanding of HIV and your status and how this may impact on your life and their lives. Disclosure is helpful as then the trusted person can support and encourage you in taking the medication and making health choices for your life. It is also important that your partner or partners get tested – no matter what the result of your test is.

Remember disclosure is a process – you can choose to share what you want to share and who you want to share it with. It is good to identify trust people and broader support systems (e.g. family, clinic, counsellor, friends, and support groups) that will encourage you and assist you in times of difficulty.



## A1.6 NATIONAL CONTACT LINES

National AIDS Helpline: 0800 012 322

Suicide Crisis Line: 0800 567 567; SMS 31393

Lifeline: 0861 322 322

DSD Substance Abuse Line: 0800 12 13 14; SMS 32312

Childline – 08000 55555

Gender-based Violence Command Centre (DSD): 0800 428 428; SMS \*120\*7867#

Mental Health Helpline: 0800 567 567

## A1.7 FREQUENTLY ASKED QUESTIONS

### WHERE DO I GO FOR A GRANT? DO I QUALIFY?

If you have a physical or mental disability which makes you unfit to work for a period of longer than six months, you can apply for a disability grant.

You get a permanent disability grant if your disability will continue for more than a year and a temporary disability grant if your disability will last for a continuous period of not less than six months and not more than 12 months. A permanent disability grant does not mean you will receive the grant for life, but that it will continue for longer than 12 months.

### HOW DO YOU KNOW IF YOU QUALIFY?

To qualify, you must:

- be a South African citizen or permanent resident or refugee and living in South Africa at the time of application
- be between 18 and 59 years old.
- not be cared for in a state institution
- have a 13-digit, bar-coded identity document (ID)
- not earn more than R64 680 (R5 390 per month) if you are single or R 129 360 (R10 780 per month) if married.
- not have assets worth more than R930 600 if you are single or R1 861 200 if you are married
- undergo a medical examination where a doctor appointed by the state will assess the degree of your disability



- bring along any previous medical records and reports when you make the application and when the assessment is done.
- The doctor will complete a medical report and will forward the report to South African Social Security Agency (SASSA).

The report is valid for three months from the date you are assessed.

*NOTE:* If you are under 18 and need permanent care due to your disability, your primary caregiver can apply for a Care Dependency Grant. If you don't have an ID, you will be required to complete an affidavit and provide proof of having applied for the document from the Department of Home Affairs. If you have not applied for an ID, you must do so within three months of applying for the grant.

If you think you qualify, go to the nearest South African Social Security Agency (SASSA) branch and fill out an application form (and other records mentioned above). At SASSA you can also ask about other grants (like child support grant, care dependency grant or old age pension) or you can get more information at the website:

<http://www.gov.za/services/social-benefits>

### **IF I'M HIV POSITIVE AND MY CD4 COUNT IS HIGHER THAN 500, WHAT SHOULD I DO?**

If your CD4 count is more than 500, you usually do not have any symptoms and you are generally feeling well. It is important to test and check the level of CD4 every 6 months. If your CD4 count goes below 500, it is best to start ARVs. You can do practical things to help strengthen your body's health like exercise, eating healthy and managing/controlling your stress levels. If you are concerned about any health related symptoms, please talk to your nurse or doctor as soon as possible.

### **WHAT DO I DO IF THE ARVS MAKE ME FEEL NAUSEOUS OR GIVE ME DIARRHOEA?**

Initially you may have side effects, for example: tiredness; diarrhoea; nausea; dizziness; insomnia. DO NOT stop your ARVs! Your body will get used to the medication, and the side effects will disappear. Consult your doctor or nurse if you experience any symptoms

### **IF I GET A RASH OR A COUGH, AND I'M TAKING MY ARVS EVERY DAY, WHAT SHOULD I DO?**

If you get any symptoms that you are concerned about, please go back to the clinic as soon as possible. Speak to your nurse or doctor. They will be able to assess you, explain what is happening and agree a way forward. Each situation is different.



If you are coughing for a period of time, have a fever, night sweats and loss of weight, tiredness and generalised body weakness, please go to the clinic as soon as possible and talk to your doctor or nurse.

### **WHAT SHOULD I DO IF I MISS TAKING A DOSE OF MY ARVS AT THE AGREED UPON TIME?**

Take it as soon as you realise and then return to your normal schedule. If you only remember when you get to the next dose, take the normal dose. It is better late than never.

Do not take a double dose to make up for the one you have missed.

It is difficult to remember every day. For some people it helps talking to a trusted person (someone in your family or a friend) or join a support group. Once you have been on your ARVs for over a year and your viral load is below the detectable limit, then there may be opportunities for you to be part of an adherence club. This means that you only come to the clinic every second or third month to collect your medication, and you do not have to wait in the long queue. This can motivate you to keep taking your medication every day.

### **I AM GOING HOME FOR DECEMBER AND WON'T BE ABLE TO VISIT THE CLINIC. WHAT SHOULD I DO?**

When going to holiday or visiting family, remember to speak to your doctor or nurse and let them know. Ask for extra medication that you will need so that you do not run out.

### **HOW LONG WILL I LIVE IF I AM HIV POSITIVE?**

We cannot give you an exact time of life. However, with ARVs you can live a healthy normal life.

### **IF I AM HIV POSITIVE, WILL I BE ABLE TO HAVE CHILDREN?**

If you are on ARVs, the chances of transmitting the HIV virus to your baby are very low. So, yes you are able to have children.

If you are planning to fall pregnant, please talk to your doctor or nurse. It is important that your viral load is undetectable and that you are physically healthy.

### **WHAT IF I GET PREGNANT WHILE I AM GETTING THESE MESSAGES?**

If you are pregnant, you need to start ARVs as soon as possible even when your CD4 count is above 500. This is important for you and your unborn baby as it will prevent transmission of HIV to your unborn baby. It is important for you to get counselling. You can sign up with your nurse or doctor for MomConnect, which provides information about pregnancy and looking after your baby.

# APPENDIX 2

## ETHICS APPROVAL LETTER



R14/49 Prof WDF Venter et al

### HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

#### CLEARANCE CERTIFICATE NO. M150606

**NAME:** Prof WDF Venter et al  
**(Principal Investigator)**

**DEPARTMENT:** WRHI  
Hillbrow Community Health Centre  
Helen Joseph Hospital

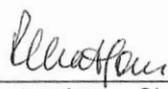
**PROJECT TITLE:** Do Smartphones Increase Linkage to and  
Retention in Care in Newly Diagnosed  
HIV-Positive Patients in Johannesburg?  
A Multi-Site Randomised Controlled Trial

**DATE CONSIDERED:** 2015/06/26

**DECISION:** Approved unconditionally

**CONDITIONS:**

**SUPERVISOR:**

**APPROVED BY:**   
\_\_\_\_\_  
Professor P Cleaton-Jones, Chairperson, HREC (Medical)

**DATE OF APPROVAL:** 10/07/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

#### DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature \_\_\_\_\_

Date \_\_\_\_\_

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES