

Introduction and evaluation of a 'pre-ART care' service in Swaziland: an operational research study

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ABSTRACT

Objective: To implement and evaluate a formal pre-antiretroviral therapy (ART) care service at a district hospital in Swaziland.

Design: Operational research.

Setting: District hospital in Southern Africa.

Participants: 1171 patients with a previous diagnosis of HIV. A baseline patient group consisted of the first 200 patients using the service. Two follow-up groups were defined: group 1 was all patients recruited from April to June 2009 and group 2 was 200 patients recruited in February 2010.

Intervention: Introduction of pre-ART care—a package of interventions, including counselling; regular review; clinical staging; timely initiation of ART; social and psychological support; and prevention and management of opportunistic infections, such as tuberculosis.

Primary and secondary outcome measures:

Proportion of patients assessed for ART eligibility, proportion of eligible patients who were started on ART and proportion receiving defined evidence-based interventions (including prophylactic co-trimoxazole and tuberculosis screening).

Results: Following the implementation of the pre-ART service, the proportion of patients receiving defined interventions increased; the proportion of patient being assessed for ART eligibility significantly increased (baseline: 59%, group 1: 64%, group 2: 76%; $p=0.001$); the proportion of ART-eligible patients starting treatment increased (baseline: 53%, group 1: 81%, group 2, 81%; $p<0.001$) and the median time between patients being declared eligible for ART and initiation of treatment significantly decreased (baseline: 61 days, group 1: 39 days, group 2: 14 days; $p<0.001$).

Conclusions: This intervention was part of a shift in the model of care from a fragmented acute care model to a more comprehensive service. The introduction of structured pre-ART was associated with significant improvements in the assessment, management and timeliness of initiation of treatment for patients with HIV.

BACKGROUND

In sub-Saharan Africa, HIV-positive adults have a high mortality rate during the first

ARTICLE SUMMARY

Article focus

- Impact of pre-ART care on the quality of care in a district hospital in Southern Africa.

Key messages

- After introduction of a pre-ART care service, a higher proportion of patients were assessed for ART, a higher proportion of those eligible started on ART and a higher proportion received key interventions.

Strengths and limitations of this study

- This was a pragmatic evaluation in a routine service setting.
- The intervention was implemented as part of routine health service delivery by existing clinical staff.
- Routine data collection systems do not link testing and HIV care data, preventing an evaluation from testing to initiation.
- The evaluation focuses on those with a known status, rather than new testers, those with tuberculosis or those who are pregnant.
- The evaluation relies on intermediate outcomes, that is, initiation on ART, rather than long-term outcomes, such as mortality.
- There is a lack of information on those requiring long-term follow-up but not ART.

year of antiretroviral therapy (ART). Mortality rates of between 8% and 26% have been reported,¹ with advanced immunodeficiency as a key risk factor.² High rates of loss to follow-up after HIV testing result in late presentation for ART initiation and are associated with poor treatment outcomes.^{3–4} In light of the negative outcomes associated with late presentation, there has been a renewed focus on the period after HIV diagnosis but before commencement of treatment.⁵ Numerous studies have investigated retention of patients following HIV diagnosis.^{3–4, 6–23} Rates of enrolment of eligible patients on ART vary widely (14%–84%), and retention of patients not yet

eligible for ART treatment remains very challenging in many of these settings (45%–70%, though the majority of these studies did not provide data for those with HIV but not on ART). Asymptomatic patients, not yet eligible for ART, may not appreciate the need for medical care at this stage and may be put off by the disruption, expense and stigma of repeated clinic visits for, what they perceive as, little treatment.⁵ Patients with low CD4 cell counts at presentation may die before presentation and so not complete ART enrolment.

There is emerging evidence of the relative success of different approaches to improve retention during this period. These include rapid clinical staging through the use of point of care CD4 tests²⁴ and the implementation of more coherent care pathways.⁵ There remains a need for a clearer understanding of how to improve patient retention at this point in resource-poor settings.

'PRE-ART CARE'

Pre-ART care spans the period between a person testing positive for HIV and needing ART. For some people, this is very short, just the time for assessment, while for others, this could be a period of years. A short period of pre-ART may result from delayed presentation for testing or a delay between receiving the initial test result and receiving (or seeking) HIV care. During the pre-ART period, a number of interventions can improve the health of people living with HIV and provide an effective pathway to ART for those who require it.^{25 26}

The components of a pre-ART care service

- ▶ Assessment for ART.
 - Regular follow-up and review.
 - Assessment for ART, including clinical staging, CD4, biochemistry and haematology.
 - Initiation for ART when agreed criteria are met.
- ▶ HIV care
 - Prevention, recognition and management of Opportunistic Infections (including co-trimoxazole and isoniazid prophylaxis, and tuberculosis (TB) screening).
 - Counselling including advice to prevent onward transmission of HIV (including promotion of condoms) and promote testing of those at risk^{25 26}

AIM

The aim of this study was to implement and evaluate a formal pre-ART care service at a district hospital in Swaziland. The pre-ART service aimed to increase the key outcomes of:

- ▶ assessment of patients for ART eligibility;
- ▶ initiation of those eligible on drug treatment;
- ▶ provision of evidence based interventions to improve health.

SETTING

The Kingdom of Swaziland is suffering a 'hyper-epidemic' of HIV infection with adult prevalence

estimated at 26%.²⁷ The Swazi National Strategic Framework for HIV and AIDS 2009–2014 recommends structured pre-ART care as part of a three pronged treatment strategy along with increasing HIV testing and the expansion of ART provision.²⁸ The framework recognised that pre-ART care was in 'its infancy', with a limited number of sites providing this package at the time.

Good Shepherd Hospital (GSH) is the district referral hospital for the Lubombo region of Swaziland, a predominantly rural area of approximately 250 000 people.

Prior to the introduction of the pre-ART care service in February 2009, HIV care prior to commencing ART at our institution was episodic. There was no continuum of care, and patients were only followed up consistently once they were started on ART. Patients with unknown status were tested in the HIV testing and counselling centre. If found to be HIV positive, a sample was taken for CD4 testing and they were instructed to return to the separate ART centre in 3 days to collect the result. If they returned, they received counselling, TB screening, co-trimoxazole and further appointments as necessary. An internal audit of services in October 2008 revealed that:

- ▶ Over 1/3 (153/407) of pre-ART hospital patients did not return to collect CD4 counts and therefore received no follow-up.
- ▶ Patients started ART late, the median CD4 at first test was 116 cells/mm³.
- ▶ Although co-trimoxazole was prescribed for pre-ART patients, there was no system of receiving a regular supply of this.
- ▶ HIV counsellors stated that they performed TB screening, but it was not offered systematically nor recorded or nor was there a system to follow-up results.

Creation of the pre-ART care service linked hospital HIV testing and ART services and aimed to improve patient follow-up by formalising previously fragmented interventions.

PROGRAMME DESIGN

The service design drew on the following concepts:

- ▶ Comprehensive care: using a patient care pathway.
- ▶ Active follow-up: structured follow-up by cell phone and adherence officers.
- ▶ Task shifting: to nurses and lay HIV counsellors.

Comprehensive care

Staff plotted the patient pathway from HIV testing to ART treatment. Service gaps along this pathway were identified and quantified. Monthly meetings were held with staff to review performance and develop the service.

Three records were introduced: (1) inpatient pre-ART file, (2) patient handheld file and (3) pre-ART registration book. The inpatient file was a way of documenting a comprehensive and systematic care plan for each

patient. The patient handheld file enabled patients to take greater responsibility for their care and to improve the continuity of care if patients presented at other facilities. The pre-ART registration book enabled follow-up when patients did not return for their appointments and monitoring of system performance.

Active follow-up

Patients who did not return for appointment were contacted by phone. Reasons for not returning were identified. Those who could not be reached by phone were followed up by the motorcycle adherence officers at their homes as part of a pre-existing service supporting HIV, TB and epilepsy services.

Task shifting to nurses and HIV counsellors

In common with many rural HIV health services in Southern Africa, the service demands outstripped the human resource capacity. When the pre-ART service started in February 2009, the staff for the HIV service consisted of two doctors, two nurses, three HIV counsellors and one pharmacist to attend to an average of 2000 patients each month. Previously assessment for ART initiation was doctor-led. The new pre-ART service was nurse-led. Nurses provided the triage for patients entering the pre-ART system and most of the clinical assessment for ART initiation. At the time of the analysis, only physicians were allowed to initiate ART drugs, creating a bottleneck. Task shifting, including nurses seeing majority of review patients and undertaking pre-ART, freed up time for doctors to initiate ART.

HIV counsellors took on additional roles of TB screening and phlebotomy from the nurses. Task shifting to nurses and HIV counsellors reduced the number of steps in the patient pathway, improved the efficiency and made the most effective use of limited resources.

INTERVENTION

A structured pre-ART care service was established at GSH in January 2009. The patient flow created is shown in figure 1.

The interventions were based on the WHO guidance. When the service was started, there were no national pre-ART guidelines, although recently a Swaziland comprehensive package of care has been published. Interventions provided as part of pre-ART care at this hospital included: baseline laboratory testing, CD4 cell count, initial clinical review and staging, regular review every 3 or 6 months, TB symptom screening, management of opportunistic infections, co-trimoxazole prophylaxis and referral to the ART service when indicated. During the study, isoniazid chemoprophylaxis was not in routine use in Swaziland.

EVALUATION METHOD

Sample

Patients with a known diagnosis were registered for the pre-ART service in the ART department and these

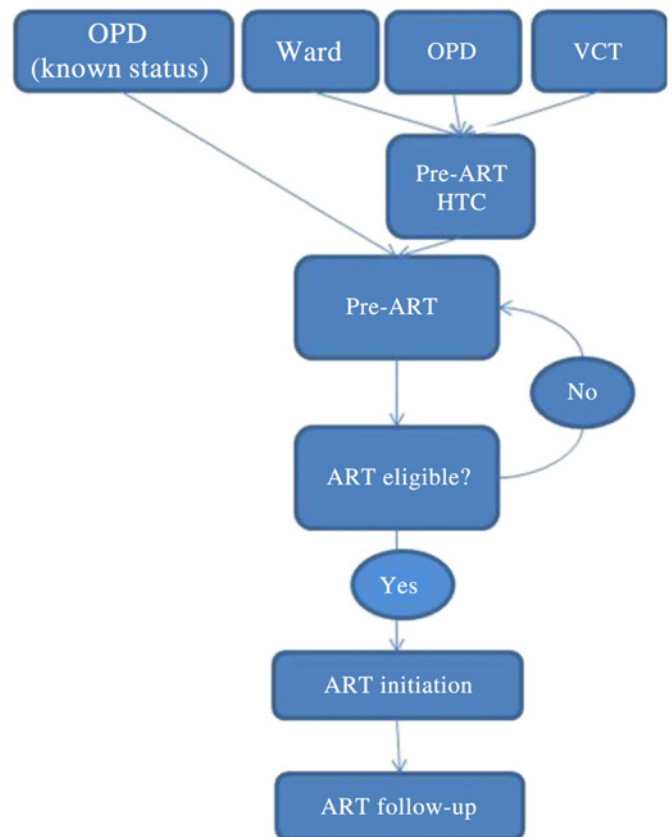


Figure 1 Flow diagram outlining the current (new) HIV pathway at Good Shepherd Hospital. ART, antiretroviral therapy; ART eligible?, definition based on the standardised WHO criteria; OPD, outpatients department; OPD (known status), patients known to be HIV positive presenting to the outpatient department; pre-ART HTC, HIV testing and counselling as part of pre-ART care; VCT, Hospital Voluntary Counselling and Testing Service; ward, general hospital wards.

formed the population for this study. This register did not include data from new testers, those who were pregnant or were known to be co-infected with TB. These groups were entered in other registers. Data were entered in a Microsoft Excel 2007 spreadsheet. Three groups were defined:

Baseline: 200 patients, February to March 2009, the first patients enrolled by the service

Group 1: 771 patients, April and June 2009, to assess the impact of the initial service implementation.

Group 2: 200 patients, February 2010, to assess the impact of the service after 1 year.

Data collection

Data were collected from the pre-ART register in June 2010. All patients had at least 3 month follow-up.

Analysis

Differences in baseline values between the three groups were examined using analysis of variance for continuous variables and χ^2 tests for differences in proportions.

Comparisons between outcomes in groups were examined between the groups using χ^2 tests and

a comparison of performance indicators using χ^2 tests for differences in proportions and Kruskal–Wallis test to look at differences in time between ART initiation in eligible patients between groups, using STATA IC 11.2. The level of statistical significance was set at 5%.

The key outcomes analysed were as follows:

The proportion of patients with a documented assessment of eligibility for ART initiation (including clinical stage, CD4 count and baseline biochemical and haematological testing) among patients recruited to the pre-ART service.

The proportion of patients started on ART among those eligible for ART initiation.

The proportion of patients who received specified interventions (TB screening, initial CD4 count, clinical staging, assessment of eligibility for ART and co-trimoxazole prophylaxis), as part of pre-ART care.

RESULTS

The demographics of the three groups reflect largely similar populations (table 1), although the proportion with CD4 counts under 200 and under 350 cells/mm³ increased in each of the three groups, and the median CD4 count was found to decrease in each of the groups.

The service's performance in assessing patients for ART eligibility and then initiating those eligible is shown in table 2. The proportions of People living with HIV (PLHIV) being assessed for ART eligibility and proportion of eligible patients being initiated on ART significantly increased in each group (χ^2 for variance, $p < 0.01$). The median time between eligibility and initiation significantly decreased ($p < 0.01$).

Rates of CD4 cell counting, clinical staging, TB screening and ART assessment increased gradually between groups (figure 2). The proportion receiving co-trimoxazole prophylaxis fell between baseline and group 1, reflecting problems with drug supply, but did rise over the 1-year period.

DISCUSSION

Following the introduction of structured pre-ART, the proportion of patients with HIV receiving appropriate

management and care significantly improved over the study period. The proportions of patients being assessed for ART eligibility and ART-eligible patients starting treatment significantly increased; the time between PLHIV being declared eligible for ART and them starting ART significantly decreased. The proportion being assessed for ART remains lower than ideal. A significant proportion of patients are testing positive, being registered for pre-ART, but then not returning for CD4 count results. Eligible patients commencing ART more rapidly is important given the very high mortality risk immediately prior to starting ART.^{1 2}

The trend in proportion of patients on co-trimoxazole is less clear. The supply of co-trimoxazole was dependent on the national system and out of the control of the service. Problems with consistent supplies of co-trimoxazole and non-implementation of isoniazid prophylaxis are commonly recognised issues in resource-limited settings.²⁹

Strengths and limitations of the study

This study provides timely evidence about the impact of a clinical intervention for a public health priority. The findings are likely to be generalisable to other low-resource settings where the prevalence of HIV/AIDS is high. The intervention was implemented as part of routine health service delivery by existing clinical staff, promoting sustainability. A randomised controlled trial would provide more robust evidence about effectiveness, but this pragmatic evaluation provides useful evidence on how to improve care in a setting where HIV/AIDS is a national emergency. While this study cannot prove causation, it demonstrates an association between the introduction of the service and improved performance. The implementation of pre-ART care involved a number of changes to HIV services at GSH. It is not possible to determine the weight of each changes' contribution.

The rapid change in performance of the service seen between baseline and group 1 (table 2) suggests that the implementation of structured pre-ART care was associated with improving performance.

The reliance on routine data limits the quality of analysis possible in this study. We were unable to link

Table 1 Summary of demographic and clinical characteristics of the three groups

	Baseline	Group 1	Group 2	p Value comparison of all groups
Patients (N)	200	771	200	
Mean age (SD) (years)	35.6 (14.9)	34.7 (14.1)	33.6 (14.4)	0.560
Gender (% female)	60	65	62	0.489
Number and proportion of adult patients with a recorded CD4 count, N (%)	127 (63.5)	496 (64.3)	154 (77)	0.002
Median CD4, range (cells/mm ³)	281 (4–2003)	292 (2–2777)	240.5 (4–1815)	0.009
Number and proportion of adult patients with a CD4 count <350, N (%)	74 (58)	303 (61)	107 (72)	0.002
Number and proportion of adult patients with a CD4 count <200, N (%)	36 (28)	167 (34)	68 (45)	<0.000

Table 2 Comparison table of assessment for ART eligibility and initiation between the three groups

	Baseline	Group 1	p Value Comparison baseline and group 1	Group 2	p Value Comparison group 1 and group 2
Number assessed for ART/all patients attended clinic, N (%)	118/200 (59)	490/771 (63.9)	0.236	152/200 (76)	0.001
Number assessed eligible for ART/number assessed for ART, N (%)	68/118 (57.6)	301/490 (61.4)	0.448	118/152 (77.6)	<0.000
Number of eligible patients initiated on ART/number assessed as eligible for ART, N (%)	36/68 (52.9)	244/301 (81.1)	0.004	96/118 (81.4)	<0.000
Median time between eligibility and ART initiation (range) (days)	61 (8–41)	39.5 (3–205)	0.006	14 (1–76)	0.0001

ART, antiretroviral therapy.

testing data (some of which is anonymous) to pre-ART information. Ideally, we would have followed cohorts of patients from testing to initiation, but this was not possible. Data were collected from the register in the ART department, which is of patients with a known diagnosis and not those with a new diagnosis. The people in this study are therefore likely to have more advanced immunodeficiency and may not be typical of all patients with HIV/AIDS. The data used excludes those who were pregnant or those on TB treatment as those services also run parallel pre-ART services. Stratifying the patient by source of referral and/or testing (eg, Voluntary counselling and Testing (VCT) or ward or outpatients) would be useful, but that information was not routinely recorded.

The differing group sizes resulted from data that had been previously entered as part of a pilot evaluation. The researchers opted to use all the available data, rather than ignoring any of it. The impact of a larger group 2 is unclear. A larger group 2 (ie, spanning a longer time period) may have increased the difference between groups 1 and 2 but lessened the difference between groups 2 and 3.

Over the study period, the proportion of patients assessed as eligible has increased. This reflects differences in health of the groups, as well as changes in international and national guidelines on CD4 threshold for initiation. The reasons for increasing numbers of patients with advanced immunodeficiency in groups 1 and 2 are unclear. This should not have affected the key outcomes of this study: the proportion of patients assessed for ART and the proportion of those eligible who were initiated.

Lessons from implementing pre-ART care

Implementing a coherent HIV pathway across multiple programmes within the hospital was a complicated process. The overall service includes HIV-positive patients in hospital TB and Prevention of Mother to Child Transmission (PMTCT) programmes in addition to the pathway described above. Integration of separate vertical national programmes (eg, PMTCT, TB, ART) at a district level to provide a coherent service and clear pathway is challenging. The recent introduction of a national integrated package of care for PLHIV may aid this.

Figure 2 Comparison of priority interventions received by the three groups. Initial CD4 cell count, $p=0.002$; HIV clinical staging, $p=0.001$; tuberculosis (TB) screening, $p<0.001$; co-trimoxazole, $p<0.001$, assessment of eligibility for antiretroviral therapy (ART), $p=0.001$.

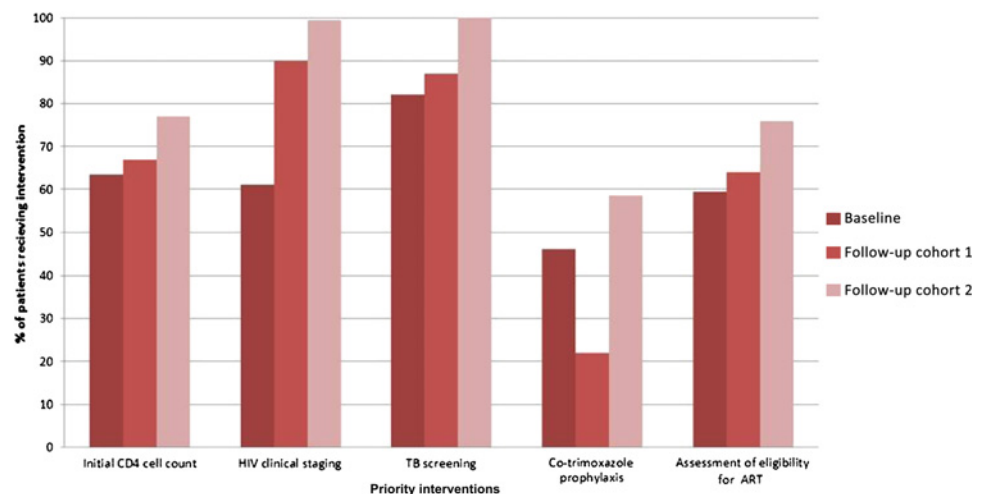
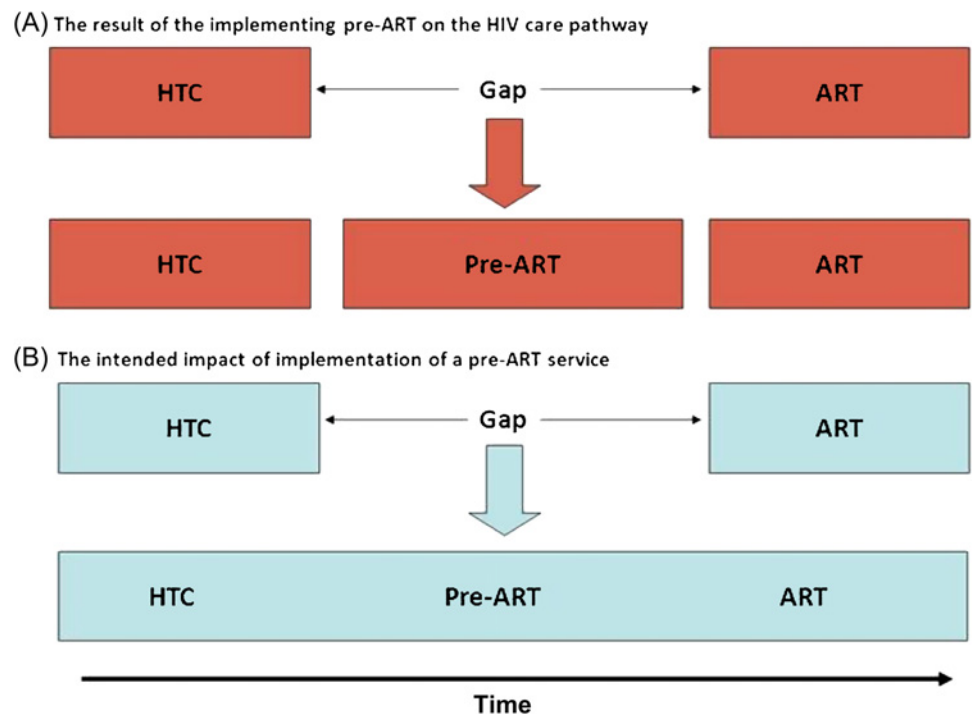


Figure 3 Flow diagram showing (A) the actual impact of pre-antiretroviral therapy (ART) implementation care pathway and (B) the intended impact. HTC, HIV testing and counselling.



Problems with monitoring, evaluating and reporting using paper-based records are well recognised as constraining HIV services in other settings.^{25–30} Separate ‘silos’ of information within the HIV programme (such as separate pre-ART registers) result in independent summaries of data about activities that are interrelated and restrict patient monitoring.

The advent and roll-out of ART in low-resource settings has resulted in a focus on drug treatment to reduce mortality.³¹ In addition, an emphasis on increasing knowledge of serostatus has aimed to detect disease earlier and enable people to access ART.³² In some areas, this has resulted in a gap in the service implementation of HIV care pathways—the link between the two.^{5, 17, 21} As testing and ART provision increase, there will be an increasing group of those with known infection who need management but not yet ART. Pre-ART services are key to managing this growing group, rather than just being a pathway to ART.

Though pre-ART has ‘filled the gap’ between, previously distinct, HIV testing and ART services, its implementation has produced a system that consists of individual service component services linked together (figure 3A), rather than a fully coherent continuum of care advocated in the literature and standardised protocols (figure 3B).^{24–26}

Decentralisation of HIV services is being implemented throughout the Lubombo region.²⁸ This may change the role of the hospital pre-ART service, as chronic HIV management is moved to primary care.²⁸ This provides the obvious next step for the service. Operational research is needed to determine the most effective way to link the hospital and primary care services and the way in which the current service will change in light of decentralisation.

CONCLUSIONS

The introduction of structured pre-ART was associated with significant improvements in the assessment, management and timeliness of initiation of treatment for patients with HIV pre-ART care provided the first step in linking HIV testing and ART services in this rural African setting. This study suggests that the introduction of a pre-ART service and consequent improved pathway has been beneficial for patients.

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Contributors SE, CM, JV, JW and JWa devised and implemented the intervention. SE and CM undertook data collection and initial evaluation. DB, WSW, JWa, JW and JWa devised the evaluation. DB and WSW undertook the evaluation and initial analysis. EP undertook the statistical analysis. DB, WSW and EP prepared the manuscript. All contributed to revising the manuscript.

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