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# Reducing Provider Workload While Preserving Patient Safety: A Randomized Control Trial Using 2-Way Texting for Postoperative Follow-up in Zimbabwe's Voluntary Medical Male Circumcision Program

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**Background:** Voluntary medical male circumcisions (MCs) are safe: the majority of men heal without complication. However, guidelines require multiple follow-up visits. In Zimbabwe, where there is high mobile phone ownership, severe health care worker shortages, and rapid MC scale up intersect, we tested a 2-way texting (2wT) intervention to reduce provider workload while safeguarding patient safety.

**Setting:** Two high-volume facilities providing MC near Harare, Zimbabwe.

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**Methods:** A prospective, unblinded, noninferiority, randomized control trial of 722 adult MC clients with cell phones randomized 1:1. 2wT clients (n = 362) responded to a daily text with in-person follow-up only if desired or an adverse event (AE) was suspected. The control group (n = 359) received routine in-person visits. All men were asked to return on postoperative day 14 for review. AEs at  $\leq$  day 14 visit and the number of in-person visits were compared between the groups.

**Results:** Cumulative AEs were identified in 0.84% [95% confidence interval (CI): 0.28 to 2.43] among routine care men as compared with 1.88% (95% CI: 0.86 to 4.03) of 2wT participants. Noninferiority cannot be ruled out (95% CI:  $-\infty$  to +2.72); however, AE rates did not differ between the groups (P = 0.32). 2wT men attended an average of 0.30 visits as compared with 1.69 visits among routine care men, a significant reduction (P < 0.001).

**Conclusions:** Although noninferiority cannot be demonstrated, increased AEs in the 2wT arm likely reflect improved AE ascertainment. 2wT serves as a proxy for active surveillance, improving the quality of MC patient care. 2wT also reduced provider workload. 2wT provides an option for men to heal safely at home, returning to care when desired or if complications arise. 2wT should be further tested to enable widespread scale-up.

**Key Words:** voluntary medical male circumcision, Zimbabwe, adverse events, active surveillance, mHealth innovation, SMS-based client-provider communication

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#### INTRODUCTION

After clinical trials found that male circumcision (MC) reduced the risk of female-to-male HIV-1 transmission by up to 60%,<sup>1–3</sup> nearly 19 million voluntary medical MC procedures were performed across 14 African countries.<sup>4</sup> MC in sub-Saharan Africa is safe and effective<sup>5–13</sup>: an adverse event (AE) rate of 2% combined moderate and severe AEs is considered acceptable as a global standard for MC safety.<sup>14–16</sup> In southern African, the average rate of reported moderate and severe AEs is approximately 0.8% (range: 0.4%–4.2%)<sup>17</sup>: 99% of men likely heal without complication.

In 2016, the United Nations set an annual target of 5 million MCs.<sup>18</sup> However, these MC expansion efforts focus on countries with severe health care worker shortages,<sup>19,20</sup> threatening already overburdened health care systems. As MC typically includes 1 or more follow-up visits within 14 days,<sup>21,22</sup> overstretched clinic staff may spend invaluable time conducting unnecessary reviews for MC clients without complications. This inefficiency negatively impacts MC clients too: men may needlessly pay for transport, miss work, and wait for unnecessary reviews.

Zimbabwe has high mobile phone ownership,<sup>23</sup> severe health care worker shortages,<sup>24</sup> and rapid scale up of MC,<sup>25</sup> making it an ideal location to test a mobile health (mHealth) intervention to reduce workload while safeguarding patient safety. Since 2013, the University of Washington's International Training and Education Center for Health (I-TECH) and its ZAZIC consortium, comprised of 3 local implementing organizations, has implemented a large-scale MC program in partnership with the Zimbabwe Ministry of Health and Child Care (MoHCC), conducting approximately 100,000 MCs annually among men aged 10 years and above with a reported AE rate of 0.4%.<sup>26,27</sup> ZAZIC MCs are performed predominantly by MoHCC clinicians, with roving support from ZAZIC clinical teams, as part of routine care. In ZAZIC sites, more than 95% of MC clients reportedly return for 2- and 7-day postoperative visits, each requiring reception, record updating, waiting, and examination. In 2017 alone, ZAZIC health care workers likely conducted up to 200,000 multistage MC reviews for men healing without complication. In ZAZIC outreach sites (outside the central health care facility), these reviews likely required multiple, multihour trips away from other routine duties.

In this context, we hypothesized that 2-way texting (2wT) using bidirectional, interactive, text-based short message service (SMS) during the initial, and most critical, 13 days after circumcision would be similar to routine, in-person follow-up for patient safety and would reduce unnecessary follow-up. Our randomized control trial had 3 aims<sup>28</sup>: (1) determine if 2-way texting (2wT) can safely reduce MC follow-up visits; (2) estimate the cost savings associated with 2wT over routine MC follow-up; and (3) assess the acceptability and feasibility of 2wT for further scale-up. If successful, 2wT would reduce provider workload and patient burden while maintaining the quality of care. This article presents the results of aim 1.

## **METHODS**

# **Trial Design**

Clients were randomized 1:1 in a prospective, unblinded, noninferiority, randomized control trial in 2 high-volume facilities providing MC to compare 2 groups of adult clients with cell phones: (1) clients who received routine care (control) and (2) those who received and responded to a daily text with in-person follow-up only if desired or if an AE was suspected (intervention). Study participants and clinic staff were not masked to treatment. This trial was registered at ClinicalTrials.gov (ID: NCT03119337) on April 18, 2017.

# Participants

Eligibility criteria were as follows: (1) men aged 18 years or older; (2) own and possess phone at enrollment; (3) provide contact details (phone, address, next of kin); (4) surgical MC; (5) willing to follow MoHCC MC protocols; (6) willing to come in day 14; (7) willing to respond to a questionnaire administered by phone 42 days after circumcision; (8) no intraoperative AE; and (9) confirmation of enrollment text.

## **Study Sites and Recruitment**

Recruitment occurred in 2 high-volume MC sites, 1 urban (Seke South) and 1 mixed rural and urban (Norton), operated by MC teams under routine MoHCC MC implementation. MC clients were recruited, informed, and, if desired, underwent informed consent by the study team at each site.

## Interventions

#### **Routine MC Care (Control Arm)**

ZAZIC follows all MoHCC protocols based on WHO guidelines<sup>21</sup> including routine surgical MC services, postoperative wound care counseling, and in-person follow-up visits on postsurgery days 2, 7, and 42 (Table 1). Patients may seek care outside scheduled visits for suspicion of AEs at any health care facility at any time but most often return to their MC site. A standardized approach is used to assess, identify, and record the severity of AEs.<sup>29</sup> All MC care, from assessment of all AEs through complete healing, is provided free by MoHCC. MoHCC policy is that clients who do not return

	Control	2T
Day 0 (day of MC)		
Routine MC registration and client intake forms	Х	Х
MC surgery and counseling	Х	Х
Study consent	Х	Х
Postoperative wound care instructions	Х	Х
Postoperative bandage removal and AE counseling		Х
In-person follow-up		
Routine day-2	Х	
Routine day-7	Х	
Study-specific day-14 (\$5 phone card provided)	Х	Х
Routine day-42	Х	
Routine LTFU tracing		
Day 2	Х	Х
Day 7	Х	Х
Daily texts days 1-13		Х
MoHCC routine AE procedures		
In-person, any day, follow-up for suspicion of AE	Х	Х
Emergency MC after-hours care	Х	Х
AE identification	Х	Х
AE severity grading	Х	Х
AE management and treatment	Х	Х
AE reporting on routine MoHCC forms	Х	Х

to the clinic for follow-up on day 2 or day 7 should be traced: 3 attempts by phone and then home visit, after which they are considered lost to follow-up (LTFU).<sup>30</sup> For the study, control arm MC clients were asked to come in on day 14 for an additional follow-up visit; control arm clients were not traced on day 14.

## MC Care Procedures (2wT Arm)

2wT men received all routine MC services (Table 1). In addition to the 5-minute, routine, postoperative care, 2wT men received an additional 10 minutes of counseling: 5 minutes on incoming texts (how to respond and ask questions) and 5 minutes on bandage removal, wound care, and AE recognition using a photo flip book showing signs of common mild or moderate AEs. Intervention men were then registered in a custom 2wT software application built using the open source Community Health Toolkit (see example app built using the Toolkit, Figure 1, Supplemental Digital Content, http://links.lww.com/QAI/ B386). 2wT clients received automated daily texts from days 1 to 13 in either English or Shona; responses were in either language. If they responded without suspicion of complication, no immediate action followed (Fig. 1). If a 2wT client responded affirmatively to any daily text with suspicion of complication, the 2wT MC nurse exchanged modifiable, scripted texts with them to determine the symptoms, frequency, and severity. Then, if deemed necessary, the client was asked to return to clinic the following day or earlier if an emergency was suspected. If 2wT patients did not respond to texts on day 2 or day 7, MoHCC tracing was activated. 2wT men were asked to return for study-specific, day-14 follow-up to review healing and verify AEs. Study-specific day-14 tracing was conducted only if there had been no client contact by day 14. Day 14 was chosen for verification because 95% of AEs within ZAZIC's MC program are reported by day 14.<sup>31</sup> The day 14 review was conducted by routine MC providers according to MoHCC review guidelines. On the day-14 visit, a \$5 cell phone credit was given to all participants to compensate for time and travel.

## Outcomes

The primary safety outcome was cumulative AE rate (moderate or severe) at  $\leq$  day 14 visit. The rates were calculated per arm as follows: (# moderate + severe AEs)/(total # who attended day 2, 7, or 14 follow-up visit). The primary workload outcome was mean follow-up visits calculated as the average number of in-person visits, not including day 14 study-specific visit. Secondary outcomes included the following: AE rates identified at day-14 visit (#AEs on day 14 visit/total # who attended day-14 follow-up visit); texting response rate; time between 2wT potential AE text and follow-up; severity of AEs. The visit date variables included the following ranges: day-2 visit included visits on days 1-4; day-7 visit included visits on days 5-10; day-14 visit include days 11-24. For day-14 visit, this range was determined to allow for minimal client delay and as a previous ZAZIC study indicated that 99% of all AEs occur on or before this postoperative day.<sup>31</sup>

To assess AE- and visit-related outcomes, all participants gave permission to use routine MC data; routine variables of interest were entered in an online database using Medic Mobile software and verified through paper and online data checks. For secondary outcomes, data on text responses and time from potential AE text and follow-up actions were ascertained from the study-specific, Medic Mobile database.

## Sample Size

Using the reported routine MC AE rate of 0.4%, the noninferiority margin was set to 1.6%, which would create a noninferiority cutoff of 2% AEs or less in the 2wT arm. Including a possible 10% LTFU, a sample of 361 participants per arm provided 90% power at an alpha of 2.5% to detect AEs greater than the noninferiority margin of  $\pm$ 1.6%. We would conclude that 2wT was non inferior if we ruled out an AE rate of greater than 2%.

## **Randomization and Masking**

Seven hundred sixty-two opaque security envelopes were randomized in 1:1 ratio. Forty additional envelopes were created to replace clients withdrawn on day 0. Site coordinators were unaware of envelope contents until the participant opened and revealed group assignment to coordinator. Study design required that participants and clinic staff were aware of allocation after assignment. Randomization affected participant intervention only after routine MC surgical procedure and recovery.

#### **Statistical Methods**

Cumulative rate of any moderate or severe AE ≤day-14 visit and AEs on day-14 visit were compared by randomized arm. P value was determined using Fisher exact test; 95% CIs for binomial proportions were calculated using Wilson score method. Farrington-Manning score method was used to calculate 95% CIs for differences in binomial proportions.<sup>32</sup> To compare follow-up visits, mean number of in-person, nonstudy visits was compared between intervention and control using a t test. Median and interquartile ranges (IQR) were calculated. Analyses were performed with Stata version 15 (StataCorp, College Station, TX) and SAS version 9.4 (SAS Institute, Inc., Cary, NC).

This study was approved by both the Medical Research Council of Zimbabwe (MRCZ) and the University of Washington Internal Review Boards. Written informed consent was obtained from all participants before enrollment.

#### RESULTS

#### **Patient Flow**

The CONSORT diagram (Fig. 2) shows participant enrollment, assignment, follow-up, and analysis. Study recruitment started on June 18, 2018 and completed on February 11, 2019; follow-up concluded on March 13, 2019.



FIGURE 1. 2wT nurse-client interactions.

## Demographics

Median age was 24 years (IQR: 19–31 years) (see Table 1, Supplemental Digital Content, http://links.lww.com/QAI/B386). The majority (82%) enrolled at Seke South, the first study site. Clients chose to receive texts more often in Shona (61%) than in English (39.0); 88% of clients used Econet mobile networks. The median daily wage was \$4.5 (IQR: \$0–\$15.0); 35% of men reported no income.

# 2wT Safety

The texting group was observed to report cumulative AEs in 1.88% (95% CI: 0.86 to 4.03) of participants, compared with 0.84% (95% CI: 0.28 to 2.43) in routine care, an increase in reported AEs within the intervention arm of 1.04% (Table 2). Overall AE rates did not differ significantly between the groups (P = 0.32). However, the 1-sided 95% CI for the difference in proportions is consistent with an increase in AE ascertainment in the texting group of up to 2.72% and therefore does not rule out an increase in cumulative AEs by day 14 of 1.6% or more, the prespecified noninferiority margin.

Comparing AE rates between the groups on the day-14 visit, there were zero AEs (95% CI: 0 to 1.20) identified among the 315 2wT participants and 1 AE (95% CI: 0.06 to 1.91) among the 293 routine men, a nonsignificant decrease of 0.34% (P = 0.48). The 1-sided CI for the difference in proportions is consistent with an increase in reported AEs in the texting group of up to 0.86% and, therefore, rules out an increase of 1.6%, the noninferiority margin. 2wT was noninferior to routine care for AEs identified on day-14 visit.

There were 25 texting clients who did not return for any in-person follow-up and were considered LTFU; 23 reported

no complications via text or phone and relatives confirmed the remaining 2 relocated.

## Workload

The texting intervention group was observed to report an average of 0.30 visits per person (median: 0) compared with 1.69 visits per person (median: 2) in the routine care group, a significant difference in means of 1.39 visits (P < 0.001) (Table 3).

There were 606 visits (median: 2; IQR: 1–2) for men in the routine arm, not including the study-specific day-14 visit (Table 3). Of men in the routine arm, 347 (97%), 235 (66%), and 293 (81.6%) came back for the day 2, 7, and 14 visit, respectively. Not including the day-14 visit, most men (62%) return for 2 in-person visits, with 31% only returning for 1. All men in the routine group returned for at least 1 postoperative in-person visit within 14 days of MC.

There were 107 visits (median: 0; IQR: 0 to 0) for men in the intervention arm, not including the studyspecific day-14 visit. There is an 85% reduction in the workload over routinely scheduled visits. Of men in the texting arm, 43 (12%), 39 (10.8%), and 315 (87%) came back for the day 2, 7, and 14 visit, respectively (Fig. 2). Not including the day-14 visit, most men (77.6%) did not return for any postoperative visits.

## **Additional Secondary Outcomes**

#### **Texting Response Rates**

Response rates were high: 285 (78.7%) responded at least once before day 2; 326 (90.0%) responded at least once by day 7; and 334 men (92.5%) responded at least once over





13 days. Only 27 clients (7.5%) never responded to daily texts; 7 of these 27 men texted the clinic at least once from a number other than their study registered number. Of the 362 2wT men, 156 (43.1%) sent at least one potential AE text over the 13 days. On an average day (see 2wT daily response

rates over time, Figure 2, Supplemental Digital Content, http://links.lww.com/QAI/B386), 56% responded with "No AE," 6% responded, "potential AE," and 38% did not respond. On day 2, 14% of men texted with a concern; fewer than 5% texted with any concern after day 7.

		(11 - 302)	- Difference in Proportions	Comparison	Superiority Comparison	
Proportion (95% CI)*	N	Proportion (95% CI)*		1-Sided 95% CI†, Difference in Proportions	2-Sided 95% CI†, Difference in Proportions	2-sided P‡
0.84% (0.28 to 2.43)	6/320	1.88% (0.86 to 4.03)	+1.04%	$-\infty$ to +2.72	-0.96 to +3.04	0.32
0.34 (0.06 to 1.91)	0/315	0 (0 to 1.20)	-0.34%	$-\infty$ to +0.86	-1.78 to +1.10	0.48
0	(95% CI)* 0.84% (0.28 to 2.43) 0.34 (0.06 to 1.91)	N         N           0.84% (0.28 to 2.43)         6/320           0.34 (0.06 to 1.91)         0/315	Proportion         Proportion           (95% CI)*         N         (95% CI)*           0.84% (0.28 to 2.43)         6/320         1.88% (0.86 to 4.03)           0.34 (0.06 to 1.91)         0/315         0 (0 to 1.20)	Proportion         Proportion         Difference in           (95% CI)*         N         (95% CI)*         Proportions           0.84% (0.28 to 2.43)         6/320         1.88% (0.86 to 4.03)         +1.04%           0.34 (0.06 to 1.91)         0/315         0 (0 to 1.20)         -0.34%	Proportion (95% CI)*Proportion ProportionsDifference in Proportions $0.84\%$ (0.28 to 2.43) $6/320$ $1.88\%$ (0.86 to 4.03) $+1.04\%$ $-\infty$ to $+2.72$ $0.34$ (0.06 to 1.91) $0/315$ 0 (0 to 1.20) $-0.34\%$ $-\infty$ to $+0.86$	Proportion       Proportion       Difference in       Difference in       Difference in       Difference in $(95\% \text{ CI})^*$ N $(95\% \text{ CI})^*$ Proportions       Proportions       Proportions $0.84\%$ (0.28 to 2.43) $6/320$ $1.88\%$ (0.86 to 4.03) $+1.04\%$ $-\infty$ to $+2.72$ $-0.96$ to $+3.04$ $0.34$ (0.06 to 1.91) $0/315$ 0 (0 to 1.20) $-0.34\%$ $-\infty$ to $+0.86$ $-1.78$ to $+1.10$

\*CIs for binomial proportions use Wilson score method.

†CIs for difference in binomial proportions use Farrington-Manning score method.

‡P-value comparing groups is by Fisher exact test.

\$Cumulative moderate and severe AEs reported from day 0 through the 14-day study visit. Includes all participants who contributed at least one visit up to and including the day-14 visit.

Participants who attended the day-14 visit after day 24 are excluded.

#### Time Between Potential AE Text and Follow-up

Of all 292 potential AE (PAE) texts received from 2wT intervention patients, the nurse filed reports for 252 interactions (86%) about patient concerns (see summary of daily text flow, Figure 3, Supplemental Digital Content, http://links.lww.com/QAI/B386): 34 (13.5%) bleeding; 81 (32.1%) pain; 44 (17.5%) pus, 46 (18.3%) wound opening; 63 (25%) swelling; 16 (0.06%) redness; and 27 (10.7%) other. Multiple symptoms could be reported per interaction. Reasons for not filling the PAE form included the following: logistical questions; PAE reported by accident; client texted later same day with no AE. For 48% of PAE texts, the nurse triaged the patient via text and did not refer for in-person review. For those referred for review, 9% did not return nor subsequently respond without concerns.

#### Severity of AEs

Overall, there were 6 moderate or severe AEs identified the texting group (3 bleeding and 3 infection) and 3 moderate

	Routine Care Arm, n = 359 (%)	Texting Arm, n = 362 (%)	Difference in Means (95% CI)	2-sided P
No. of clinic visits*	606	108		
Mean (SD)	1.69 (0.61)	0.30 (0.64)	1.39 (1.30 to 1.48)	< 0.001
Median (IQR)	2 (1 to 2)	0 (0 to 0)		
Total visits per client*				
0	9 (2.5)	281 (77.6)		
1	111 (30.9)	62 (17.1)		
2	224 (62.4)	14 (3.9)		
3	13 (3.6)	4 (1.1)		
4	2 (0.6)	0		
5	0	1 (0.28)		

or severe AEs in the routine group (2 bleeding and 1 infection) (see Table 2, Supplementary Digital Content, http://links.lww.com/QAI/B386). Mild AEs were not included in study outcomes. All AEs were related to MC.

#### DISCUSSION

Although MC follow-up via 2-way SMS between patients and providers could not be definitively shown to be noninferior, 2wT should be considered safe. 2wT identified more AEs (1.88%) than those observed in routine care (0.84%) and still falls below the globally accepted standard for MC safety of 2% AEs. Increased AE ascertainment via 2wT is consistent with improved quality of care. 2wT is also demonstrably noninferior when assessing both arms in the same way at the same time. At the day-14, in-person visit, there were no incident AEs among 2wT men and 1 incident AE among routine; there was no surplus of unidentified AEs within the texting group. The study also demonstrated reduced visit workload as compared with MC follow-up with scheduled in-person visits. By using 2-way SMS to identify men who needed or desired in-person review, 2wT enabled men without concerns to heal independently, reducing burdens on providers and patients. This follow-up method was provided largely within routine MC service delivery, suggesting advantages for MC scale-up and sustainability in the region. There are several lessons learned for replication of this follow-up approach.

2wT likely serves as a proxy for active surveillance of AEs, improving the quality of patient care. Recent active surveillance conducted by ZAZIC in both rural and periurban sites in Zimbabwe found average AE rates of 4.6%, ranging from 1% to 8%.<sup>33</sup> Therefore, we believe that the increased rate of identified AEs within the texting arm reflects improved AE ascertainment and not a true increase in AEs. Moreover, daily SMS responses from participants likely helped increase AE identification by encouraging clients to seek care when complications were suspected and by encouraging improved AE documentation. Active surveillance efforts typically lead to increases in reported AE rates: evidence from resource-intensive, patient-tracing efforts in large-scale MC programs

in Kenya found AE rates of between 4% and 18%,<sup>5,9,34</sup> higher than global AE averages. Improved AE ascertainment via 2wT was not based on active tracing but on daily reminders for men with identified concerns to return for review. Therefore, 2wT may provide a less intensive, but effective alternative, for improved surveillance efforts. In turn, this increases identification and management of AEs within a routine MC setting, a benefit for client safety.

The increased ascertainment of AEs may also be the result of enhanced postoperative counseling and daily followup, critical components of the 2wT intervention. The daily, SMS-based nurse-to-client communication throughout the period of highest risk for AEs affirmed the counseling messages and provided client reassurance. The augmented counseling also likely raised healing vigilance by providing men with bandage removal instructions, information on wound care, and photographic examples of early-stage complications. When prompted by the daily texts, men were likely better prepared to observe their wound, recognize early complication signs, and report findings via SMS. For those concerned, subsequent nurse interaction via SMS- or phonebased counseling offered reassurance and, if needed, encouraged 2wT men to return promptly for in-person visit on any postoperative day. The daily interaction provided to clients by 2wT also strengthened the continuum of care, improving MC program quality.

In theory, 2wT-based daily interactions could affect AE rates in either direction (see Table 2, Supplemental Digital Content, http://links.lww.com/QAI/B386: Type, timing, and severity of AEs). 2wT could reduce AEs by catching and managing mild AEs early, preventing some reportable moderate or severe infections. Of 9 mild AEs, 7 (78%) were among texting men between days 3 and 14 (see Table 2, Supplemental Digital Content, http://links.lww.com/QAI/ B386: Type, timing, and severity of AEs), suggesting that 2wT may encourage timely treatment. Alternatively, triaging by SMS or phone could lead to late diagnosis resulting from false reassurance and delayed care seeking. However, delays most likely increase infection severity<sup>31,33</sup>; with no severe infections in the texting group, it appears that 2wT encouraged prompt care seeking, and delays in diagnosis were unlikely to be clinically significant. In the texting group, 2 severe and 1 moderate bleeding were identified. In both severe cases, the men texted but returned before waiting for a response, indicating understanding of the instructions to return swiftly in an emergency. The client with moderate bleeding texted and returned after brief exchange with the nurse. Three 2wT men with moderate infections texted with a potential AE and returned in-person after receiving counsel from the 2wT nurse.

This study has several limitations. First, increased AE ascertainment in the texting arm was anticipated and considered a sign of quality care. However, selection of the 1.6% noninferiority margin was based on 0.4% AE rate from passive surveillance in Zimbabwe,<sup>25,26,27,31</sup> a rate that reflects sizeable AE underreporting,<sup>33</sup> muddling evidence for 2wT noninferiority. Second, the daily SMS reminder was intended to raise awareness of potential complications and encourage care seeking, likely leading to more AE identification. Third,

AEs could be underreported: men could seek care for AEs at another clinic and outcomes among men without follow-up visit are unknown. Fourth, although day-2 attendance among routine men for bandage removal was high, attendance at the day-7 visit was 65%, reaffirming previous evidence on suboptimal attendance at routine visits.6,35,36 As moderate infections were found among texting men on days 4,7, and 11, it is possible that routine group AEs were undetected during this period and resolved on their own. Fifth, the time between potential AE texts and follow-up visits could not be determined for multiple reasons, including clients sending subsequent "no AE" after "potential AE" texts; interactive messages resolving complications; and client decision to return for an in-person visit spontaneously. Finally, results could vary in other settings. Despite these limitations, we believe that the strength of these findings is indicative of the potential benefits for 2wT to improve the quality of care in routine MC settings.

## CONCLUSIONS

Although the study could not demonstrate conclusively that SMS was noninferior, 2wT appears safe for patients. 2wT ascertained and reported more AEs than routine care, suggesting that this follow-up method approximates active surveillance, improving the quality of patient care. Increased AE ascertainment was also likely attributable to improved counseling: texting men also were empowered to observe their healing and report potential complications promptly. In addition, 2-way SMS appeared to reduce the visit workload for providers and patients while maintaining quality care. For providers, reduced in-person follow-up could free health care workers to perform other duties, including additional MC surgeries. For patients, fewer visits could decrease patient costs, both economic and social, reducing a barrier to MC uptake. Implementation of 2wT within an existing MoHCC MC program structure increases the likelihood of program scalability and sustainability. As the rate of unnecessary, inperson care in both Zimbabwe and other regional MC programs is likely high, and potential gains in efficiency are large. Future research is needed to further test 2wT in diverse field (rural, urban) and patient (device-based, guardians of minor clients) contexts to better inform 2wT adaptation and replication for scale.

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