Microbicide trials for preventing HIV/AIDS in South Africa: Phase II trial participants’ experiences and psychological needs

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ABSTRACT
The Microbicide Division of the Department of Medical Microbiology at MEDUNSA, South Africa, recently completed a phase II expanded safety trial of the candidate microbicide Carraguard. A microbicide is a vaginal product that women might use, if proven safe and effective, to protect themselves from HIV and possibly other sexually transmitted infections (STIs). The study participants were from Ga-Rankuwa and its neighbouring areas, an historically disadvantaged residential township near Pretoria. We conducted six focus group discussions with phase II trial participants to evaluate their experiences with trial participation and their psychological needs. Participants spontaneously talked about their experiences with the study gel and speculum examinations. They felt that they had received high quality medical care. They indicated that their personal hygiene and knowledge of the female reproductive system, HIV and other STIs had improved, which helped their families and empowered them as women. Participants valued being able to discuss their anxiety about HIV/AIDS with study staff. They felt that the study provided them with a supportive environment in which their personal problems (not necessarily restricted to HIV/AIDS) could be addressed. Some recommended that the study staff improve their professionalism and punctuality. They suggested the formation of participant support groups, and expressed a preference to remain involved in the trial. Some participants appeared to have become dependent on services provided during the trial. We have taken the results of these focus group discussions into account during planning for a phase III efficacy trial of Carraguard to be conducted in the same and other similar communities.

Keywords: HIV prevention, South Africa, microbicide, ethical challenges in microbicide trials.
RÉSUMÉ
La Division de Microbicide du Département de Microbiologie Médicale de l’Université Médicale d’Afrique Australe, MEDUNSA, Afrique du Sud, a récemment accompli la phase II de l’épreuve de sûreté renforcée du candidat microbicide Carraguard. Un microbicide est un produit vaginal que les femmes pourraient employer, s’il est prouvé sûr et efficace, pour se protéger elles-mêmes contre le VIH et probablement d’autres infections sexuellement transmises (STIs). Les participantes à l’étude étaient de Ga-Rankuwa et de ses environs, une banlieue noire résidentielle historiquement désavantagée près de Pretoria. Nous avons conduit des discussions en six groupes d’étude avec les participantes à la phase II de l’épreuve pour évaluer leurs expériences concernant la participation à l’épreuve et leurs besoins psychologiques. Les participantes ont spontanément parlé de leurs expériences relatives aux études du gel et aux examens du speculum. Elles ont estimé qu’elles avaient reçu le soin médical de haute qualité. Elles ont indiqué que leur hygiène et connaissance personnelles du système reproducteur femelle, de VIH et de tout autre STIs s’étaient améliorées, qui ont aidé leurs familles et les ont émancipées comme femmes. Les participantes ont estimé qu’elles étaient en mesure de discuter leur inquiétude au sujet de VIH/SIDA avec le personnel de l’étude. Ils ont estimé que l’étude leur a fourni un environnement de soutien dans lequel leurs problèmes personnels (pas nécessairement limités au VIH/SIDA) pourraient être adressés. Certaines ont recommandé que le personnel d’étude améliore son professionnalisme et ponctualité. Elles ont suggéré la formation des groupes de soutien de participantes, et ont exprimé leur préférence de rester impliquées dans l’épreuve. Quelques participantes ont semblé être devenues dépendantes des services fournis pendant l’épreuve. Nous avons tenu compte des résultats de ces discussions de groupe d’étude pour la planification de la phase III de l’épreuve d’efficacité du Carraguard qui devra être conduite dans la même communauté et d’autres communautés semblables.

Mots clés: prévention de VIH, Afrique du Sud, microbicide, défis éthiques dans des épreuves de microbicide.

ARTICLE ORIGINAL

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Background
The Microbicide Division of the Department of Medical Microbiology, MEDUNSA, South Africa, recently completed a phase II expanded safety trial of the candidate microbicide Carraguard gel (Population Council, New York, USA). Carraguard is a carrageenan-based gel made from a seaweed extract. It is inserted into the vagina using a disposable, plastic applicator. If proven safe and effective, it is hoped that women can use it to protect themselves from HIV and possibly other sexually transmitted infections (STIs). This would be a significant breakthrough in HIV prevention, because many women find it difficult to negotiate condom use with their partners (van de Wijgert & Coggins, 2002).

The study participants were from Ga-Rankuwa and its neighbouring areas, a historically disadvantaged residential township next to MEDUNSA, approximately 45 km northwest of the city of Pretoria. The trial was conducted in the Ga-Rankuwa community because of its high HIV prevalence rate — 19% of women screened for the phase II trial tested HIV positive (Coetzez, Hoosen, Blanchard, de Kock, Sebola, Friedland et al., 2002). This community is therefore in need of novel HIV prevention strategies such as microbicides and HIV vaccines.

Implementing microbicide trials is challenging from both a methodological and ethical point of view (Mauck, Rosenberg, Van Damme & The International Working Group on Microbicides, 2001; Kilmarx & Paxton, 2003). For example, in addition to the microbicide being studied, researchers are ethically obliged to provide all study participants with interventions that are known to reduce HIV risk, such as condom promotion, voluntary HIV counselling and testing, safer sex counselling, and treatment of curable STIs and vaginal infections (De Zoysa, Elias & Bentley, 1998; Potts, 2000; De Zoysa, Elias & Bentley, 2000; van de Wijgert, Elias, Ellerton, McGrory, Blanchard, Friedland et al., 2000; Pollack, Pine & Beattie, 2000; Lurie & Wolfe, 2000; Stein, Meyer & Susser, 2003; Padian, 2003; Jones, van de Wijgert & Kelvin, 2003). In the phase II trial, we provided all of these services to the participants free of charge. However, the study counsellors noticed early in the
trial that many study participants were in need of more extensive psychological support, often not directly related to trial participation or HIV/AIDS. The study counsellors addressed these needs as best they could by providing support themselves or through referrals. However, while many consider providing participants with medical and psychosocial services essential, providing extensive services that are otherwise not available in the trial community may also be construed as undue inducement (CIOMS, 1993; World Medical Association, 2000; Pollack et al., 2000).

Several studies have shown that ensuring truly informed consent is challenging, particularly when working with vulnerable populations (Friedland, McGrory, Marumo, Sebola, Magwaza & de Kock, 2002; Qwana, Morar, Mantell & Ramjee, 2002; Coletti, Heagerty, Sheon, Gross, Koblin, Metzger et al., 2003). Participants often have difficulty understanding complex research concepts (such as randomisation and placebo), and ‘wishful thinking’ is common. For example in microbicide trials, participants often believe that they are receiving an active microbicide, even though the efficacy of the microbicide under study is not known, and they could have been randomised to the placebo group. Furthermore, it is not yet clear how best to involve male partners in microbicide trials without compromising the autonomy of the female participants (van de Wijgert, Khumalo-Sakutukwa, Coggins, Dube, Mwale & Padian, 1999; Coggins, Blanchard & Friedland, 2002).

To prepare for future microbicide trials in the same and similar communities close to MEDUNSA, we conducted focus group discussions with experienced phase II trial participants to further investigate these topics. This paper presents the focus group findings.

**Method and process**

**Phase II expanded safety trial of Carraguard**

We conducted a phase II, triple-blind, randomised, placebo-controlled, expanded safety trial of the candidate microbicide Carraguard at two sites in South Africa: Ga-Rankuwa near Pretoria and Gugulethu, Cape Town. Women were eligible for trial participation if they were 18 years or older, not pregnant, HIV-negative, STI-free (women had to be treated before being enrolled in the trial), planning on living in the study area for at least 1 year, not participating in any other clinical trial, and if they had no genital tract abnormality or surgery in the previous 6 weeks. They were also required to understand and agree to undergo the study procedures, including regular HIV testing and being informed of the test results, and regular gynaecological examinations. Written informed consent was obtained from all women who were eligible and agreed to participate.

In Ga-Rankuwa, a total of 200 women were recruited. Half of the women were randomised to Carraguard gel and the other half to a matching placebo, methyl cellulose gel. Women were asked to insert one applicator of study gel three times a week (with or without sex), and to use study gel with condoms every time they had sex. They were asked to visit the study clinic monthly for a minimum of 6 and a maximum of 12 months. At each study visit, they underwent HIV and safer sex counselling, a blood draw for HIV testing (quarterly), a speculum exam including sampling for a variety of reproductive tract infections, a face-to-face structured interview regarding their sexual behaviour and use of study gel and condoms, and they were given new supplies of study products. Participants regularly interacted with the following members of the phase II study staff: a receptionist, administrative staff, study coordinator, research nurses, interviewer/counsellors, and a community liaison officer. Study staff communicated with participants in the local language (Setswana) and/or English. Most of the participants could read and write.

**Focus group discussions**

We planned to conduct eight focus group discussions with randomly selected phase II participants, but we reached information saturation by the sixth group. The six groups varied in size from nine to 12 participants, and included a total of 64 of the 200 phase II trial participants. Written informed consent for the focus group discussions was obtained from each volunteer and verbally confirmed at the beginning of each discussion.

The discussions were conducted in local Setswana. Two facilitators led the discussions and two assistants audio-recorded them and took notes. The facilitators and assistants were female, local Setswana speakers, and independent from the phase II trial staff. To minimise courtesy and other biases, they had had no prior contact with the study participants or study staff. The
facilitators were senior MSc Clinical Psychology students at MEDUNSA who had experience with facilitating group discussions. The tape-recorded discussions were transcribed verbatim and translated into English.

The facilitators first explained the main objectives of the discussion to the group and then gave each participant a chance to give feedback about her trial experiences. These spontaneously mentioned experiences were recorded on a flipchart and discussed in the group. Thereafter, the facilitators continued the discussion using a semi-structured moderator’s guide, including the following main focus areas:

- In what way did you, your partner, and your relationship benefit from the study?
- What did you and your partner like and dislike about the study?
- How did you relate to study staff and what they did?
- How did you relate to study concepts, study procedures, and the study gel?
- What improvements or changes could be made?
- What did the study not cater for that you would like to be included in future studies?

We conducted a qualitative, thematic analysis of the transcripts and flipcharts.

**Results**

**Spontaneously raised topics**

Participants in one group spontaneously gave feedback about their experiences with the monthly gynaecological examinations. Their opinions about the speculum examinations varied. Some women reported experiencing discomfort when certain nurses inserted the speculum; others thought that the discomfort could be related to the participant herself being tense and anxious during the examination. Yet other women thought that the discomfort could have been the result of the wrong size speculum being used; others were not aware that the speculum came in different sizes. A few women claimed that they were never questioned about their gynaecological history during the clinical examination whereas others said that they were. This gave rise to a heated debate in the group.

In three groups, the participants spontaneously talked — with enthusiasm — about their experiences using study gel. (Note: at the time of these discussions, the women did not yet know which study gel they had used). In one of these groups, some participants felt that the gel enhanced sexual pleasure by acting as a lubricant and by facilitating contraction of vaginal muscles. Others thought that the gel tended to be messy, dripping out after insertion, making them feel wet and uncomfortable. It is not clear from the data which of these opinions about the gel predominated. Some male partners had complained about the wetness, thereby causing concern among the women that gel use might, in some cases, have a negative effect on sexual relationships. In a second group, participants said that they sometimes even stopped using study gel after their partners complained. A few women from a third group reported having had difficulty squeezing all the gel out of the applicator. They recommended that the applicator opening be widened. One woman from one of the groups thought that the gel has cleansing properties; another reported a marked reduction in menstrual pain when using study gel. The majority of women in a fourth group suggested that if the research were to be successful, they should be able to purchase the microbicide at a reduced price, because they took a risk by participating in the study.

Most participants in two of the groups spontaneously mentioned the high-quality medical care they received during the study. They thought that the care they received was much better than the care they would normally receive at local community clinics. When asked how the medical care could be further improved, some women expressed a wish for contraception to be provided at the study clinic; they indicated that they did not like going to local community clinics because they often felt judged by the clinic staff and were not given a choice of contraceptive methods. They also felt that the nature of microbicide trials called for free provision of contraception as a benefit of trial participation. Others suggested the addition of blood pressure and diabetes screening to the services provided at the study clinic, as well as a thorough clinical examination after completing study participation.

All participants spontaneously expressed appreciation about the generally positive interactions with study staff. Some participants in two of the groups thought that when presenting with a problem it would have been better if they could have consulted the same study nurse and counsellor until the problem had been
resolved. In addition, they felt that they should have been allowed to choose a counsellor without fear of offending other study staff.

Results from the guided discussions

Perceived study benefits for self and partner

During the semi-structured part of the group discussions, using the focus group guide, most participants in all groups confirmed that they felt that they had received high-quality treatment for STIs and a few other illnesses during the study. This is evident from the following quotes:

- ‘I received good medical examinations at no expense.’
- ‘I gained knowledge of my health status.’
- ‘The study provided me and my partner with effective treatment for sexually transmitted diseases.’

Most participants also indicated that their personal hygiene, awareness of femininity, and knowledge of the female reproductive system, HIV and other STIs had improved. This often resulted in improved self-esteem and self-confidence:

- ‘Using the gel and discussing female sexuality with the study clinicians and counsellors have helped me improve my personal hygiene and this has improved my self-confidence.’

Almost all of the participants in all groups thought that their sexual relationships improved during the study. They cited an increased sexual drive, easier penetration when having sex, better communication with their partners, and feeling emotionally closer to them. Several women in one group said that they experienced a sense of loss when they reached the end of the study; they felt that their partners became more distant when the study gel was no longer being used.

Most participants in all of the groups thought that their partners benefited from the study in other ways as well: they gained knowledge about condom use, learned to communicate more freely about sex, were indirectly screened for STIs, and received treatment, or referral for treatment, for STIs when necessary. Some participants felt that the study staff should provide STI treatment to all male partners at the study clinic, instead of referring some of them to local community clinics, to ensure high-quality treatment. Some participants also felt that their partners should be invited for HIV testing at the study clinic.

Most women said that their partners were supportive of them throughout the study; they would, for example, often remind them to insert study gel. However, a few participants reported problems with their partners because they experienced the study gel as messy. A few women in one group indicated that their partners would sometimes refuse to use a condom during sex because they preferred to use the study gel alone, even after they had explained the risks involved. Several women indicated that the study booklet and pamphlet helped to explain those risks to their partners. They felt that even though their partners were invited to come to the study clinic for information, better efforts should be made in the future to give male partners an opportunity to ask study staff questions.

Participant relationships with study staff

Most participants in all groups reported that the study increased their knowledge about sexual transmission, prevention, and treatment of HIV and other STIs. They stated that their anxiety and fears of HIV/AIDS were addressed, and that myths and misconceptions were clarified.

- ‘The knowledge that I gained from the study staff made me change my lifestyle — I can say no to unsafe sex.’
- ‘The study staff gave me the confidence to convince my partner to use a condom and show him its correct use.’

Many women said that they were able to pass this knowledge on to their families, friends and community members at social clubs or at church during group discussions on women’s issues, which empowered them as women. They reported improved communication about sexuality with their spouses and children. They also reported that the study provided them with a supportive environment in which their personal problems (not necessarily only related to HIV/AIDS) could be addressed.

Most participants in all of the groups said that their relationships with study staff were generally satisfactory. They experienced the study staff as supportive and even helpful with problems that were not directly related to the study. However, a few complaints surfaced as well. In four of the groups, participants indicated that some study staff sometimes appeared impatient, moody, or judgmental, and some were perceived as providing preferential treatment to certain participants. Several participants in three of the
groups were annoyed with long waiting times and delays at the study clinic. They suspected that too many appointments were scheduled, which not only caused long waiting times at the clinic, but also exhaustion of study staff.

**Participant experiences with study concepts and procedures**

The focus group results indicate that most participants had a good basic understanding of the requirements of the study, including the purpose of the informed consent process and the need to use condoms during sex. For the most part participants said they appreciated receiving repeated explanations of study concepts by study staff during study follow-up; they thought that this improved their understanding of study concepts. Generally participants in all groups understood that they were at risk for contracting HIV or other STIs when not using a condom during sex. One woman, however, admitted that she had lied about condom use during the study interviews with counsellors. She was worried at the time that she would lose study benefits if the study staff found out that she had not used condoms. A few participants in three groups had difficulty understanding the purpose and need for randomisation. Many women in one group indicated that they would like to know now that the study has been completed which study gel they had used.

**Participant recommendations for future studies**

As noted above, participants recommended the addition of a few services offered at the study clinic, including STI treatment of male partners (in the phase II trial mostly done by referral), provision of contraception, and screening for high blood pressure and diabetes. A few women indicated that they would like to choose their own counsellor and have access to this same counsellor throughout the study. However, most participants did not have a problem with interacting with different study staff members. When asked how best to address participants’ psychosocial support needs, many women from five of the groups suggested the addition of a psychologist or social worker to the study team and the formation of support groups for participants during (and even after) the study. This would enable them to share information, solve problems related to study participation, and support each other. The participants thought that these support groups should be coordinated by study staff, preferably a psychologist or social worker.

Several participants in two of the groups expressed discontent with the meal coupons that they received in order to get a free meal at MEDUNSA hospital while attending the study clinic. (Participants were given meal coupons in lieu of refreshments.) They felt stigmatised by the remarks made by cafeteria staff referring to them as ‘the coupon people’. Some participants suggested that participants be given money or grocery coupons instead of meal tickets, which they could then use to buy food for their children.

Many participants in two of the groups wished for continued involvement in the study and recommended post-study follow-up visits, such as quarterly visits to check their health. Several women felt abandoned after completing the study, particularly because they no longer received the various benefits. Some women suggested that participants who completed the study be given the opportunity to assist with recruitment for the next study; they thought that this would create jobs for the many unemployed women. They also suggested that experienced phase II participants be given the opportunity to serve in the community advisory groups (CAGs) for the upcoming phase III effectiveness trial.

**Discussion**

The focus group discussions showed that most participants generally felt that they had benefited from their participation in the Carraguard phase II trial. They talked spontaneously about their experiences with the study gel and speculum examinations, and the high-quality services they received at the study clinic. They indicated that their personal hygiene and knowledge of the female reproductive system, HIV and other STIs had improved and that this had helped their families and empowered them as women. Participants valued the opportunity to discuss their anxiety about HIV/AIDS with study staff. They felt that the study provided them with a supportive environment in which their personal problems (not necessarily restricted to HIV/AIDS only) could be addressed. However, the participants also expressed some criticism and made recommendations for improvements in future trials. These will be discussed in more detail below.

Participant opinions about the monthly speculum examinations varied and their memories about the procedure were inconsistent. The phase II trial data
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Among other things, we adapted the phase II study participant education process (Friedland improving, and expanding the informed consent and these problems in subsequent trials by evaluating, Vinckerman, Heise & Watts, 2003). We tried to address from HIV and increased risk-taking (Foss, et al., 2002). This may result in a false sense of protection needed to determine how best to minimise the wishful thinking effect and improve understanding of difficult clinical trial concepts. It may also help to better educate and inform the general public about microbicides and clinical trials.

Several participants indicated that they felt abandoned at the end of the study. They were not happy about not having access to high-quality services at the study clinic. They requested post-study support groups, continued access to medical and psychosocial services, and (paid) involvement in future trials (e.g. helping with recruitment or taking part in CAGs). The fact that most study participants were poor raises ethical questions about participants becoming dependent on study services. While everyone agrees that it is important to provide good services at study clinics, it is important to strike a balance between providing good services and encouraging study participants not to become dependent on the study clinic. This may be achieved in several ways.

Firstly, it is important to ensure that participant expectations are realistic from the outset; they should be aware that a (temporary) study clinic cannot replace community services provided by clinics and other service organisations in the long run. Even if trials are conducted at existing clinics, there has to be a limit to the services provided within the context of the trial.

Secondly, research teams could help build and strengthen services in the community, and refer participants to these community services as opposed to providing all services at a study clinic. The extent to which this is possible will depend on what services are already available in the community, the willingness and availability of local governments, service providers, and community-based organisations to cooperate with the research team, and the availability of funds (e.g. funds for strengthening services in the community could be included in trial budgets). However, too many unrealistic demands on research teams could overwhelm them, and slow down the product development process.

Thirdly, the input of the community itself is crucial.

The participants stressed the importance of study staff members’ professionalism and punctuality. Unfortunately, while microbicide trial staff are almost always trained in counselling, interviewing, and relevant medical procedures, they are often not trained in client management using a client-centred approach, clinic management, time management and/or stress management. Such training could greatly improve study staff ability to manage clients effectively. Furthermore, future clinic schedules should allow for unscheduled study visits, meetings, and trainings, and back-up study staff should be available to replace absent team members when necessary.

Although most participants seemed to have a basic understanding of the study concepts and procedures, not everyone seemed to understand the need for randomisation. Furthermore, it is not clear from our data whether we were able to adequately address the wishful thinking effect. For example, some women seemed to attribute their study gel experiences to Carraguard, even though they did not know at the time of the discussion whether they had used Carraguard or placebo gel. Other studies confirm that many clinical trial participants struggle to understand the concept of a randomised, placebo-controlled clinical trial (Featherstone & Donovan, 2002; Qwana et al., 2002, Coletti et al., 2003) and that wishful thinking is common in microbicide trials (Qwana et al., 2002). This may result in a false sense of protection from HIV and increased risk-taking (Foss, Vinckerman, Heise & Watts, 2003). We tried to address these problems in subsequent trials by evaluating, improving, and expanding the informed consent and participant education process (Friedland et al., 2002).

Among other things, we adapted the phase II study educational materials (Friedland, Marumo, de Kock, Skoler, Ngcozela, Monedi et al., 2004) for the phase III efficacy trial of Carraguard. Additional research is clearly show, for example, that women were questioned about their gynaecological history at every study visit, and yet, some participants claimed that this was not the case. Furthermore, a quantitative survey with 100 experienced phase II trial participants at the MEDUNSA site showed that when asked how often they would ideally want to have a speculum examination the majority preferred monthly examinations over bimonthly, quarterly, or biannual examinations (van de Wijgert, Jones, Pistorius, de Kock, Sebola, Friedland et al., 2002). We therefore hypothesise that the speculum examination is often not very well liked, but at the same time considered an essential part of high-quality medical care.
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Hence during 2002 we started discussions with the community in Ga-Rankuwa, Soshanguve and nearby communities by conducting a community stakeholder analysis and subsequently establishing CAGs. This process was started long before the phase III was to begin, in order to develop CAGs to be involved in the phase III trial plans.

CAGs have been established successfully, and have proven to be useful in several other microbicide trial communities (Kimlaxr, Ramjee, Kitayaporn, & Kunasol, 2001; Limpakarnjanarat, Manopaiboon, Tharawan, Kimlaxr, Korattana, Elias et al., 2000).

Finally, the establishment of participant support groups, as was suggested by the participants themselves, may also facilitate self-reliance. While study team members could help establish these groups, the groups should be encouraged to function autonomously as quickly as possible to maximise self-reliance and sustainability.

The women talked with enthusiasm about the study gels, but had mixed feelings about some aspects of the gels, particularly their lubricating properties. Quantitative acceptability data from the phase II trial show that the gels were found to be acceptable overall (Blanchard, Coetzee, Hoosen, Friedland, Sebola, de Kock et al., 2002). However, different women have different sexual needs and preferences, and this was evident in the group discussions. Several participants believed that they should have access to Carraguard at a reduced price because they participated in the study. Whether and how microbicide trial participants will benefit from the development of a safe and effective microbicide is a topic of intense debate among advocates, product developers, researchers, financial sponsors, and policymakers. However, research teams should make sure that their participants understand that it will still take many years before such a safe and effective microbicide is on the market (if ever). Furthermore, participants should understand that these complex, macro-level decisions involve many key players in different countries, and that it will not be clear for a long time which benefits — if any — specific trial communities might get.

In preparing for the large-scale phase III efficacy trial of Carraguard, the study team considered the recommendations made by the study participants. We decided to provide contraception at the study clinics. We made an effort to involve male partners by including men in the CAGs, inviting men to attend community workshops on microbicides, and organising educational workshops for male partners of trial participants. However, the study team decided that it was not logistically feasible to allow each participant to see the same study nurse and counsellor throughout the study. Furthermore, results from a quantitative survey of phase II trial participants showed that the majority of them had no problem having to interact with multiple study staff (van de Wijgert et al., 2002). To avoid future complaints about preferential treatment, the study team drafted a policy on how to handle such requests consistently.

In conclusion, the focus group discussions provided useful feedback to the study team and helped to prepare for an upcoming phase III efficacy trial of Carraguard in this community as well as other communities in South Africa.

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