PREVENTING HIV THROUGH SAFE VOLUNTARY MEDICAL MALE CIRCUMCISION FOR ADOLESCENT BOYS AND MEN IN GENERALIZED HIV EPIDEMICS

WEB ANNEX 1.1
GUIDELINE DEVELOPMENT PROCESS AND GROUPS; DECLARATIONS OF INTERESTS
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The World Health Organization (WHO) Department of Global HIV, Hepatitis and STI Programmes developed this guideline according to WHO standards and requirements for guideline development, 2nd edition, 2014 (1) and under the oversight of the WHO Guideline Review Committee. The Secretariat within the WHO Department of Global HIV, Hepatitis and STI Programmes coordinated the guideline development process, which was informed by the WHO Guideline Steering Group composed of staff members from eight WHO departments. The Steering Group provided comments on scope, PICOs, recommendations and guideline content. In determining the need for new guidance, current WHO guidance was considered (see section 6, below).

An evidence synthesis team consisting of several researchers conducted systematic reviews. Tim Farley led the reviews on the impact of voluntary medical male circumcision (VMMC) among men, women and in the community and on younger adolescents; Caitlin Kennedy led the reviews on economic compensation and service delivery approaches to enhance uptake. A consultant from the University of California San Francisco served as guideline methodologist. Other consultants undertook additional literature searches focused on other factors, such as acceptability, ethics, human rights and feasibility, to inform the making of recommendations. The WHO Secretariat selected search terms and the studies to be considered.

1. Contributors and their roles

As per WHO standard practice, three types of groups were engaged to inform the guidance:

- The Guideline Development Group provided inputs throughout the guideline development process. These inputs addressed the scope, PICO questions, review of evidence and development of recommendations according to the GRADE methodology2 as well as review and approval of the guideline. The Group consisted of 22 content experts from outside WHO who are national HIV programme managers and implementers and representatives of civil society from five regions – predominantly the African Region, given the focus of this intervention. More members were men (16) than women (six) since the intervention is for men and most urological experts are men. Some observers also participated at the guideline development meeting but not in recommendation making.

- The External Review Group was composed of individuals interested in diverse aspects of HIV prevention and male circumcision for HIV prevention, including those affected by the guideline, such as clinicians, additional field experts, programme planners and men. This group provided inputs and perspectives at specific stages of the guideline development process, including review of nearly final sections of the guidance.

- Key external partners that work with WHO on VMMC for HIV prevention also were involved, including from the United Nations Joint Programme on HIV/AIDS (UNAIDS), the United Nations Population Fund (UNFPA); donors and implementing partners such as agencies involved in the United States President’s Emergency Plan for AIDS Relief (PEPFAR): the Centers for Disease Control (HIV Prevention and Health Care Workforce), the United States Agency for International Development (USAID) and the Office of the Global AIDS Coordinator; the Global Fund; and the Bill & Melinda Gates Foundation.

- Members of the WHO Technical Advisory Group (TAG) on Innovations in Male Circumcision, which is a standing advisory group of the WHO Department of Global HIV, Hepatitis and STI Programmes, were also engaged. The TAG provides advice on technical innovations in male circumcision and reviews data from clinical studies. The TAG was represented in both the Guideline Development Group and External Review Group to ensure an accurate understanding and consideration of the TAG’s assessment and conclusions regarding devices and clinical methods.

Contributors’ declarations of interests

In accordance with the WHO handbook for guideline development, all members of the Guideline Development Group and External Review Group who were not with a specific organization completed the standard WHO Declaration of Interests (DOI) form. Guideline Development Group members completed the form prior to engagement on that group and were also instructed to let the Secretariat know of any changes to their declared interests over time. In addition, they provided their curricula vitae and their biographies (which were posted online for a minimum of two weeks for public response). The WHO Secretariat evaluated the responses for potential conflicts of interest. At the Guideline Development Group meeting, the Secretariat and Chairs (Afua Hesse, Tim Hargreave) presented a summary of the DOIs, and all participants had the opportunity to confirm, append or amend any interests already declared. One participant declared a specific interest; the Secretariat deemed this not to be a conflict.

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1 That is, questions concerning Population, Intervention, Comparator and Outcome (PICO) that define systematic reviews of evidence.
2 Grading of Recommendations, Assessment, Development and Evaluation.
A virtual consultation took place in early 2018 to obtain the inputs of the Guideline Development Group on scope and PICOs; a second took place in mid-2018; and a face-to-face meeting was held in November 2018 in Geneva discussed the evidence. Only members of the Guideline Development Group contributed to the recommendation decisions; other observers and external partners did not.

2. Scope of the guideline

The scope of the guideline took into consideration the previous WHO recommendations and the need for updates, the inputs of several WHO departments as participants in the WHO Guideline Steering Group, the Strategic and Technical Advisory Committee of the WHO department, Member States, key stakeholders and key informants, including the Guideline Development Group. Final PICO questions represented thematic areas that they considered high priority.

The first step toward development of recommendations was to develop key questions in the PICO format (Population, Intervention, Comparator and Outcome). These questions determined the primary focus of the guidance and recommendations. The PICO questions were first developed by the Secretariat and then revised and agreed by the Guideline Development Group, which also agreed on prioritization of outcomes as either “critical” or “important”. The questions and prioritized outcomes determined the evidence to be obtained.

The PICO questions were as follows:

1. Does male circumcision, compared with no circumcision, reduce the incidence of HIV infection in circumcised men, in female partners of circumcised men and in the community?
2. Among young adolescent boys (10–14 years) seeking circumcision for HIV prevention (or within public health VMMC programmes), compared with older adolescents, is offering VMMC safe and acceptable?
3. Is circumcision with selected device-based methods, when compared with other device-based or conventional surgical circumcision methods, efficacious, safe and acceptable?
4. Should economic compensation (financial or in-kind) be provided for accessing VMMC services, compared with no compensation, to increase VMMC uptake (also HIV testing)?
5. Do home- or community-based service delivery/outreach interventions (or other structural interventions) increase VMMC uptake?

The recommendations and guidance are both clinical and policy-oriented. The predominantly clinical recommendations will assist ministries, health care workers and implementers to provide VMMC safely and will enhance the confidence of all stakeholders, including adolescent boys and men, in the performance of clinical methods. Policy-makers, programme managers, donors and implementers will be able to use updated recommendations to increase VMMC uptake, to make the transition to sustainable services for adolescents and to further advocate, and direct resources into, evidence-based interventions. Key programmatic considerations for public health HIV prevention programmes are provided to share information emerging from development of the guideline. Matters concerning service packages are incorporated throughout to reflect the changed HIV landscape and the goals of universal health coverage as well as those of the WHO AA-HA! Guidance (2).

Prioritizing outcomes

A list of potential outcomes of interest was circulated among a subgroup of the Guideline Development Group and then discussed in virtual meetings with the group. Each reviewer independently scored the importance of each outcome on a scale of 1 to 9.

Then, these scores were averaged to determine the relative importance of each outcome. Outcomes considered critical were used to focus the gathering of evidence, including the systematic reviews, to inform the recommendations.

Organized by thematic area, the primary outcomes of interest are as follows. (Definitions are provided in each chapter.)

- **VMMC for HIV prevention**: Reduced incidence of HIV infection in circumcised men, in female partners of circumcised men and in the community was prioritized as “critical”. Harms and benefits and adverse events (moderate, serious or severe) also were prioritized as “critical”. The reduced risk of acquiring STIs other than HIV and high-risk HPV was prioritized as “important”.

- **adolescents ages 10–14 years**: Safety, acceptability and maintaining effective coverage of VMMC for HIV prevention were prioritized as “critical”.

- **use of devices** as alternative clinical methods: the safety of use of devices, compared with conventional surgical methods, was prioritized as a “critical” outcome, as were eligibility for circumcision by device-based methods, adequate removal of the

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1 Scores of 1 to 3 indicated an outcome considered not important; 4 to 6 indicated an outcome considered important; 7 to 9 indicated an outcome considered critical.
foreskin (efficacy) and final cosmetic result. Pain (in preparation for, during or after the procedure, while wearing or during removal of the device), healing time, procedure time, period of post-procedure sexual abstinence, return to activities of daily living, device and wound care and required visits were prioritized as “important”.

- **enhancing uptake of VMMC among men:** Uptake of VMMC by adult men (ages 18 years and older) was deemed a “critical” outcome; “important” outcomes were uptake of HIV testing within the VMMC service, uptake of safer sex education and counselling within the VMMC service and changes in community expectations with regard to compensation.

### 3. Retrieving the evidence, assessing quality, and synthesis

The WHO Secretariat formulated a comprehensive search strategy in an attempt to identify all relevant studies for each key question and outcome, without limit on the basis of language or publication status (published, unpublished, in press or in progress). Reviews not yet available in peer-reviewed journals are included in these online annexes on the WHO website.

In addition to conducting online searches in major electronic databases for relevant studies, the Secretariat commissioned literature reviews on other factors relating to evidence development: harms and benefits, values and preferences, ethics, human rights, resource use and costs. Unpublished reports on these reviews are available from WHO (write hiv-aids@who.int).

**Assessing the quality of and confidence in the evidence**

The Secretariat assessed the certainty of the evidence (that is, the extent to which one can be confident that an estimate of the effect of associations is correct), applying the GRADE methodology. With inputs from systematic reviewers and the methodologist, the Secretariat rated the quality of evidence as high, moderate, low or very low for each critical outcome (1). In keeping with the GRADE approach, evidence profiles were prepared. Evidence based on randomized controlled trials (RCTs) was classified as high quality, but the rating was downgraded if the Secretariat judged that there was a risk of bias, inconsistency of results, indirectness of evidence, imprecision or publication bias. The evidence from observational studies was initially classified as low quality, but it could be upgraded to moderate if there were, for example, very precise estimates owing to large numbers of subjects, or it could be downgraded to very low quality if the Secretariat judged that there was a risk of bias, inconsistency of results, indirectness of evidence, imprecision or publication bias.

### 4. Moving from evidence to decisions

**Other factors and evidence to develop the recommendations and considerations**

With the support of the methodologist, the Secretariat and systematic reviewers reviewed the evidence profiles, which were then shared with the Guideline Development Group.

Various factors that inform decisions on recommendations were assessed, using the evidence-to-decision framework (1). This framework calls for explicit and systematic consideration of evidence on interventions in terms of specified domains: benefits and harms, values and preferences, equity, human rights and ethics, resources required, acceptability and feasibility. The Secretariat developed draft content according to this framework for each question; these drafts were then completed during the meeting of the Guideline Development Group.

The Guideline Development Group assessed the strength of each recommendation based on:

- the quality of the evidence (that is, the degree of confidence in the findings of the studies);
- the balance between anticipated benefits and harms;
- the values and preferences\(^1\) of stakeholders affected by the recommendation;
- resource use and the cost implications of adding male circumcision devices to existing VMMC services;
- human rights, ethics and equity considerations.

All groups – the Guideline Development Group, the External Review Group and the WHO Guideline Steering Group – reviewed the recommendations.

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\(^1\) Values and preferences, defined as per the WHO handbook on guideline development, pertain to the relative importance that people assign to the outcomes associated with the intervention or exposure – not the intervention itself.
5. Producing, disseminating, implementing and evaluating the guidance

The WHO Secretariat drafted the guidance, including the recommendations, the programmatic considerations and the annexes. Draft versions of the guidance were circulated to members of the Guideline Development Group and the Steering Group and to external reviewers for structured feedback on content, accuracy, user-friendliness and any other aspects. All responses were considered in developing the final draft of the guidance. Overall, there was full consensus on the recommendations; the minimal variations in opinion were resolved in virtual small group discussions or communication.

5.1 Dissemination of the guideline

The guideline and annexes are available online in a web-based version and in PDF format for download on the WHO website (www.who.int/hiv/topics/malecircumcision) and the website of the Clearinghouse for Male Circumcision for HIV Prevention (www.malecircumcision.org). The guideline is also available in print in limited numbers. WHO is disseminating the guideline virtually, with a focus on countries in East and Southern Africa. The guideline is being sent electronically to policy-makers responsible for decisions on VMMC including decisions on resource allocation, to WHO Regional and Country offices and to programme managers, clinicians and researchers working on VMMC for HIV prevention. Print copies are available on request from WHO and at national and international conferences. WHO will support translation into Portuguese, as this is the main other language, besides English, used by countries implementing VMMC for HIV prevention. When devices are introduced into a country, one measure of the effectiveness of the guideline will be the uptake and safety of VMMC as monitored through national programmes.

In selected countries with the need to and interest in implementing the recommendations, WHO will support specific knowledge transfer (based on the specific audiences, appropriate communication materials and communication channels), adaptation activities and implementation/operations research (predominantly through technical support and follow-up). WHO will also disseminate this guideline at health professionals’ large-scale meetings (virtual and face-to-face) such as major HIV prevention, adolescent health, surgical, nursing, patient safety and behaviour change conferences.

5.2 Implementing, evaluating and updating the guideline

WHO Country Programme Officers will be contacted 12 months and 24 months after publication of the guideline to gauge utilization in-country and how any recommendations have been implemented or have influenced policy and programme decisions. The mechanisms for this contact will be determined during the guideline introduction. Webinars will be held at least every six months with relevant working groups, programme managers, key partners and implementers and other interested parties to discuss:

1. enhancing uptake of interventions through sharing of practices and determining additional barriers to be addressed;
2. lessons for and challenges to the transition to services for adolescents; and
3. safety monitoring.

The evidence-based recommendations will be reviewed again in five to seven years, or earlier if new evidence warrants. This schedule aligns with global targets set for 2025 and 2030 to ensure that recommendations are relevant for the subsequent five years.

6. Review of related guidance and recommendations on VMMC

The WHO Secretariat undertook a review of the existing WHO guidance and recommendations on the main areas of anticipated focus of the new guidance to inform the scope and reduce duplication and then sought feedback from the WHO Guideline Steering Group. Diverse guidance already existed on VMMC and to a moderate degree on adolescent boys’ health. The most relevant guidance and key recommendations are listed below.

6.1 New data on male circumcision and HIV prevention: policy and programme implications, 2007 (3)

Table A1.1 shows the 2007 conclusions and recommendations that are relevant to this guidance update. The first three items, in dark type, are the primary recommendations. The statements that are not in dark type would now be considered programme and implementation considerations.
Male circumcision should never replace other known methods of HIV prevention and should always be considered as part of a comprehensive HIV prevention package which includes: promoting delay in the onset of sexual relations, abstinence from penetrative sex and reduction in the number of sexual partners; providing and promoting correct and consistent use of male and female condoms; providing HIV testing and counselling services; and providing services for the treatment of sexually transmitted infections.

Where male circumcision is provided for minors (young boys and adolescents), there should be involvement of the child. Messages and counselling should stress that resumption of sexual relations before complete wound healing may increase the risk of acquisition of HIV infection among recently circumcised HIV-negative men and may increase the risk of HIV transmission to female partners of recently circumcised HIV-positive men. Men who undergo circumcision should abstain from sexual activity for at least six weeks after the operation. Messages should be carefully tailored, culturally sensitive, draw on local language and symbols, and be appropriate to the particular level of development and understanding of the population groups for which the messages are designed. Messages should be addressed to both men and women.

Clear messages should be developed to inform communities about what is known and what is not known about male circumcision, including lack of data on direct protection for women or for either partner during anal sex with men or women.

Countries and institutions promoting male circumcision for HIV prevention should ensure that it is promoted and delivered in a culturally appropriate manner that minimizes stigma associated with circumcision status.

Countries and international development partners should make resources available to support community and stakeholder consultations, involving traditional practitioners in places where they perform male circumcision, to ensure engagement and participation of all relevant partners in the design of safe male circumcision programmes.

The socio-cultural implications of male circumcision should be assessed at national and local levels with the participation of key stakeholders and taken into account in the design and implementation of policies and programmes.

Countries should ensure that male circumcision is provided with full adherence to medical ethics and human rights principles. Informed consent, confidentiality and absence of coercion should be assured.

Where male circumcision is provided for minors (young boys and adolescents), there should be involvement of the child in the decision-making, and the child should be given the opportunity to provide assent or consent, according to his evolving capacity. Depending on the local laws, some mature minors may be able to give independent informed consent. Parents who are responsible for providing consent, including for the circumcision of male infants, should be given sufficient information regarding the benefits and risks of the procedure in order to determine what is in the best interests of the child.

Policy-makers and programme managers should maximize the opportunity that male circumcision programmes afford for education and behaviour change communication, promoting shared sexual decision-making, gender equality and improved health of both women and men.

Countries with hyperendemic and generalized HIV epidemics and low prevalence of male circumcision should identify priority geographic settings where male circumcision is likely to have the greatest impact on the HIV epidemic and progressively expand access to safe male circumcision services within the context of ensuring universal access to comprehensive HIV prevention, treatment, care and support.

Such countries should consider scaling up access to male circumcision services as a priority for adolescents, young men and, as indicated by the local epidemiology and other considerations, older men at particularly high risk of HIV.

Countries with other HIV epidemic situations should carefully consider the potential impact that promoting male circumcision and expanding safe circumcision services will have on their HIV epidemic.

Careful monitoring and evaluation of male circumcision service delivery for possible untoward effects such as increases in unsafe and unprotected sex and increases in sexual violence should be undertaken to ensure that programmes promoting male circumcision for HIV prevention meet their desired objectives.

Male circumcision services should not be delivered in isolation, but as part of a recommended minimum package which includes information about the risks and benefits of the procedure, counselling about the need to adopt and maintain safer sex practices, access to HIV testing, condom promotion and provision, and the management of sexually transmitted infections.

Based on the current available evidence, male circumcision is not recommended for HIV-positive men as an intervention to reduce HIV transmission to women.

If medically indicated, male circumcision should be provided to all men irrespective of HIV status.

Source: WHO 2007 (3).
6.2 Male circumcision quality assurance: a guide to enhancing the safety and quality of services, 2008 (4)

This guide provides 10 standards for assuring quality of services. Standard 3 specifies: “The facility has the necessary medicines, supplies, equipment and environment for providing safe male circumcision services of good quality”. Specifically, the guidance states:

- Minor surgery is currently performed.
- Appropriate equipment for resuscitation is available.
- Staff are appropriately trained and competent or are available and willing to be trained.
- Sterilization and infection control compliance exist.

These considerations do not preclude setting up services at the primary care level, in remote settings or in mobile units.

6.3 Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men, 2018 (5)

The first edition of this clinical manual was developed at the time of the 2007 recommendations to describe how to perform circumcision in the context of HIV prevention rather than for medical reasons. It also provides guidance on related services in the minimum service package and infection prevention and control. The second edition was released in April 2018.

6.4 Guideline on the use of devices for male circumcision for HIV prevention, 2013 (6)

The key recommendation stated that:

- WHO prequalified male circumcision devices are efficacious, safe and acceptable as additional methods of male circumcision for HIV prevention among healthy men 18 years and older in high HIV prevalence, resource-limited settings.

This recommendation applies in settings where:

- the devices are used by health care workers, including physicians and mid-level clinicians, who are appropriately trained and competent in the use of the specific device; and
- surgical backup facilities and skills are available as appropriate to the specific device.

The recommendation was based on the evaluation of two specific devices – an elastic collar compression device and a collar clamp device – as sufficient data were available only on these two devices. This recommendation was considered conditional and to be reviewed when further data became available, which is now the case. Additionally, data are available on new methods and new considerations regarding methods, such as age for conventional methods.

6.5 Practice statements on method safety from the WHO Technical Advisory Group on Innovations in Male Circumcision (TAG) (7–10)

These published reports serve as background to the new guidance as well as an internal report on other issues reviewed by the TAG in 2017. WHO and PEPFAR issued safety notices on use of the forceps-guided method among young adolescents, tetanus risk with use of elastic collar compression method and urinary fistula.


The recommendation on VMMC in these guidelines is:

- VMMC is not recommended to prevent HIV transmission in sex between men, as evidence is lacking that VMMC is protective during receptive anal intercourse. Men who have sex with men may still benefit from VMMC if they also engage in vaginal sex. MSM should not be excluded from VMMC services in countries in eastern and southern Africa where VMMC is offered for HIV prevention.

An initial review of the evidence shows that there is limited new evidence of high quality on this topic, and the findings have not changed.
6.7 Guidance on communication and demand creation for VMMC


These documents provide models (social ecology model, cycle of planning, the diffusion of innovation, stages of change) and approaches and tools for use in the context of VMMC uptake. While these documents remain relevant to VMMC, the guidance is not nuanced enough and does not consider specific interventions that have been studied to date.

Other agencies, such as USAID and PEPFAR, also have published guidance on demand creation.

6.8 WHO guidance relevant to services, health interventions and programming for adolescents

References


Table A1.2. WHO Guideline Development Group declarations of interests
Meeting date: 12–16 November 2019, Johannesburg, South Africa

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A: involved in academic work related to the topic of the meeting/guideline
B: declared any commercial financial interest related to the topic of the meeting/guideline
C: declared any commercial financial interest not directly related to the topic of the meeting/guideline
D: declared non-commercial interest or grants related to the topic of the meeting/guideline

*: If the answer is “yes”, please explain.
**: Please indicate either “no” or describe to what extent the restriction was applied:
  _ excluded from the whole meeting/guideline process for guideline development meetings
  _ participation during discussions only
  _ excluded from ratification process
  _ served as external reviewer only
Table A1.3. External reviewers of the guideline

The draft guideline was shared widely, with feedback provided by the following:

<table>
<thead>
<tr>
<th>Expertise or stakeholder</th>
<th>Name</th>
<th>Institution, affiliation</th>
<th>Gender</th>
<th>Region</th>
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<tr>
<td>Programme manager</td>
<td>Cynthia CHASOKELA</td>
<td>Directorate of Nursing Services, Ministry of Health and Child Care Zimbabwe</td>
<td>F</td>
<td>African</td>
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<tr>
<td>Young person</td>
<td>Francis MUTUA</td>
<td>Dance4Life</td>
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<td>Subject matter experts</td>
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<td>Pain control</td>
<td>Anna TADDIO</td>
<td>University of Toronto</td>
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<tr>
<td>adolescent sexual/reproductive and child health and HIV prevention research</td>
<td>Nelly MUGO</td>
<td>University of Nairobi</td>
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<tr>
<td>Economist</td>
<td>Peter STEGMAN</td>
<td>Independent</td>
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<td>Demand creation, enhancing uptake</td>
<td>Elizabeth GOLD</td>
<td>John Snow International</td>
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<td>Saul JOHNSON</td>
<td>Genesis Analytics</td>
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<td>Michael KIRBY</td>
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<tr>
<td>Clinical urology</td>
<td>Ira SHARLIP (member of WHO Technical Advisory Group on Innovations in MC)</td>
<td>University of San Francisco</td>
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<td>Donors</td>
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<td>Technical support</td>
<td>Maria Augusta CARRASCO</td>
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<td>Steph DAVIS</td>
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<td>United Nations agencies</td>
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<td>Richard DELATE</td>
<td>UNFPA</td>
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