The Male Latex Condom

Specification and Guidelines for Condom Procurement

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Department of Reproductive Health and Research
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CREDITS

Design: Karen Dickerson and Erica King/Family Health International (FHI)
Production and layout: Karen Dickerson/FHI
Editorial contributions: Suzanne Fischer and Karen Dickerson/FHI
Photos (most repeated on cover): Chapter One: Richard Lord; Chapter Two: Cathryn Jirlds/FHI; Chapter Three: Alex Treml; Chapter Four: Richard Lord; Chapter Five: San Balogh/FHI; Chapter Six: Giacomo Pirozzi/UNICEF/HQ00-0104; Chapter Seven: Richard Lord; Annexes: Richard Lord

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Do you have a question or problem?
Contact our team of experts at:

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We will help you find the right answer.

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These guidelines are a result of review of the latest available evidence and an extensive consultative consensus-building process with individuals that represent the interests of manufacturing industries, the International Organization for Standardization (ISO), testing laboratories, national regulatory boards, research institutes, bulk procurement agencies, social marketing companies, international agencies and nongovernmental organizations, consumer groups, and family planning and HIV/AIDS prevention programme managers.

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FOREWORD

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that every day approximately 14,000 people become infected with the human immunodeficiency virus (HIV) that causes AIDS, and the vast majority are infected through sexual intercourse[1]. In 2002, over 40 million people were living with HIV or AIDS. Of these individuals, nearly 50% are women and one-third are between 15 and 24 years of age. The World Health Organization (WHO) estimates that globally there are 340 million preventable and curable sexually transmitted infections (STIs) annually[2]. The number of people infected with STIs grows larger every year.

Yet there is compelling evidence that male latex condoms, when used consistently and correctly, protect against unwanted pregnancy and the transmission of HIV[3]. Condoms also protect against several other STIs, although the level of protection has not been quantified for each specific STI[4]. Male latex condoms may be less effective in protecting against STIs that are transmitted by skin-to-skin contact, since the infected areas may not be covered by the condom[4].

> "There is compelling evidence that male latex condoms, when used consistently and correctly, protect against unwanted pregnancy and the transmission of HIV, the virus that causes AIDS."
>
> UNAIDS. *Making Condoms Work for HIV Prevention: Cutting Edge Perspectives*. Draft, 2004.

Promotion of condom use is an essential component of any HIV/STI prevention and care programme. Evidence confirms that the successful promotion of condom use as part of a comprehensive HIV prevention programme focused on behaviour change is effective in reducing HIV[5].

A condom is a simple, low-cost device, but it has to meet demanding performance requirements. The technology used to manufacture condoms has not changed significantly over the last ten years. However, the quality of the product has been considerably improved by better process control and more stringent standards of production.

Natural rubber latex condoms are made in large quantities (many billions per year). Rubber latex is a raw material that can be subject to variable quality depending upon a number of factors including the location of the plantation, seasonal and climatic changes, and the procedures used to concentrate the latex. The manufacturing process is complex, requiring strict process-control procedures and quality assurance measures. If the correct quality and quality control procedures are followed, the latex is converted into a condom that offers an excellent combination of thinness, strength and elasticity.

The purchase of poor-quality condoms will adversely affect every aspect of condom promotion and programming. Not only is it a waste of limited budgetary resources, but also it damages the credibility of the one inexpensive device that has been proven to prevent the transmission of HIV. It is therefore important for policy-makers, programme managers, providers, and procurement officers to know how to apply the essential elements of condom quality assurance to guarantee that a quality product is manufactured, purchased, promoted and distributed to the consumer. The same arguments apply equally to national regulatory bodies. The condom is an important medical device and needs to be regulated and controlled as such.

For more than 12 years, WHO, the United Nations Population Fund (UNFPA) and UNAIDS have taken the issue of condom quality very seriously. WHO, UNFPA and UNAIDS have worked with partners from donor, international and nongovernmental organizations; research institutions; the private sector, including the manufacturing community; testing laboratories; consumer groups; and the International Organization for Standardization (ISO) to advocate for the development of a new and rigorous quality assurance for the production, procurement

and distribution of condoms. The manufacturing community has developed improved technologies, and research has generated more awareness of the type of quality assurance systems and laboratory tests needed to ensure that a quality product is manufactured and distributed. In February 2002 the latest version of the International Standard *ISO 4074:2002* for the manufacture of the natural rubber male latex condom was published.

The *Specification and Guidelines for Condom Procurement* was first published by WHO in 1989. It has been periodically updated to provide the latest information both on the capability of the condom industry to manufacture high-quality male latex condoms and the quality assurance procedures that must be followed to manufacture, procure and promote such a product.

Establishing standards and product specifications is a dynamic process that must be responsive to the outcome of research and new information. To ensure that this document reflects the latest available information, WHO, in collaboration with Family Health International, UNFPA and UNAIDS, has:

- Commissioned a review of the literature to determine the technical basis for the male latex condom specification.
- Commissioned a review of the literature to collate the latest available evidence on the efficacy and effectiveness of the male latex condom to prevent the transmission of STIs/HIV.
- Commissioned a review of the literature on available evidence on determining whether two sizes of condoms are sufficient for all potential needs.
- Convened an Informal Technical Consultation in collaboration with the WHO Africa Regional Office (WHO/AFRO) and the Reproductive Health Research Unit, Department of Obstetrics and Gynaecology, University of the Witwatersrand, Chris Hani Baragwanath Hospital, in Soweto, Johannesburg, South Africa, in May 2002. This meeting involved 32 participants, including representatives from bulk procurement agencies; international organizations and nongovernmental agencies; manufacturers; testing laboratories; programme managers from Thailand, China, South Africa, Ghana, Nigeria and Zimbabwe; and the national bureaus of standards of Tanzania and South Africa. The purpose of the meeting was to review the 1998 WHO publication *Specification and Guidelines for Condom Procurement* against the latest available information, programmatic experience and the newly published *ISO 4074:2002* standard. A report of the meeting is available from the documentation centre of WHO, Department of Reproductive Health and Research (WHO/RHR), (e-mail: rhrpublication@who.int) and will be published on the WHO/RHR web site (http://www.WHO.int/reproductive-health).
- Convened a meeting with delegates to the International Standardization Organization Technical Committee 157 (ISO/TC/157), who were responsible for the revision and publication of *ISO 4074 — Male Natural Latex Condom*. This meeting took place during the 19th annual meeting of the delegates to the ISO/TC/157 with support from the Malaysia Board Standards and Secretariat to the ISO. The meeting was held on 12 July 2002 in Kuala Lumpur, Malaysia, and involved 67 delegates representing manufacturers, testing laboratories, scientists and consumer groups from 19 countries. The purpose of this meeting was to review and receive comments on the revised *Model Specification* for the male latex condom in order to foster consensus and commitment to support the use of the *Model Specification* and recommended procurement procedures.
- Conducted an external review of the revised *The Male Latex Condom — Specification and Guidelines for Condom Procurement* between January and March 2003. The document was sent to 120 reviewers who represent the interests of bulk procurement agencies, international organizations and nongovernmental agencies, manufacturers, testing laboratories and programme managers. The response rate was 60%. Comments

were collated and reviewed by a small team of technical experts prior to undertaking the final revision of this document.

- Reviewed the *Model Specification* in June 2003 against the conclusions and recommendations made at the 20th annual meeting of delegates to the ISO/TC/157, who were responsible for the revision and publication of *ISO 4074 — Male Natural Latex Condom*, in Denver, Colorado, June 2003.

The Male Latex Condom — Specification and Guidelines for Condom Procurement is designed to provide a set of purchase specifications and procurement guidelines that ensures the highest level of safety consistent with high-volume purchases, the needs of different populations, harsh environmental conditions and the probability of less than ideal storage conditions. It is a guide to help policy-makers, and procurement and programme managers make the right decisions to procure, distribute and promote a quality product.

UNFPA will also publish jointly with WHO a complementary manual: *Condom Programming for HIV Prevention — An Operations Manual for Programme Managers*. This manual is designed to give programme managers a practical and specific seven-step approach to improve the effectiveness of existing condom programmes or create a new condom programme. An essential step in this process is obviously the logistics management cycle. The operations manual refers to the logistic management after condoms have been procured and arrive in-country. *The Male Latex Condom — Specification and Guidelines for Condom Procurement* details the application of the quality assurance measures required to manufacture, procure and receive in-country quality condoms.

To request documents, contact the Help-Line (HELPLINEcondomquality@fhi.org) or:

World Health Organization
Documentation Centre
Department of Reproductive Health and Research
Avenue Appia
CH-1211 Geneva 27
Switzerland
lamberts@who.int

This document will be available on the Web (http://www.WHO.int/reproductive-health) in early 2004.

Family Health International
P.O. Box 13950

WHO has worked with many partners to generate the evidence and gain the consensus needed to recommend these procedures. The importance of following these guidelines cannot be overemphasized, as it addresses the issues related to the performance of condoms, the comfort