



WHO



UNAIDS

# The Male Latex Condom

## 10 Condom Programming Fact Sheets

Programming  
Fact Sheets



*Family Planning and Population  
Reproductive Health Technical Support*

# Fact Sheets Introduction



Photo: ISI



## Introduction

### Fact Sheets on the Male Natural Rubber Latex Condom

One of the most practical and effective means of preventing unwanted pregnancies and the transmission of sexually transmitted diseases (STDs) is the familiar male natural rubber latex condom. The evidence suggests that, if used consistently and correctly, the latex male condom is:

- an effective contraceptive which does not have systemic side-effects;
- an effective means of protection against STDs, including the human immunodeficiency virus (HIV), that causes AIDS.

Therefore, natural rubber latex condoms are of prime importance in the fight to stop the spread of AIDS.

The dissemination of evidence regarding the efficacy of condoms can be used to promote the use of condoms both as a contraceptive method and as a barrier against the transmission of STDs, including HIV.

WHO and UNAIDS have developed this series of fact sheets to summarize the latest scientific evidence, basic concepts and best practices in key areas of condom programming.

The fact sheets cover:

- 1 Scientific facts on the male natural rubber latex condom
- 2 Condom programming
- 3 Condom quality assurance
- 4 Condom promotion
- 5 Logistics management
- 6 Research
- 7 Improving staff performance
- 8 Social marketing of condoms
- 9 Male and female synthetic condoms
- 10 Bibliography and further resources

The fact sheets:

- address the major areas of condom

programming and provide references to sources of further and more detailed information;

- provide a source of basic information on the key elements of condom programming for reproductive health, family planning and STD/HIV prevention for policy-makers, programme managers and service providers in both governmental and nongovernmental programmes.

The fact sheets can be used as a basis for:

- generating a higher level of confidence in promoting condom use;
- developing higher levels of competence in the major areas of condom programming;
- gaining commitment to and financial resources for condom programming among policy-makers and donors;
- improving ongoing condom programmes;
- increasing public awareness of the effectiveness of condoms when used to prevent unwanted pregnancy and the transmission of STDs/HIV.

For more detailed information on all aspects of condom quality, research, specifications, procurement, distribution and programming, refer to:

- WHO Specification and Guidelines for Condom Procurement.
- Monograph: *The Latex Condom*.
- Fact Sheets, Bibliography and further resources.
- The three “Best Practice” documents of UNAIDS.



# Fact Sheet 1

## Scientific Facts on the Male Natural Rubber Latex Condom



Learning about condoms

*Photo: WHO*

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# The Male Latex Condom – Fact Sheet 1

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# 1. Scientific Facts on the Male Natural Rubber Latex Condom

## The condom

A male condom is a sheath worn on the erect penis to prevent the exchange of body fluids during sexual intercourse. The use of a sheath to prevent pregnancy has been an established practice for many years and reference to the use of condoms for pregnancy prevention dates back to the 16th century.

With the emergence of the AIDS pandemic in the last decade, the use of condoms has taken on a new significance. It is a fact that:

- Anyone who engages in sexual activity is at risk of contracting the human immunodeficiency virus (HIV), that causes AIDS, except when one is in a monogamous relationship with an uninfected partner.
- Throughout the world 75–80% of HIV infections in adults have been transmitted through unprotected sexual intercourse.
- HIV is more likely to be transmitted when either or both partners have, or have had, a sexually transmitted disease (STD).
- The World Health Organization (WHO) estimates that 340 million new cases of curable STDs occur annually.
- The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that by the year 2000 approximately 40 million people worldwide will be infected with HIV, the virus that causes AIDS.

A substantial body of evidence exists to support the claim that natural rubber latex condoms, when used consistently and correctly, can protect against unwanted pregnancy and STDs, including HIV.

Carefully monitored studies have demonstrated that consistent and correct use of condoms is an effective means of protecting users and their partners against unplanned pregnancy and STDs, including the human immunodeficiency virus (HIV), the virus that causes AIDS.

## What types of condoms are available?

Until recently, latex rubber condoms and the less popular lambskin condoms were the only types of condom on the market.

However, in the last three years the development and marketing of non-latex synthetic male and female condoms have marked the beginning of a new generation of condoms.

At present many of these new products are still at the design stage and it will be a number of years before synthetic condoms are marketed at a price that is competitive with that of latex rubber condoms. (For more information on synthetic condoms, refer to Fact Sheet 9).

## The male natural rubber latex condom

The modern natural rubber latex condom is based on technology developed in the 1930s. The fundamentals of the technology have changed little, but latex condoms now being produced by most reputable manufacturers are generally of very high quality. Apart from technological advances in the manufacturing process, manufacturers have continued to improve their product in order to increase acceptability by:

- developing a wide range of design modifications;



- responding to the growing body of research on a wide range of issues related to the quality of condom production.

Currently, condoms that are manufactured in accordance with international standards, and are packaged and stored correctly, will if used consistently and correctly substantially reduce the risk of unwanted pregnancy and/or the transmission of STDs/HIV.

Laboratory studies confirm that intact latex condoms form an effective impermeable barrier to spermatozoa and pathogens, including HIV, herpes virus, hepatitis B virus, cytomegalovirus, gonorrhoea, and chlamydia trachomatis.

The technology to produce high-quality condoms exists, but there can be dramatic variations in the quality of condoms produced by different manufacturers. To avoid buying poor-quality condoms, WHO recommends that the purchaser follows the quality assurance measures detailed in the *WHO Specification and Guidelines for Condom Procurement*.

## How effective is the male latex rubber condom?

Numerous epidemiological and clinical studies have been conducted on the risk of STD transmission in condom users. Most are conclusive that consistent use reduces considerably the risk of STD/HIV transmission.

For example, in Thailand, the promotion by the government of 100% condom use by commercial sex workers led to a dramatic increase in the use of condoms from 14% in 1989 to 94% in 1994, and an equally dramatic decline in the nationwide numbers of bacterial STD cases (from 410,406 cases in 1987 to 29,362 cases in 1994).

The most convincing data on the effectiveness of condoms in preventing HIV infection has been generated by prospective studies undertaken on serodiscordant couples, when one partner is infected with HIV and the other is not. With regular sexual intercourse over a period of two years, partners who consistently used condoms had a near zero risk of HIV, whilst inconsistent use carried considerable risk averaging 14–21% (an incidence of 4.8–5.4 per 100 person years).

Studies have also confirmed that consistent and correct use of condoms is the most important factor in preventing pregnancy.

In general, the failure rate for perfect use (i.e. a condom used correctly at every act of intercourse) is approximately 3%, and for typical use (condoms not used for every act of intercourse) the failure rate is 12%.

Carefully monitored studies have demonstrated conclusively that:

- consistent and correct condom use prevents STD/HIV infections.
- latex condoms which have been appropriately tested are effective barriers to spermatozoa and pathogens.

## Effectiveness – the Clinical Evidence

The reasons for the technological improvement in manufacturing condoms are several, but clearly the most prominent is the threat of AIDS. As a contraceptive, the condom did not command a great deal of scientific attention. In the past, the condom has generally been relegated to a secondary role in most family planning programmes despite documentation of a high level of efficacy among experienced users. When it became clear that HIV was transmitted sexually, and public recommendations of condom use for protection were being widely made, the scientific community renewed its interest in condoms.

### Condom breakage

A large number of studies on condom breakage report rates that vary from less than 1% to more than 10%. The wide variation in breakage rates is attributable to variations across studies with respect to both condom characteristics (e.g. old condoms are more likely to break than new ones) and user characteristics (e.g. less experienced users break condoms more frequently).

One serious problem with many such studies is that they too often studied either the characteristics of the condoms used or the characteristics of the population using them. Rarely were both factors studied simultaneously. More recently, studies have addressed both factors and demonstrate conclusively that the characteristics of the population using the condom affect significantly the rate of breakage reported.

It is a fact that:

- poor-quality condoms break more frequently than condoms that pass recognized standards of manufacture;

- younger and less experienced users break condoms more frequently than do those who have learned to use condoms properly.

There seems to be no single answer for the rate of condom breakage: it depends on who is using which condoms.

### Condom slippage

The choice of width of condoms is important because this is one of the main factors in determining whether the condom is easy to put on, stays on during use, and is comfortable to the user. The dimensions of the condom need to conform to the intended population of users. There are considerable variations between individuals and, generally, there is no established market of differently sized condoms even in developed countries. The sizes most commonly marketed are 49 mm and 53 mm.

In general terms, condom sizes are classified as either *wide* or *narrow*. This classification is based on studies in Australia, Thailand and the USA, and on the experience of major agencies. The wider condoms (flat width 51–54 mm) will be preferred in Africa, Europe, Latin America, the Middle East and North America, and the narrower condoms (47–50 mm) are preferred in several Asian countries.

In recent years, condom manufacturers have learned how to make condoms thinner to increase sensation and comfort without increasing the risk of breakage. The general principle is, however, the thinner the condom, the smaller the force required to break it.

It is important for programmes to determine and monitor consumer design preferences since a condom of the wrong size and thickness will not be acceptable. This will contribute to both method failure and user failure.

## Human behaviour

One finding from several studies carried out by Family Health International (FHI), and other studies on social marketing programmes, is that breakage is not randomly distributed through a study population. That is, some couples account for a disproportionately large fraction of the breakage reported. The implication of this finding is that what “risk” there may be in using condoms is greatest for a relatively few “breakers”.

Further, in the various studies it has been possible to isolate these couples and interview them to identify certain behavioural patterns that are linked to condom breakage. For example, men who have experienced problems with condoms are twice as likely to experience similar problems in the future, and the more inexperienced the user the higher the probability of improper use such as:

- using the same condom twice;
- unrolling the condom before putting it on;
- withdrawing to put the condom on after starting intercourse;
- using a condom inside out;
- using oil-based lubricants;
- opening the packet with sharp nails or scissors.

Given the difficulty in communicating complex or lengthy messages to the public, it is likely that messages directed at factors identified as leading to breakage, such as these, will be more effective than detailed instructions aimed at all factors that might lead to failure.

## Condoms lubricated with spermicides

There is evidence to suggest that the use of spermicidal lubricants in condoms is inappropriate for the following reasons:

- There is no evidence that current surfactant spermicides improve the effectiveness of condoms.
- Spermicides can cause irritation of mucous membranes, which may reduce acceptability and increase the risk of infection.
- Most spermicidal lubricants will dry up when exposed to air. Therefore, they are exceptionally dependent upon package integrity.
- Shelf-life of condoms with spermicidal lubricant is limited by the shelf-life of the spermicide.
- Evidence suggests that surfactant spermicides weaken the integrity of condom package seals.

## Lubricants

The lubricant applied to lubricated condoms during manufacture is sufficient for most users. Some people, especially those participating in prolonged vaginal intercourse or in anal sex, require additional lubricant which can be applied as needed.

If the user applies lubricants to the condom, the choice of substance used is of critical concern. There have been many cases of ordinary household products being used as lubricants, and the majority of these have a highly damaging

effect on the condom. Indeed, most of them cause deterioration in the properties of the latex within minutes. Even some products that are marketed for use in the vagina such as medication for yeast infections have a deleterious effect on latex and should be avoided, if possible.

A number of water-based lubricants, such as KY jelly, are completely harmless to condoms. These are available on the market and it is strongly recommended that only these specialised products be used when separate or additional lubricant is required.

*The following household products have been used as sexual lubricants. They have a highly deleterious effect on latex and should on no account be used in conjunction with a condom:*

mineral oils	baby oils	petroleum jelly
suntan oils	edible (cooking) oil	palm oil
margarine	coconut oil	dairy butter
coconut butter	fish oil	insect repellents
burn ointments	haemorrhoid ointment	rubbing alcohol

**DO NOT USE THESE PRODUCTS TO LUBRICATE CONDOMS**

## Reliability

### Research into condom quality

A wide research programme was initiated in the mid-1980s, much of it funded by WHO, and US Agency for International Development (USAID).

Standards organizations, the bodies that provide technical definitions of products manufactured or distributed within their jurisdictions, such as the International Organization for Standardization (ISO), WHO and the American Society for Testing and Materials (ASTM), became the centres of hotly debated ideas about more stringent quality control demands on the condom as a life-saving medical device.

For the first time, research institutes began studying the relationship between the laboratory testing of condoms and their performance in use and behavioural research to determine barriers and inhibitions in use.

### Product stability

The Program for Appropriate Technology in Health (PATH) examined the physical properties of latex condoms and demonstrated, among other things, that the product was measurably weakened by oxidation over time but that silicone lubrication provides some protection against this process.

Moreover, if the condom is isolated from the air by means of impermeable, hermetically sealed aluminium foil packaging and further protected against possible package damage by silicone lubricant and antioxidant properties within the formulated latex, the well made condom will withstand all likely environmental extremes for many years.

Heat was also shown to degrade latex properties, probably through the propagation of vulcanizing cross-links among the latex molecules, leading to a more brittle and breakable product. PATH has, however, demonstrated that the accumulated heat, or the caloric load, required to generate this process is comfortably beyond that generated by the average temperatures ordinarily found even in tropical countries.

It would be difficult to overstate the significance of this carefully executed and widely reviewed research. It continues to be the case that expiration dates for newly manufactured condoms are not easily determined.

This study, however, has raised the level of confidence to the point that routine testing of stored condoms, even in the tropics, is no longer recommended as a critical component of quality assurance. It should still be undertaken at periodic intervals, particularly if there is any sign of deterioration in the packaging or when condoms have been stored for over three years.

### Shelf-life and expiry date

*This edition of the WHO Specification is the first to include a requirement for shelf-life and expiry date.* Eventually, a claimed shelf-life will have to be supported by real-time stability studies conducted under temperatures that represent the severest average conditions likely to be encountered during storage and distribution.

While some manufacturers already have such data, it is not yet universal, and all manufacturers are encouraged to commence real time stability testing on their products. This involves storing several lots of condoms at 35° C over the full intended shelf-life, and periodically doing inflation tests on a suitable sub-sample. For



example, 30 to 50 condoms could be tested every 6 months. In this way the rate of deterioration of physical properties can be established. Compliance with the inflation requirements for new condoms at the end of the shelf-life is also required.

As an interim measure, WHO will accept accelerated ageing tests conducted at higher temperatures for shorter times, as an indication of shelf-life. The manufacturer may present any suitable data available, plus the rationale used to infer the claimed shelf-life.

## Condom leakage

The fact remains that condoms are not perfect and that failures do occur. At the same time, more has been learned about the problem of leakage, and even here confidence about condoms has risen.

Multiple studies have demonstrated that properly manufactured and appropriately tested latex condoms are impermeable to semen and to all pathogens of relevant size.

It is a fact that if condoms are tested in accordance with the criteria established by the major standards organizations and WHO there will be little if any threat of unwanted pregnancy or infection through leakage.

## Latex allergies

Latex protein sensitization became an issue in the early 1990s, mainly in connection with the increased use of rubber latex gloves and latex medical devices. Latex allergies are considered very rare among the general population (0.08%) and tend in the majority of cases to be rather mild.

Allergies generally occur in children and

adults repeatedly and continuously exposed to latex products such as, gloves, multiple operations and medical procedures. Persons who are aware that they have a latex allergy should use non-latex condoms.

## Quality management

To achieve high quality, condoms must be well designed and formulated, and carefully made. To maintain that quality until the condom is supplied to the user, storage and distribution systems need to be effective. Both the manufacturer and the large-volume purchaser should develop and maintain a quality management programme to establish the procedures, structures and record-keeping necessary for effective and sustainable quality management. A well designed factory and product, together with an effective top-down quality management system, form the foundation for consistent quality over the long term.

## International Organization for Standardization (ISO)

The ISO has created a number of model standards for quality management. Perhaps the best known is the internationally recognized ISO 9000 series of standards which prescribes in great detail the documentation, procedures and structures to be followed in factories to facilitate the production of a consistent standard in the output of services and products.

The systems of quality management, generally known as “good manufacturing practice” (GMP) can be used by most factories regardless of the product and are audited by regulatory bodies. Other ISO quality management guidelines are ISO 13485 and ISO 13488 are intended to be versions of ISO 9001 and ISO 9002 applied specifically to medical devices. Europe uses EN

46001 and EN 46002, which are very similar to ISO 13485 and 13488. The USA uses its own code of GMP, with slightly different emphasis from the ISO requirements.

WHO suggests that purchasers should not rely unduly on certification of GMP to ensure that condoms supplied are of high quality and meet the required specification. The proof of the technical competence also involves evidence of appropriate design and the verification of consistent compliance with performance requirements of standards and specifications as detailed in the *WHO Specification and Guidelines for Condom Procurement*.

The international basis for condom standards is provided by ISO 4074 - Rubber Condoms. This document is drafted by a technical committee (ISO TC 157) and is currently under extensive revision. Many of the product tests prescribed by WHO in the *Specification and Guidelines for Condom Procurement* are derived from ISO 4074.

## National regulatory authorities

National regulatory authorities such as United States Food and Drug Administration (USFDA) and other key agencies control GMP and end-product condom standards in many developed countries.

The Medical Device Directive, adopted by all European Union countries and Switzerland, requires conformance with the European CEN standard for condoms, and with EN 46001 or 46002, from June 1998. Compliance with the European requirements at factory level is assessed by a series of so-called notified bodies, appointed by each member nation.

Regulatory agencies license drugs and medical devices for use in the country or region, carry out audits and test products. They may adopt standards issued by standards authorities and make them mandatory. They generally have the authority to recall products and close factories in the event of continued non-compliance with their regulations.

Drug controllers, AIDS prevention authorities and ministries of health are beginning to take on a similar role in developing countries. A number of these authorities have based their standards on the *WHO Specification*, and several are actively participating in the drafting of the new ISO condom standard 4074.

## What is meant by a standard?

Safety and efficacy standards are published by national or international regulatory authorities or standards bodies to establish a minimum level of quality for products (e.g. condoms) that are made or imported, and sold, within a particular country or region.

A standard is concerned primarily with safety, security and efficacy and usually covers only essential performance attributes that should not be compromised. A standard is not concerned with the special requirements of individual buyers but with the quality of the product that is produced.

Design features that are a matter of choice and discretion (e.g. colour) will not normally figure in a standard (except perhaps to stipulate that any pigment used must be non-toxic and non-irritant). Standards also provide consensus on the procedures and protocols to use when carrying out basic tests for quality verification.

The principal international standards authority is the ISO, a worldwide federation of national standards bodies responsible for drafting international standards for manufactured products based on the best available evidence.

## What is a specification?

A specification is a statement of a buyer's requirements, and will cover all attributes and features of the product, both the essential, general and performance requirements and the discretionary design requirements. A specification may contain within it some or all of a standard as its essential performance requirement.

## The WHO Specification and Guidelines for Condom Procurement

The *WHO Specification and Guidelines for Condom Procurement* (published jointly by WHO and UNAIDS) translates the scientific evidence used by ISO as the basis for establishing manufacturing standards into a step-by-step guide for programme managers and procurement officers. It describes how to develop a specification and follow quality assurance procedures to procure high quality condoms.

The *WHO Specification and Guidelines for Condom Procurement* suggests that purchasers should not rely unduly on GMP certification to ensure that condoms supplied are of high quality and meet specifications. The technical competence of the manufacturer should always be verified by

incorporating into the procurement process a system to pre-qualify suppliers prior to awarding a contract and lot-by-lot compliance testing prior to purchasing a consignment of condoms.

This ensures that quality assurance measures are incorporated into the procurement process. Pre-qualification, before or during the tendering process, assesses the capability of the manufacturer to produce good quality condoms. Lot by lot compliance testing assesses the quality of the product before accepting the shipment of condoms from the manufacturer.

## Laboratory testing of condoms

Third-party test laboratories play an important role in providing objective testing of condoms for pre-qualification of suppliers and for lot-by-lot compliance testing prior to delivery. Some also provide other quality management services, including diagnosis of quality problems, GMP training and review, inter-laboratory comparison of test equipment, procedures, and stability trials. Other organizations provide independent sampling services, travelling to the manufacturer's factory or warehouse to take random samples for testing.

## The quality of laboratory testing

In choosing a testing laboratory, purchasers should give due weight to whether or not a candidate laboratory participates in voluntary inter-laboratory trials.

Inter-laboratory comparison of condom test laboratories is an important service that has come into existence in recent years. It helps to ensure that the measurements made by the manufacturer, regulatory authority and test laboratory are compatible, and contributes to avoiding disputes due to measurement differences or errors. The



laboratory should also be part of an internationally recognized laboratory accreditation scheme. This scheme is similar to the GMP certification offered according to ISO 9000, with the additional requirement of a technical review by an experienced independent technical auditor of the competence of the laboratory staff, and efficacy of the equipment and procedures.

# Fact Sheet 2

## Condom Programming



Photo: WHO



## 2. Condom Programming

### Condom programming and programme management

Condom programming identifies the key activities required to ensure successful and effective procurement, promotion and delivery of high quality condoms.

Managers of programmes for reproductive health care, family planning, STD/HIV prevention and social marketing can use the principle of condom programming to plan and implement the support activities required to link condom supply with demand.

### Strengthening policy

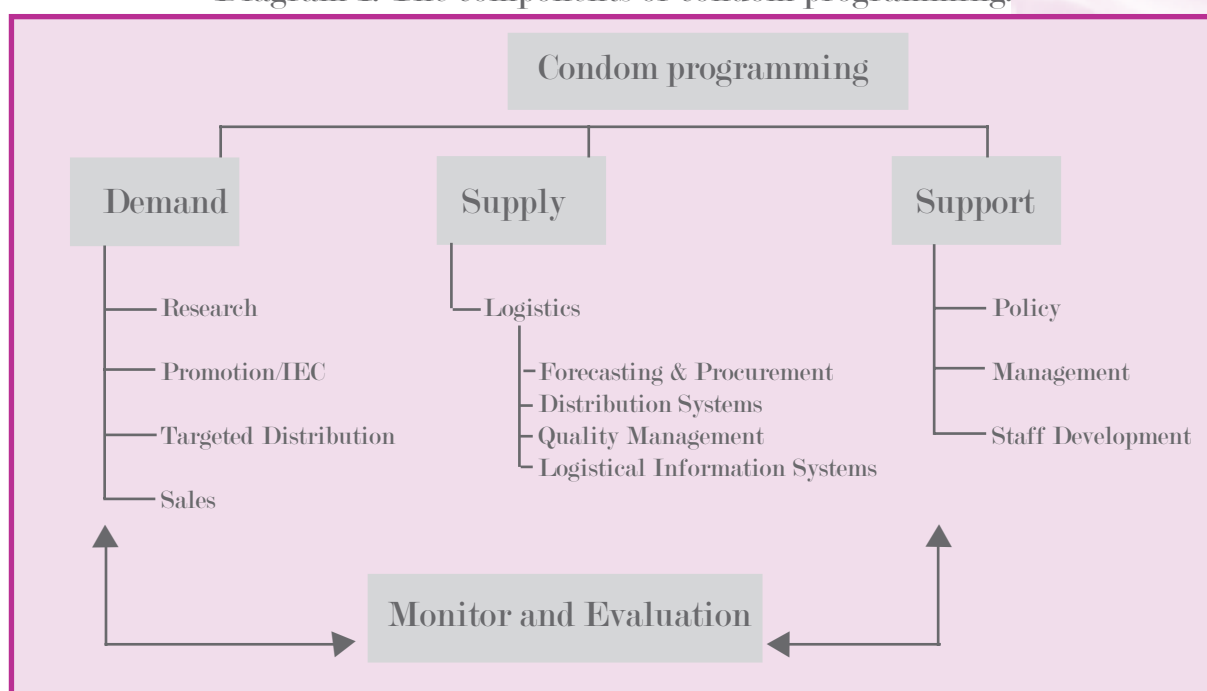
Condom programming requires the full support of policy-makers. Policy-makers must have a proper understanding of the important reproductive health care benefits provided by good quality condoms in preventing both unwanted pregnancy and the transmission of STDs/HIV/

AIDS. To gain this support, policy-makers must be convinced that condom programming can successfully ensure the equitable distribution of accessible, affordable high-quality condoms.

If policy-makers are convinced, they will:

- advocate the inclusion of condom programming in all planned reproductive health care interventions;
- advocate reduction of the impact of laws and regulations on condom use;
- obtain support from political, religious and community leaders to promote the use of condoms;
- influence public opinion and overcome political or cultural barriers to promoting condom use;
- allocate sufficient resources to support each component of condom programming.

Diagram 1: The components of condom programming.



### Programme managers

Programme managers need to use all available sources of information to campaign strongly for the inclusion of condom programming activities in all planned reproductive health care interventions.

The programme manager will have overall responsibility for developing and implementing the condom programming strategy. This will mean coordinating the development of a workplan that includes the following components:

#### *Research*

It is important to distinguish between research that is done to assist the planning of a new or revised programme and the research that is required to assess the effect of the programme when it is running.

The research that is carried out as part of planning the programme will seek answers to questions about potential suppliers, consumers, their environments and the key indicators to be used in monitoring programme performance. In contrast, the activities carried out to monitor progress and evaluate impact during programme implementation will collect regular information for tracking performance by using indicators established by the programme. Thus, prior research is important not only for programme planning but also for subsequent programme monitoring.

It is important for a manager to know whether the right promotional messages are reaching the right people at the right time, and whether these messages are effective in motivating people to seek the dual protection offered by condoms. It is equally important to know whether the distribution system is functioning well at all levels and whether condoms are easily accessible

to the target population. A professional research firm may be called in to undertake such assessments but the programme management must be able to commission the work, brief the consultants and, sometimes, conduct small-scale *ad hoc* research studies using internal resources. In addition, the programme manager must be able to interpret the research results and plan future actions based on them (refer to Fact Sheet 6 on Research).

#### *Identifying target populations*

Although large portions of any population may be at risk of unwanted pregnancy and/or STDs/HIV, some individuals and groups, on account of their age, marital status, geographical location and sexual behaviour, are at greater risk than others. Programme managers must be able to identify the various target groups in order to design appropriate promotional campaigns and distribution infrastructures to reach different people in the most cost-effective way (refer to Fact Sheet 4 on Promotion and Fact Sheet 8 on Social Marketing).

#### *Planning promotion*

The effectiveness of promotion in a condom programme depends on the appropriateness of the messages promoted and of the media through which they are transmitted. Although professional assistance may be used for parts of the campaign, it is often the programme manager's responsibility to decide on both the form and the detail of the promotion (refer to Fact Sheet 4 on Condom Promotion).

#### *Planning distribution*

No matter how powerful the promotion, the programme will not be effective without a well functioning infrastructure for the supply and distribution of good-quality condoms. Condoms

will simply not reach the target populations. The programme manager must ensure that all elements of the distribution network are used to meet the needs of all the populations at risk (refer to Fact Sheet 8 on Condom Social Marketing and Fact Sheet 5 on Logistics).

### *Projecting future requirements*

Possibly the most difficult task facing a programme manager, especially in the early days of the programme, is to estimate the quantity of condoms that will be required. This estimate must be made since the whole procurement operation depends on it. Early projections may turn out to be very different from actual demand, but as managers become more experienced and better able to evaluate the effect of promotion on condom uptake they will be able to forecast requirements more accurately and for longer periods. It is advisable for all programme managers to have some training in logistics management, particularly forecasting requirements, establishing inventory control systems, and carrying out quality assurance measures throughout the distribution chain (refer to Fact Sheet 5 on Logistics).

### *Procurement*

Managers must be aware not only of the standards and specifications required for purchasing good-quality condoms, but also of the procurement and quality assurance procedures for the production, procurement and distribution of condoms (refer to the *WHO Specification and Guidelines for Condom Procurement*).

Four different methods can be used to purchase condoms and the method selected will depend on the needs of the particular programme. Managers often fail to consider the time factor involved in procuring condoms and this can result

in a shortage of supply. The procurement of condoms has to be planned well in advance of requirements. An estimate of the average time-frame required to procure condoms is 8–12 months.

### *Evaluation of logistics*

In a well-run programme, management must be concerned to keep the logistics system at peak efficiency. The performance of the system should be regularly assessed and improvements should be made where necessary.

### *Quality management*

Programme managers are responsible for seeing that the condoms that reach consumers are “fit for use”. They will be concerned with the initial good quality of the condoms supplied to the programme and will take steps, through logistics management, to ensure that storage and transportation procedures maintain that quality through to the consumer. An effective programme manager will ensure that sufficient supplies are available and are being used in accordance with the principle of first in, first out.

In pursuit of “total quality management”, programme managers will carry out regular checks to make sure that the condoms have not deteriorated (refer to Fact Sheet 3 on Condom Quality Assurance and Fact Sheet 5 on Logistics).

### *Consumer feedback*

Feedback from consumers is an important input to planning, and all programme workers should be trained to record and report any comments about the condoms, whether favourable or otherwise. After all, if consumers do not like the condoms, they will not use them and the programme will fail.

### *Staff performance*

The programme is dependent on the skills and motivation of its staff. The programme manager can use a variety of different techniques to help improve staff performance. These include:

- arranging a formal technical introduction to the programme for all new staff;
- working as a team (coordinating the planning process with the staff, clearly defining their activities, monitoring implementation and providing supportive feedback);
- arranging structured training opportunities for staff at the place of work (such as regular study days or study periods, supervised practice, on-the-job training and mentor programmes) and supervising staff on a regular basis in a constructive and positive manner;
- sending staff on short-term training courses in the aspects of programming for which they are responsible (in addition to providing learning experiences, these courses help to establish relationships that can lead to long-term cooperation and mutual assistance);
- seeking short-term technical assistance from outside the country when the expertise is not available locally.

(Refer to Fact Sheet 7 on Improving Staff Performance.)

### *Monitoring and evaluation*

Continued success depends on programme management's ability to build on its strengths and to correct its weaknesses. To do this, management must develop straightforward criteria for monitoring and evaluating each key area of activity, including research, promotion and logistics management.

### *Coordination*

Other public, private and nongovernmental agencies in the country may also be working on condom promotion and distribution, and some may rely on the national programme for supplies or other support. The programme management must be able to coordinate the requirements of these agencies and should be responsive to their needs and concerns. Remember that the work of these organizations contributes jointly and materially to the spread of knowledge and condom usage among the target populations.

### **Budget and financial control**

All activities and commitments involving the expenditure of money must be included in the budget. These include procurement, promotion, distribution, quality management, research, training, external technical support, personnel services, travel, meetings, administration, personal transportation and so on.

Management is responsible for controlling income and expenditure, maintaining proper accounts, budgeting, reporting and possibly fundraising, as well as negotiating contracts with suppliers of goods and services and with staff. Activities must be costed and prioritized according to the needs of the programme and the resources available. The priority at all times must be to ensure a continuous supply of high quality condoms to the end user.



### Difficulties faced by condom programming in some countries

Social and political pressures sometimes constrain the efforts of family planning and STD/HIV prevention programme workers to promote the use of condoms. These pressures may be the result of government regulations, or they may be part of the social, cultural and religious environment that determines what is acceptable in the community. In some cases, these barriers can seriously obstruct the ability of the programme to implement effective activities. The following are examples:

- Provision of condoms may be restricted to married couples.
- Distribution of condoms may be permitted only through certain outlets.
- Condoms may cost more than target audiences can afford.
- Condom promotion may be banned.
- Condom use may be associated with extra-marital sex.

If local regulatory requirements do not insist on compliance with good quality standards, poor or variable quality condoms may become available. As a result, some users may have bad experiences with condoms and may no longer use them.

Restrictions may be placed on the content of advertising and promotional messages, or on the media in which they are permitted to appear. These restrictions may be the result of legislation, or may be imposed by the media in an effort not to offend. Similarly, restrictions are sometimes placed on the freedom of programme workers to explain the dangers of unprotected sex to students

and young people, or on family health programmes.

### How can a programme manager overcome these obstacles?

It would be a daunting task for a programme manager to try to overturn social and religious mores that have grown up over centuries. There are, however, many ways in which one can work with the community to try to influence the views of opinion-formers and the public. This will gradually help to create an environment in which the normal work of the programme is seen as perfectly acceptable and in the interests of the population at large.

Here are some of the ways in which the programme manager can solicit, and sometimes gain, the collaboration and support of community leaders:

- Hold seminars and present evidence-based key facts to convince decision-makers about the protection that condoms offer the individual against unwanted pregnancy and the transmission of STDs/HIV. Use facts to demonstrate the potentially disastrous consequences for the nation of not taking action to promote consistent and correct condom use. The audiences at this kind of seminar should include government leaders, religious leaders, prominent business people, economists, the press, health service providers and the private sector.
- Arrange for visits of decision-makers to neighbouring countries where the promotion and use of condoms against unwanted pregnancy and STDs/HIV is accepted and widespread. Direct and personal exposure to the problems of other countries and the steps they are taking to



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## The Male Latex Condom – Fact Sheet 2

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overcome them often has a powerful effect on political consciousness.

- Work to make condoms more affordable. This may include lobbying government to reduce taxes and import tariffs, seeking bulk purchasing benefits through a public sector purchasing agency, or persuading donors to provide supplies that can be marketed at subsidized prices through social marketing programmes.
- Lobby government and businesses to lift restrictions on distribution in order to increase the range of outlets that are permitted to sell condoms, so that consumers can more easily obtain the condoms recommended by the programme.
- Lobby government to eliminate restrictions on who may obtain condoms, and to decree that they shall be available to all sexually active people, regardless of age or marital status.
- Persuade the government that regulation of condom quality is essential and that only condoms made and tested to internationally accepted quality standards should be allowed on the market.
- Work to eliminate restrictions on the use of advertising and promotion for condoms, whether imposed by the government or by the media.
- Gain the support of the education sector for more widespread and more explicit health education in schools, universities, colleges and places of work. Campaign for children to be taught about sex and the dangers of early pregnancy, about AIDS and other STDs, and about the importance of using condoms as soon as they become sexually active.
- Empower women to negotiate the use of condoms with partners so that they can protect both themselves and their partners.

# Fact Sheet 3

## Condom Quality Assurance



Inflated Condom

*Photo: London International Group*



# 3. Condom Quality Assurance

## Condom quality control

Condoms must be of good quality to prevent unwanted pregnancy, and to prevent the transmission of STDs, including human immunodeficiency virus (HIV). If condoms are not of good quality, consumers will be reluctant to use them and will continue to be at risk of infection or pregnancy. If condoms leak or break during use, the risk to the user may approach the risk of using no condom at all. Therefore, poor-quality condoms can damage not only the health of the users but also the reputation of the agency or national body supplying the condoms. This ultimately will affect all family planning and STD/HIV prevention programmes.

To ensure that condoms are fit for use when they reach the consumer, considerations about quality must influence and direct virtually every activity in a condom programme.

Not only must the condoms be of good quality when they leave the factory, but care must be taken at every stage of the journey from factory to consumer to ensure that they do not deteriorate significantly during storage or transport.

## Quality condoms

Firstly, the specification for the condoms must be right for the population for whom they are intended. A condom that is too narrow or too wide, or has too much or too little lubricant or powder, or is of a colour that has negative connotations, will not be acceptable to a large segment of the population. If a condom is not acceptable, it is not fit for use.

Secondly, the condom must meet the user's expectation and not place them at undue risk. It

must have adequate strength and elasticity, so that it will not break during use. It must be free from holes, so it will not allow body fluids (and possibly the HIV virus) to pass through. Moreover, it must have a package that remains securely sealed to protect the condom throughout its shelf-life.

## What are the responsibilities of a programme manager?

The clients of the family planning or STD/HIV prevention programme regard the programme manager as the source of the condoms distributed by the programme. Thus, the manager is responsible for making sure that the condoms arrive in the hands of the consumer in top condition and are of a quality consistent with specification and needs of the user.

The programme manager must be vigilant to see that all necessary measures are taken to assure quality at each of the following points in the procurement process (for fuller details, refer to the *WHO Specification and Guidelines for Condom Procurement*).

### *The specification*

The specification should be written very carefully since it details:

- the *general requirements* which specify the safety of the constituent materials and other characteristics of the condom, such as shelf-life;
- the *performance requirements* that specify the essential attributes of the condom, such as strength, elasticity, breakage and freedom from holes, in order to address the fundamental aspects of safety and efficacy;
- the *design requirements*, such as colour, odour, width, thickness and length that can be adapted to clients' needs and preferences.

### *Pre-qualification*

The proliferation of condom manufacturers in recent years has made it very important to find a competent supplier who can meet the specifications, quality requirements and delivery schedule demanded by the condom programme. Pre-qualification is a procedure designed to test the capability of a manufacturer to produce homogenous lots of good quality condoms on a continuing basis and exclude those who are unable to do so before or during the tendering process.

Anyone involved in the purchase of condoms should review the pre-qualification and tendering procedures detailed in the *WHO Specification and Guidelines for Condom Procurement* in order to avoid selecting a manufacturer whose products are substandard or does not have the production capacity to meet delivery schedules.

### *Compliance testing*

As each shipment is assembled at the supplier's factory, the supplier notifies the buyer that it is ready for delivery. The buyer then arranges for samples to be taken randomly from each lot of the shipment and sent to an expert testing laboratory for analysis.

WHO recommends that lot-by-lot testing is routinely carried out on all shipments until a manufacturer's record of consistently supplying high-quality condoms gives the buyer the confidence to reduce the frequency of sampling and testing.

These random samples, taken in accordance with sampling tables published by the International Organization for Standardization (ISO 2859-1), are statistically representative of the entire lot. This is known as lot-by-lot testing. It provides reasonable assurance that the entire lot is of acceptable quality.

The testing laboratory's report is given to the buyer. If the lots have passed the tests, the manufacturer is instructed to ship the condoms. If requested, a copy of the test report can be sent to the programme manager or can be included with the shipping documents.

If a lot does not pass all the *performance* tests, it is unacceptable and the manufacturer is instructed not to ship it but to destroy it. No doubt some manufacturers find a market elsewhere for their failed lots, which is why buyers must always be suspicious of bargain lots of condoms unless they know that proper compliance testing has been carried out and that the condoms have recently passed all the tests.

In the case of *minor* failures of *design* requirements it may well be in the interest of the purchaser to accept such lots rather than to suffer interruptions in supply. The failure to comply must be brought to the immediate attention of the supplier and persistent non-compliance should lead to the lots being rejected.

### Laboratory tests

The laboratory first inspects the samples to make sure the condoms conform to the general design specifications of the buyer and then subjects them to stringent performance tests. These include the airburst test, which indicates whether the condom is likely to break during use, and the water or electronic test which reveals any holes that could cause leakage. All condom test

requirements are detailed in the *WHO Specification and Guidelines for Condom Procurement*.

The laboratory also tests the integrity of the package since a latex condom needs an airtight and impermeable, hermetically sealed package in order to maintain its quality throughout its journey to the consumer.

### The cost of compliance testing

Most buyers budget between 6% and 10% of the cost of the condoms themselves for compliance testing. This should not be considered an additional cost but an integral part of the cost of obtaining good quality condoms.

Compliance testing can also be considered an insurance against substandard condoms reaching the distribution system, which could cause damage both to the consumer's health and to confidence in the programme.

### Maintaining the quality of condoms

The programme's logistics management team has the greatest responsibility for ensuring that the condoms remain in peak condition once they arrive in a country. However, every programme worker should understand the need for special care in handling and storing condoms.

*Here is a checklist to guide the programme manager and programme workers in their handling of condoms:*

- For the initial procurement, use an experienced procurement agency such as WHO or UNFPA. Alternatively, choose a manufacturer that has been pre-qualified. Refer to the *WHO Specification and Guidelines for Condom Procurement* for guidance on pre-qualifying manufacturers.
- A factory with a currently valid certificate of compliance with ISO 9000 (GMP) (Certificate of Good Manufacturing Practice) offers some evidence that the factory is well managed, but GMP alone cannot ensure that a quality product will be produced. WHO suggests certificates alone do not ensure a quality product. Certificates should be used to assist in the pre-qualification of the manufacturer.
- Have an independent, qualified testing laboratory conduct the pre-qualification and lot-by-lot compliance testing.
- Ensure that good storage conditions are in place at every point in the distribution system.
- Ensure that the transportation of condoms is as rapid as possible and takes place under satisfactory conditions.
- Make sure the condoms are not unduly exposed to environmental conditions during transportation, including during loading and unloading.
- Ensure that condoms are distributed from all storage facilities according to the principle of FIFO (first IN, first OUT).
- Carry out regular random visual inspection of samples taken from all levels of the distribution system. If any of the condoms or their packaging appears damaged or in any way different from the norm, send a sample from the affected lot to a qualified laboratory for testing.
- If feasible for the programme, draw samples for laboratory testing from all stocks that are more than three years old prior to distribution.

- Supervise the quality of staff performance in the care, handling and storage of condoms, and instil a quality consciousness into all elements of the logistics system.
- Give condom users advice on care, use and disposal of condoms.
- If possible, determine whether the condoms have been transported or stored under adverse conditions.
- If the problem appears serious, quarantine the condoms and send random samples from the affected lots to an independent laboratory for testing.

### Managing complaints

It is important to have a response for dealing with complaints swiftly and decisively. When complaints about condom quality are made, it is the manager's responsibility to verify if there is any evidence of real departure from quality requirements. The following procedure should effectively limit any damage to the programme when complaints arise:

- Identify the lots that have given rise to the complaints.
- Obtain the views of field managers, service providers and consumers about the problem.

If the tests show the condoms to be unacceptable, have them destroyed. If the tests indicate that the condoms are still acceptable for use, programme managers may choose to accelerate their consumption by immediate distribution. It is only possible to establish a system to manage complaints if records of lot numbers, distribution and storage are maintained. Without an appropriate record system it is virtually impossible to track faulty lots of condoms.

Some complaints may not be about quality. For example, users often confuse dissatisfaction about size, odour or comfort with issues of quality. To prevent this type of complaint, the research and logistics units need to work together to track consumer reaction to the product and then adjust the specifications for future condom orders if necessary.



# Fact Sheet 4

## Condom Promotion



Photo: PSI

Mr Lover Man





# 4. Condom Promotion

The fundamental tasks and challenges in condom promotion are:

- to inform and educate about the need to avoid the risk of unwanted pregnancy and/or STDs/HIV in sexual contacts;
- to promote the health benefits of using condoms consistently and correctly;
- to advocate responsible sexual behaviour and motivate people to take suitable precautions;
- to inform the target population about the availability of condoms (where they can be obtained free or purchased, when and at what price);
- to promote the use of condoms as normal and free from stigma;
- to disseminate factual information on the quality, efficacy and effectiveness of condoms in preventing unwanted pregnancy and the transmission of STDs/HIV.

### Advertising in the mass media

The mass media – newspapers, television, radio and cinema – are powerful agents in reaching large audiences. Advertising is most effective when it can present images that suggest: “Here is a great product that many people just like you (or people you would like to resemble) use to their great satisfaction”. Advertising may also emphasize quality, value and effectiveness.

Rarely should advertising directly threaten those who do not buy the product with a deadly disease like AIDS, because instilling fear through advertising is frequently counterproductive.

However, if the audience has received information from other sources about AIDS, or about the financial burden of having too many children, or the danger that infertility may follow an infection by an STD, mass media advertising can be used to reinforce those messages. All programmes that promote the use of condoms should at least be linked with reproductive health activities since this ensures complementary and supportive promotional messages

### Small media

By their nature, mass media are indiscriminate because they are designed to reach large audiences. Techniques with a finer focus are needed to direct messages at more specific target groups and to handle controversial material, such as explicit instructions for correct condom use.

Some of the small media promotional techniques that have been successfully applied in promoting responsible sexual behaviour and condom use are:

- wall charts, cartoon strips, magazines and booklets, pamphlets, leaflets, flip charts, instructional fliers, games, toys, balloons, key rings;
- telephone hotlines;
- outdoor advertising (billboards, bus signs, posters, stickers);
- speakers in schools, universities and other group meetings, with videos, slide-shows and audio cassettes;
- peer education in youth organizations;
- special events, sports days, carnivals.

## Counselling

Face-to-face discussion is probably the most effective means of informing and encouraging others. It offers opportunities for responding to intimate questions and doubts, for restatement and rephrasing, and for establishing rapport between people.

Counselling sessions and clinic settings are both ideal environments in which to introduce condoms and to encourage their correct and consistent use. Peer educators, volunteers or paid individuals from the target group may also be employed to carry messages (and sometimes condoms).

Of course, all counsellors must first be personally convinced or persuaded of the importance and ethics of condom use before they meet the public. The wrong attitude will convey the wrong message.

Mass media advertising reaches a mass audience at a low cost per head whereas trained counsellors, clinicians and peer educators are expensive, since in addition to personnel costs programmes must also take into account the cost of training and supervision. Well targeted mass and small media advertising should support opportunities for counselling and one-to-one promotion.

## Development of a communications programme

It is essential that all communication and promotional activities be integral parts of an overall strategy and that messages do not conflict.

### Strategy

The development of a sound national condom promotion strategy must first answer the following questions:

- What behaviour do we wish to change (and what do we not want to change)?
- What are the beliefs and attitudes, myths and misconceptions, of our population about using condoms?
- Which groups are the most important to target as advocates or opponents of condom use?
- What social, cultural and psychological barriers influence the use of condoms for different at-risk groups?
- What are the most effective ways of communicating with the target groups?
- What do the target groups need to know?

Only when these questions have answers is it possible to develop a media campaign, prepare a timetable and budget, and produce the materials.

### Pre-test and revise materials

Pre-testing involves trying out ideas and prototypes of materials on a group of individuals who are representative of the target population. The drafts are presented to gain feedback on whether or not they will work as intended or need to be revised.

It may be tempting to speed up the process of producing materials by undertaking only a superficial pre-test of the materials under development. This can be a costly mistake because, if messages are inappropriate, misunderstood or unappealing to the target group, time and money will be wasted using them. Moreover, the messages themselves may create or reinforce negative attitudes towards condoms or the programme.

### Monitoring

There are no simple means of ensuring that a given communications strategy or message will produce the desired results. Pre-testing of concepts and messages can provide only a partial indication that people will react in the way the promoter expects and desires. All communications programmes should be monitored regularly to determine whether the messages are acceptable and understandable to the target audience and have the intended impact.

### Evaluation

The test of whether or not the communications actually work is the degree to which behaviour is moving towards the targets. How can one be sure that it is the campaign that has effected a change in behaviour? The answer is that one cannot be sure from just one campaign.

It is, however, extremely important to know what is happening at the population level with regard to the use or non-use of condoms. One source of such information is the large surveys that are regularly conducted in many parts of the world, such as the contraceptive prevalence surveys and Demographic and Health Surveys.

It is possible to request the inclusion of special modules in population-based surveys, but it is important to be aware that national surveys are structured and stratified to meet other objectives and may not provide the precision required in a programme's target populations.

Another means of addressing the particular information needs of many condom programmes is to use a system of behavioural sentinel surveillance. This tracking device provides periodic data on key behaviour, including condom use, among key target groups. The sampling frame is designed in accordance with the strategy of the programme and is sensitive to the changes that the programme is designed to produce. It is the counterpart of the biological data generated in epidemiological sentinel surveillance and provides direct information on the issues that concern condom programme managers.

What evidence is there that promotion increases condom use?

The most dramatic evidence is provided by the condom social marketing programmes in Africa, where intensive and continuous advertising campaigns have always been an integral part of condom promotion programmes, and where sales increased from 20 million in 1987 to 122 million in 1994.

Highlights among programmes included in these figures are:

- Ethiopia, where sales increased from 700,000 in 1990 to 17 million in 1994;
- Cameroon, which went from 740,000 in 1989 to 7 million in 1994;
- Nigeria, which saw an increase from 1.1 million to 45 million between 1990 and 1994;
- Zaire, where sales increased from 900,000 in 1988 to more than 18 million in 1991 when the country was experiencing social and economic disorder.

In campaigns directed towards specific audiences, the results, though less dramatic, have provided ample evidence of the effectiveness of promotion in condom programming.

- In Zaire, a drama produced for radio and television, and aimed at urban young people aged 12–19 years, contained three key messages. Post-transmission surveys showed that more than 44% of those who had seen or heard the play remembered the messages.
- In Côte d’Ivoire, regular purchase of condoms by sex workers increased from 74% to 90% after promotion via peer leaders.
- In Thailand, a government policy of having 100% condom use in brothels contributed to significant increases in condom use and a drop in STD rates. In one province, condom use by sex workers more than trebled and STD rates among sex workers fell from 13% to 0.5%.
- A nongovernmental organization in Switzerland promoted “Hot Rubber” condoms to men who have sex with men by placing promotional materials and free samples in non-traditional outlets such as gay bars and saunas, and advertised in gay print media. The condoms could also be ordered by mail from the organization. Sales trebled from 170,000 to 500,000 between 1989 and 1993 and, following the extension of the marketing strategy to include heterosexuals, doubled again to 1 million by 1994.

# Fact Sheet 5

## Logistics Management



*Photo: WHO*





## 5. Logistics Management

What is logistics management for condoms in a reproductive health programme?

The goals of logistics management can be summarized by the “six rights”:

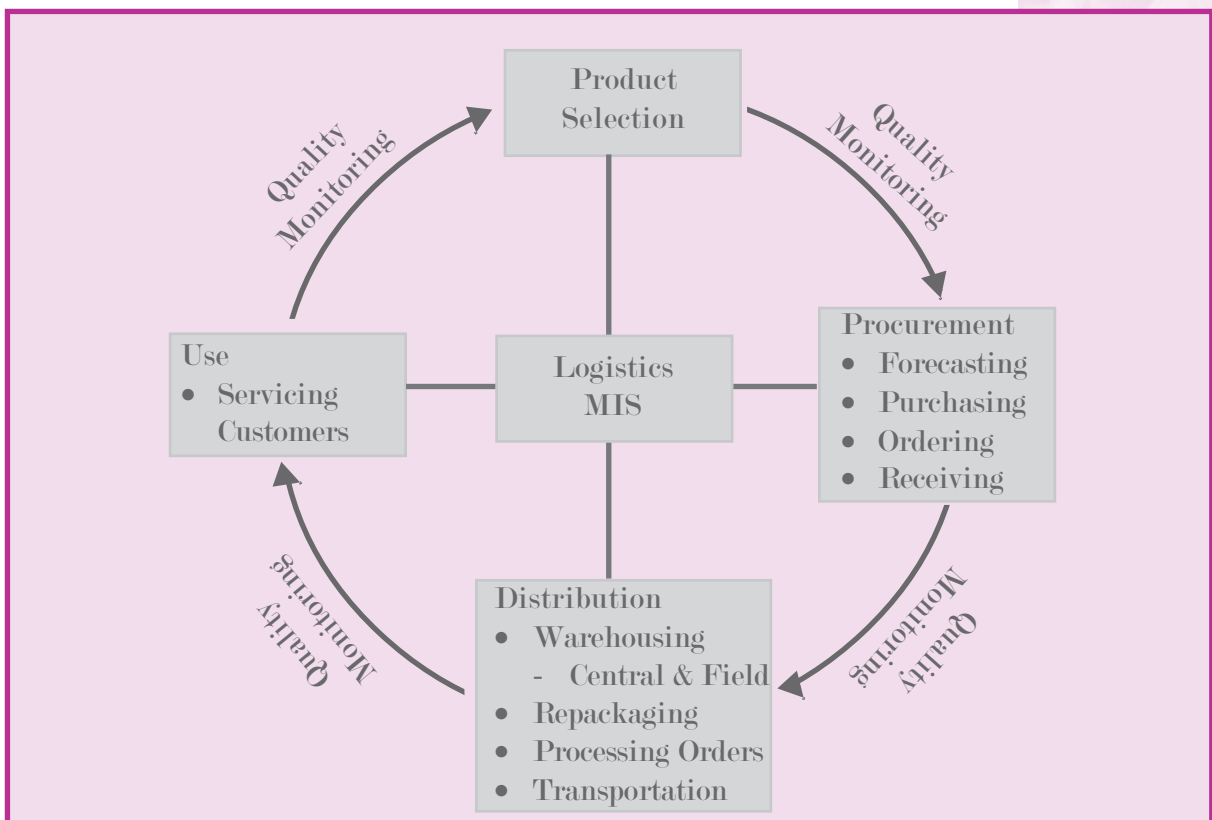
The *right* quantity  
of the *right* quality product  
in the *right* place  
at the *right* time  
in the *right* condition  
at the *right* price.

This means that consumers must have adequate supplies of high-quality products when and where they need them and that the programme should use resources efficiently. Meeting the “six rights” requires good management at each phase in the logistics cycle:

Failure in any of these rights results in inefficiencies, wasted resources, bad publicity and lower budgets. Yet these are not the only results that can emerge from failure in any of these rights. Stock-outs, inferior products and badly handled shipments of condoms in a family planning or AIDS prevention programme can mean that people may be denied the means to protect themselves against unwanted pregnancy or a deadly infection, as a direct result of mismanaged logistics.

The requirements of logistics management are so *demanding*, and the consequences of poor performance are so *serious*, that logistics management has become a professional field in itself in both the public and private sectors.

The following conceptual framework for logistics management shows the relationship between the various components:





*Product selection* is done by a panel of appropriate experts who determine what products are needed to carry out the objectives of the programme, usually considering consumer demand, the budget, and local conditions. Some programmes may choose only condoms, whereas others may include a range of contraceptive methods or essential drugs. When selecting products and quantities, the panel must consider the market criteria and whether the logistics system will be able to provide adequate storage and transport.

*Procurement* includes forecasting quantities that will be needed, preparing a detailed specification, pre-qualifying and selecting a supplier or working with a donor, budgeting, ordering, and receiving appropriate numbers of high-quality supplies. It is important to consider the time factor involved in the procurement process and to plan on the basis of a realistically estimated time-frame. Refer to the *WHO Specification and Guidelines for Condom Procurement*.

*Inventory management* regulates the flow of products from supplier to central warehouse through intermediate distribution points and on to outlets. It entails scheduling shipments, warehousing, transporting products, and managing stock levels. Managing stock levels involves monitoring and controlling the stock on hand at each level of the system. Managers at each level must consider the rate of consumption, the lead time for new orders at all levels of the system, and the need to hold adequate stocks at intermediate points to avoid shortages.

*Serving customers* who use the condoms, contraceptives or other products is the ultimate goal of the logistics system. If the products the customers want are available in adequate numbers and in good condition, the logistics system has functioned effectively. For logistic purposes, a condom distributed at the lowest level of the distribution chain is a condom used.

*Quality management* measures must be taken at each step in the logistics management chain. These range from choosing a supplier to ensuring that products move swiftly through the supply chain to the consumer so that the consumer receives the highest quality product. Proper storage conditions are particularly important for condoms which may deteriorate rapidly if improperly stored.

*The logistics management information system (MIS)* is the system of collecting, processing, tracking, reporting and analysing data on product stock levels and use. This critical system communicates supply status and need at all levels of the programme so that appropriate decisions can be made to avoid stock-outs and to ensure optimal quantities of supplies. The MIS also includes the records that help to maintain quality assurance throughout the system. The MIS is shown in the centre of the cycle because no part of the logistics system can work well without accurate and timely information.

# 5.1 Forecasting

## Why should a programme forecast the number of condoms or other supplies it needs?

Forecasting means predicting how many condoms or other products the programme will need in order to provide services for a given time period in the future. An accurate forecast helps to ensure that adequate supplies are always available. Not forecasting or forecasting inaccurately may result in the need for emergency orders which are time-consuming for staff and cost more than regular orders. If supplies run out, clients may view the programme as unreliable and promotional efforts will be wasted. In the case of a condom stock-out, clients may be exposed to unwanted pregnancy or a serious or fatal disease.

Forecasting so that the programme does not overestimate its needs is equally important. Condoms are expensive and the cost of storing and transporting amounts that are larger than needed increases overall costs significantly. With an oversupply, condoms may become damaged or reach their expiry date before they can be used.

## How is forecasting done?

Forecasting is a combination of science, art, common sense and experience. One must rely on gathering all available related information and making the best forecast based on historical data and “educated guesses” about how the future will differ from the past.

For a reproductive health programme, forecasting generally involves looking at the quantities of supplies that have been dispensed to users in the past and projecting this consumption pattern into the future, making adjustments for anticipated programme changes. What has happened in the recent past is generally the best

source of what will happen in the short-term future (i.e. up to three years). The further a forecast is projected into the future, the more unreliable the figures will be. That is why periodic monitoring of the forecast figures in comparison with real data must be an integral part of managing a programme. The forecast figures provide a tool to use for making decisions about inventory management, such as adjusting delivery schedules and adding or canceling orders.

Three sources of data are commonly used to estimate product needs:

### 1) *Historical demand based on logistics data*

Logistics-based forecasts are most accurate when good historical data exist on the quantities of products dispensed to users. Sources for these data include distribution to intermediate warehouses at all levels of the system, and sales and consumption (dispensed-to-user) records at the lowest level of the system.

### 2) *Historical demand based on service statistics data*

Service statistics data recorded at clinics and other delivery sites can be used to forecast condom need in any programme where client visits are counted by method and standard protocols are used for dispensing supplies. For an STD/HIV prevention programme, the usual number of condoms dispensed may depend on the client being served.

The target population may be segmented according to differences in sexual practice, number of acts of sexual intercourse, and frequency of condom use. For example, an adolescent client would not receive the same number of condoms as a commercial sex worker.

### 3) *Population-based estimates*

New programmes that have little or no historical data on which to base forecasts often make estimates using population data. Needs are calculated on the basis of census results, surveys, or behavioral studies of a geographical area or of a specific population to be served.

The following factors must be considered when making estimates:

- current use of condoms (condom prevalence) in the population;
- the number of persons having sex with non-regular partners (including sex workers and their clients);
- estimated average coital frequency per year for each target group or segment of the population (e.g. sex workers, military, adolescents);
- estimated percentage of times that condoms are used (e.g. only with non-regular partners or all the time with a regular partner for pregnancy prevention);
- percentage of the population always using condoms;
- estimated increased demand as an outcome of specific promotional activities.

### Which of these forecasting methods should be used?

Each of these three forecasting methods has advantages and disadvantages. The choice of a method should be based on the type of programme, how recently it was established, and the types and quality of data that are available. If possible, use more than one method and then compare the results. Programme staff should be asked about future planned activities that may change demand, such as promotion programmes, the opening or closing of clinics, or new distribution methods. First and foremost, programme managers must examine forecasts to ensure that they make sense in light of what the programme is actually doing. If a population estimate is used to forecast need, the capacity of the programme must be considered. Programme targets are often used to forecast need but must also be compared with logistics data to ensure that overly ambitious targets do not result in extreme overstocking.

For guidance on how to use these types of data in forecasting, consult *Family Planning Logistics Guidelines* by the Centers for Disease Control and Prevention and *The Forecasting Cookbook* by John Snow International. Also see *Resources for logistics management* at the end of this fact sheet.

### 5.2 Procurement

#### How can a programme procure condoms?

First, the programme must write condom specifications. These specifications provide a detailed description of the condoms to be purchased and serve as the legal basis for the procurement contract.

The specifications must incorporate the minimum standards of quality with respect to *general* and *performance requirements* for consumer protection, as well as *design requirements*, which describe local needs and preferences such as size, colour and lubrication.

Some countries have national standards. Others use those developed by the International Organization for Standardization (ISO). Whatever choice is made, it should reflect the most up-to-date changes in condom technology. Detailed information regarding unique specifications for local programmes can be found in the *WHO Specification and Guidelines for Condom Procurement*. This provides essential information on the steps that must be taken to write a specification and procure high quality condoms to meet the needs of different target populations.

The next steps will vary considerably depending on whether the programme is receiving supplies from a donor or purchasing them. If donors such as USAID, UNFPA, WHO or IPPF are supplying the products, the programme's role is to assist with an accurate forecast by providing reliable data and the results of a physical inventory. Programme staff should work closely with the donor to develop delivery schedules and to monitor the forecast so that these schedules can be adapted as needed. The shipping schedule should be economical (taking advantage of shipping containers when possible) but must not overwhelm the storage facilities in the country.

#### Should a government do its own procurement?

If a programme chooses to buy supplies, procurement is often done through a procurement agency for a fee. The agency will negotiate the price and undertake the quality assurance procedures for pre-qualification and procurement. The programme manager will control and monitor specifications and shipping schedules.

The other option is to buy directly from the manufacturer. For this, a programme needs personnel who are skilled in international tender procedures. The programme takes on all responsibility for quality control and negotiation. Because of the direct link to the manufacturer, the best price may be obtained in this process, but the staff time and expertise needed may reduce that advantage.

#### How long does it take for condoms to arrive after they are ordered?

The time between ordering and arrival varies with different supply sources and even with different items coming from the same source. If a donor is supplying the products, and keeps supplies in stock at a central location, lead time could be less than six months by sea freight but might be significantly more. Air freight is generally much faster, but the time savings must be weighed against the increased cost.

If the programme orders from a local supplier, transport time is not an issue, but the production schedule of the local plant may be a constraint and should be established before a tender is accepted.

When condoms are being procured directly from a manufacturer, a typical process including international competitive bidding, the prequalification process of suppliers and lot-by-lot compliance testing will cover a period of 12–16 months. It is critical to plan activities far enough in advance to allow for these lead times.

### What about budgeting?

It will be necessary to estimate costs, request funds, and confirm the availability of those funds for the actual procurement process. The availability of foreign currency has been a constraint in many cases. Prices of condoms will vary considerably according to the source. Check with donors for the price of their condoms.

For more information on the procurement process, consult the *WHO Specification and Guidelines for Condom Procurement* and *Competitive Procurement of Public Sector Contraceptive Commodities, A Reference Manual* prepared by the Programme for Appropriate Technology in Health (PATH).



### 5.3 Inventory Management

#### Why is inventory management so important?

Inventory management procedures are designed to prevent stock-outs and overstocking.

*Stock-outs* are a major problem because they may result in unwanted pregnancies and disease transmission. In addition, they reduce client confidence in the programme and frustrate programme workers. They are a common cause of programme failure.

*Overstocking* is a costly problem because it ties up programme resources. Excess supplies take up storage space and may result in product expiration and waste. Deterioration that takes place in lengthy storage may cause quality assurance problems.

#### What is an inventory control system?

An inventory control system is a way to manage stock levels by providing guidance about stock levels all along the supply chain, from the central warehouse to clinic outlets or community based distribution points.

There are two types of system:

Allocation or “Push” systems, in which the central and intermediate warehouses decide how often and how many supplies should be sent to the lower-level storage facilities and outlets.

Requisition or “Pull” systems, in which the outlets, community-based distribution (CBD) agents and/or intermediate level facilities decide how much they need and request that amount from the higher-level facilities.

Consider the following factors when deciding which type of system is best suited for a particular situation:

- *The management skills of the individuals working at each level in the system.* More skill is required at all levels in a “pull” system. New systems may start with “push” and, as staff gain experience, move towards a “pull” system.
- *The information available at each level about actual consumer usage.* In a “push” system, timely and accurate data must be available at the central level; in a “pull” system, the data processing capacity at lower levels must be strong.
- *The number and quantity of different items managed.* It is difficult for the central level to manage many different types of supplies, as a “push” system requires, unless the inventory control system is highly automated.

Inventory control systems are based on a maximum level, the most stock that should normally be held, and a minimum level, the level at which an order for more supplies should be initiated. Maximum and minimum levels should be set for each level of the logistics system, measured in months of supply.

For example, if three months of supply is the minimum and six months is the maximum, the clinic would be understocked if it had less than a three-month supply and overstocked if it had more than a six-month supply. There are several variations of maximum and minimum systems, which may be implemented according to the country situation.

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For more information on choosing and implementing an inventory control system, refer to *Family Planning Logistics Guidelines* (Centers for Disease Control and Prevention/John Snow Inc., 1993).

### How can a programme manager know whether supplies are adequate or not?

The maximum-minimum system measures stock levels in months of supply. If stock levels are between the maximum-minimum boundaries, they should be adequate. All managers should be able to calculate how many months of supply they have on hand for each product in their clinic. Then, if they know when the next delivery is

expected or how long it takes to get a delivery after they order, they can determine whether their supplies are adequate. Clinic managers should also know how to make an emergency order, if necessary, to keep from running out of stock.

To calculate months of supply, two figures are needed: an average consumption rate (i.e. average number of condoms dispensed to users per month) and current stock on hand.

The average consumption rate in a programme that is relatively stable can be measured by taking the average consumption of the last six months. In new programmes where consumption may be more variable, a three-month figure may provide a more useful average.

#### *Example:*

Condoms distributed	
January	2000
February	2100
March	2300

At the end of March, the stock on hand was 3200 condoms.

What is the average monthly consumption?

$$\text{Total: } \frac{6400}{3 \text{ months}} = 2133 \text{ average monthly consumption.}$$

How many months of supply are on hand?

Months of supply =  $3200/2133 = 1.5$  months of supply.

Formula:                      Months of supply =  $\frac{\text{Stock on hand}}{\text{Average monthly consumption}}$



### 5.4 Storage and Distribution

#### Why is storage so important?

If procurement specifications and quality assurance requirements are correct, condoms shipped from the factory will be newly manufactured, of good quality, and in good condition. Condoms made from latex rubber are perishable if exposed to excessive heat, humidity, light or air pollution. They may lose their strength and thus put the user at risk of breakage.

Research undertaken by PATH into product stability has demonstrated that silicone lubrication provides some protection against oxidation, and that if the condoms are hermetically sealed in aluminum foil and plastic laminated packaging, and stored in cartons, they are robust with a shelf-life of at least five years.

This research confirms that properly packaged good-quality condoms do not deteriorate when stored at the average temperatures normally found in tropical countries. This is an important research finding that may have significant implications for reducing the cost of storage in the longer term. At present, storage still remains an important issue since many manufacturers do not package their condoms in foil and procurement officers are unaware of the need to specify the type of condom packaging required to protect condoms.

If quality assurance measures have been followed during the procurement process, conditions of warehousing and transport have a major role in ensuring that the good quality condoms received reach the user in good condition. Condoms are protected with individual packaging, inner boxes, and outer cartons. They should be left in their original packaging as long as possible, which is one reason why orders should be rounded up to the next whole number of unopened inner boxes.

#### How to determine if the warehouse space is adequate

To determine whether the warehouse space is adequate, it is necessary to know the number of condoms (or any other item) to be stored, the number of condoms in a carton, and the dimensions of the carton.

Condoms ordered x number of condoms in a carton  
= number of cartons

Number of cartons x carton size (in cubic metres)  
= space needed for condoms

Condoms should be stacked or palletted. Floor space needed depends on how cartons are stored. Since cartons should generally be stacked only 2.5 metres high (usually five cartons high), it would be necessary to divide by 2.5 metres to obtain the size of the floor space. Then, to ensure adequate handling space, another 100% should be added for aisles, loading and packing space.

For estimating the space required to store palletted condoms, first measure the length and width of a pallet to determine the units of square space each pallet can hold. For example, a pallet that measures one metre by one metre can hold one square metre of cartons on the first layer. Calculate the number of cartons that can be arranged on the pallet's first layer, then measure the height of the carton and work out how many cartons can be stacked on each other up to the limit of 2.5 metres

The following guidelines can be used by supervisors to check the storage conditions at each level of the logistics system.

### Guidelines for proper storage

- Store condoms in a clean, well-lit and well-ventilated area, out of direct sunlight.
- Secure storeroom from water penetration.
- Protect areas regularly against insects and rodents.
- Store cartons in a space where temperatures do not exceed 35° C for extended periods.
- Arrange for proper security while still allowing appropriate access to supplies.
- Ensure that fire safety equipment is available and accessible.
- Store away from oils, insecticides, chemicals, electric motors and fluorescent lights.
- Stack cartons at least 10 cm (4 inches) above floor level, preferably on wooden or metal pallets, at least 30 cm (1 foot) from the wall or any other supplies, and no more than 2.5 m (8 feet) high, unless special equipment is available.
- Arrange cartons so that identification labels, expiry dates and/or manufacturing dates are visible.
- Store in a manner that permits “first expiry/first out”, counting, and general management.

- Separate and dispose of damaged or expired products without delay according to standard procedures.

All storage systems must be supported by a recording system that can track the location of condoms by lot number and control the inventory on the principle of “first in, first out.”

### What is the storage life of condoms?

Storage life (or shelf-life) is the usable life of products, and depends on favorable storage conditions. Country standards or regulatory bodies determine guidelines for products. Research data indicate that latex condoms lubricated with silicone and hermetically sealed in foil packaging remain stable for well over five years. To date, however, regulatory bodies are reluctant to approve shelf-life labeling in excess of five years.

In the future it will become mandatory for a claimed shelf-life to be supported by real-time stability studies conducted at temperatures that represent the severest average conditions likely to be encountered during storage and distribution.

While some manufacturers already have such data, it is not yet universal, and all manufacturers are encouraged to commence real-time stability testing on their products. This involves storing several lots of condoms at 35° C over the full intended shelf-life, and periodically doing inflation tests on a suitable sub-sample. (For example 30 - 50 condoms could be tested every 6 months.) In this way the rate of decay of physical properties can be established. Compliance with the inflation requirements for new condoms at the end of the shelf-life is also required.

As an interim measure, the *WHO Specification and Guidelines for Condom Procurement* proposes that accelerated ageing tests conducted at higher temperatures for shorter times, should be accepted to determine shelf-life and expiry dates. The manufacturer may present any suitable data available, plus the rationale for the claimed shelf-life.

The procedures of ISO 11346 or any reasonable simplification of them can also be used. Future editions of ISO 4074 will provide condom-specific methods for determining shelf-life. Until these test requirements in ISO 4074 are finalized, WHO will adopt a flexible approach to determining the acceptability of the method of extrapolation from high temperature results to 35° C.

In order to generate simple, interim, shelf-life information it is suggested that oven conditioning be done at two temperatures, 70° C and 50° C. Typically, it would be expected that the mean inflation properties do not drop by more than 25% over the stated shelf-life, and that the inflation requirements of ISO 4074 part 6 be met at the end of the shelf-life. Shelf-life would be ascertained by extrapolation from the 70° C and 50° C data. The test to ISO 4074 would be performed on condoms stored at 50° C after the period that corresponds to the shelf-life at 35° C.

Condom packaging should be printed with the *manufacture* date and the *expiry* date. The cartons should have the lot number, month and year of manufacture, month and year of expiry (expressed in four digits for the year and two digits for the month), manufacturer's registered address, nominal width of the condoms, and the number of condoms in the carton.

### What aspects of transportation are important for the logistics manager?

Efficient and reliable transportation is the lifeblood of any logistics system. Good planning and an understanding of the impact of transportation are indispensable components of effective logistics management.

- The cost-effectiveness of the method of transportation used is of paramount importance. For goods coming from a manufacturer overseas, deliveries should be planned well ahead so that relatively inexpensive, if slow, surface transport can be used. When urgent shipments must be sent by air freight, the cost of transport increases considerably. Once the goods are within the country, the choice between commercial carriers, public or programme-owned transport has to be considered, and a comparison of costs may produce surprising results.
- As with storage, the effect of environmental conditions during transport must be considered. However, it is not always possible to provide ideal conditions on the vehicles used for inland transport. It is therefore desirable to keep transit times to a minimum. Routine speedy delivery results in the need to hold lower levels of stock whereas, if delivery times are uncertain, stock levels need to be increased to avoid stock-outs. This increases both the costs to the programme and the storage space required at the outlets.
- Climatic conditions are also important. Managers must plan to accommodate known seasonal changes that will affect their ability to transport supplies in a timely manner.

- The decision-makers who plan and allocate budgets should ensure that sufficient funds are available throughout the distribution system to cover the costs that have to be paid locally, such as vehicle costs, fuel, and allowances and wages of drivers and other transport staff.
- Every consignment should be properly documented in order to provide proper control of the operation.
- It may often be preferable to use an independent, existing transportation system, rather than incur the cost of setting up a duplicate system for the condom programme. For example, the programme could consider the system used for the distribution of essential drugs. Any such transport system should be thoroughly evaluated to determine whether it can handle the increased quantity of products, especially since condoms are bulky and there are generally large quantities to be transported. Reliability of supply is critical to the success of the programme.

### Is it necessary to have a separate logistics management system for the STD/HIV prevention programme?

No, not always. It may be more efficient or cost-effective to link the STD/HIV prevention programme to the Ministry of Health contraceptive or health commodities supply system in order to avoid putting a duplicate system in place. It is desirable, when considering this option, to make sure that the existing supply system is operating well and is capable of carrying the additional load of the STD/HIV prevention programme without losing effectiveness. Adequate resources *must* be allocated to the system so that it can handle the increased load.

# 5.5 Logistics Management Information System

Accurate and timely data are essential if a logistics management system is to work effectively. This includes documentation of shipments ordered, shipments received, and deliveries to points further down the chain, as well as reports from the field on products received and distributed to users. Quality assurance records should also be kept on file for reference. Reports should be submitted often enough to be useful monthly or possibly quarterly depending on stock levels and the distribution system.

Four items of data are essential for managing a contraceptive logistics system:

- *Stock on hand*, which are the quantities of usable stock available at all levels of the logistics system at a particular point in time;
- *Rate of consumption*, which is the average quantity of commodities dispensed to consumers during a particular period of time;
- *Lead time*, which is the time required for new supplies to arrive and be available for use, measured from the moment the order is placed;
- *Losses/adjustments/transfers*, or the quantity of products removed from the distribution system for any reason other than consumption by clients (e.g. losses, expiration, or transfers).

These four data items allow a manager to determine the status of the stock of the entire system. They are captured in several types of records:

- *Stock transaction records* (including records of amounts ordered,

shipped, received, issued, and transferred at all levels of the system);

- *Stock-keeping records* (stock cards and any other records that keep track of the quantities of supply on hand);
- *Consumption records* (records of the quantities dispensed to clients, such as the daily activity register);
- *Inventory reports* (which summarize information on stock transactions and balances and should be submitted at regular intervals from all levels of the programme);
- *Quality assurance records* (including test requests and results, complaint forms, inspection control reports, and forms for recording the quality of shipments received).

It is important that all logistics data be recorded in terms of *individual units or pieces* and not by strips, boxes or cartons (e.g. 1000 condoms, and not 10 boxes). If programmes receive supplies from several different sources, then strip, box and carton amounts may vary.

The completeness and accuracy of reporting determines the quality of data that a programme can use to manage its supplies. Forms should collect the data that is essential and ensure that there is a definite use for each additional piece of information collected. Any data not clearly needed for programme management decisions should be omitted. It is also important to remember to keep reporting systems simple and avoid oversophistication, which may be costly and problematic to maintain.



## Resources for logistics management

Refer to Appendix VI of the *WHO Specifications and Guidelines for Condom Procurement* for a list of documents and resource materials available from WHO and other agencies, such as John Snow Inc. (JSI), Family Health International (FHI), Crown Agents Services Ltd., Centers for Disease Control and Prevention (CDC), Program for Appropriate Technology in Health (PATH), and UNFPA.

### What written resources are helpful for logistics management?

*Family Planning Logistics Guidelines* by the Centers for Disease Control and Prevention (CDC) and John Snow Inc. (JSI), funded by USAID, 1993. For English copies, contact CDC, Programme Services and Evaluation Section, 4770 Buford Highway NE MSK-22, Atlanta GA 30341, USA. Fax: 770-488-5967.

For French or Spanish copies contact JSI, Family Planning Logistics Management Project, 1616 North Fort Myer Drive, Arlington, VA 22209, USA.

*The Forecasting Cookbook* by JSI. For copies contact JSI at the above address.

*Competitive Procurement of Public Sector Contraceptive Commodities, A Reference Manual* prepared by the Program for Appropriate Technology in Health. May 1993.

*WHO Specification and Guidelines for Condom Procurement* issued by the World Health Organization, Geneva.

# Fact Sheet 6

## Research



*Photo: WHO*





# 6. Research

### What is the place of research in condom programming?

Research plays a vital role as an aid to decision-making in condom programming. There are two main categories: the research that is done to assist the planning of a new or revised programme, and the research required to assess the effect of the programme and make adjustments to it when it is running. It is important to distinguish between these two types of research.

The research undertaken as part of the planning process is designed to provide baseline information about potential suppliers, consumers, their environments and the key indicators that are used to monitor programme performance. In contrast, the research carried out during programme implementation is used to answer specific questions related to the evaluation of the impact and effectiveness of programme activities. Information is also collected on a regular basis in order to monitor progress and track performance, using indicators established by the programme. Thus, prior research is not only used for programme planning but also provides the foundation for subsequent programme monitoring.

### What type of information is needed?

No condom programme can be successful if the users of condoms have difficulty in getting the condoms they need when they need them and at a price they can afford. Nor will the programme be successful if the product is considered socially or culturally unacceptable by the target population, or is viewed as ineffective or of poor quality.

Research can help define the problems of accessibility, highlight potential outlets and distribution opportunities, and estimate demand for condoms.

Research can also help to improve the understanding of issues related to acceptability and use by defining behavioural factors, barriers, and consumer and provider biases that must be overcome to make the condom more acceptable to the end-user.

In addition, research can help define consumer preferences in the context of local culture and customs. It can show what product attributes are acceptable and what information, education and counselling efforts are required to enhance acceptability and promote consistent and correct use.

### Programme planning: is research necessary?

Condom programmes have been operating for more than 30 years and an enormous amount of data has been accumulated. But data is not information unless it is useful to a programme. Appropriately formulated, research can provide programme managers with the information they need both to make effective programme decisions and to determine the effectiveness and impact of decisions that have been taken. Research supports strategic planning but it does not provide quick answers to difficult programmatic questions or a blueprint for programme planning.

A manager should, however, always make sure that the research is really needed.

A great deal of time and resources can be wasted in gathering information that already exists or, even worse, is collected but is not used.

To have any value, research must answer specific questions, that have not previously been answered, or that have not been answered adequately or conclusively. What often happens is that people do not check whether answers

already exist in a certain area, or they assume that previous research cannot be generalized to their particular circumstances.

Before a piece of research is formulated it is important to be very clear about why this information is wanted and in what way it will be used. It is then important to seek out and review what is already known in the subject area since this information may already be available but not known to the programme manager. If the information is not available, such a review will help to clarify precisely what information is available and the kinds of issues that require addressing through additional research.

### Programme monitoring: is research necessary?

Monitoring is the ongoing measurement of planned project activities. Monitoring helps managers evaluate whether project activities are on target. It provides data which, when analysed, will either identify the progress being achieved or reveal deficiencies in programme management. This information can be used to guide the decision-making process to plan either the future direction of programme activities or the remedial action required to improve components of the programme. Monitoring generally uses key indicators to track progress and frequently requires the programme itself to collect some, if not all, of the data on a routine basis.

The programme should also use secondary data from other agencies, such as national epidemiological and demographic surveys, to ensure regional and international consistencies and standards.

### How can a manager define research needs?

Many managers may think of research in terms of designing questionnaires and doing surveys. This kind of activity, where the researcher seeks the source data, is called *primary research*. Yet similar studies have often been done before and other agencies may have collected, or may be collecting, similar data. The identification, investigation and analysis of these other sources is called *secondary research* or *desk research*.

Money and time are always scarce, so it is important to concentrate on identifying operational research issues affecting specific country situations that will be of benefit to the programme. Do not waste resources by repeating research that has already been undertaken.

A review of the existing literature and data will help to:

- provide an assessment of the need to formulate a piece of research;
- justify the type of research that is needed;
- provide a clearer perspective of the type of methodology to use and the time, money and human resources needed to undertake and analyse the study.

### Sources of information

There is a large fund of knowledge about the condom and about condom programming. But the question that must be answered is: do you as a programme manager know where to find this information and does it answer the questions you need answered?

Spend time reviewing the information that exists locally, such as epidemiological and demographic data, contraceptive prevalence studies and published materials, articles and papers issued by international and nongovernmental agencies, and scientific journals.

To help in this search for information, the package of materials of which this fact sheet is a part contains relevant referenced information on procedures for production, procurement and distribution of condoms, a series of fact sheets on condom programming, the condom monograph which reviews specific areas of research, and a bibliography.

The secondary review of existing sources of information is not a waste of time, but adds to the body of knowledge that currently exists. Moreover, it provides the basis on which a manager can make a rational decision on the type of research that is required.

### How do you proceed with research?

The process of research can range from informal investigations of secondary sources undertaken by programme managers and staff to structured surveys, planned and carried out by trained investigators. *The Rapid Assessment Protocol for Planning Condom Services* (WHO/GPA/TCO/PRV/95.8), issued by WHO, gives guidance on how to gather relevant information when planning a condom programme.

There are numerous methodologies and techniques that can be used to gather information, such as:

- Qualitative research generally involves either interviewing individuals or undertaking focus group discussions. It can be used to identify behaviour, attitudes and practices of target groups and others, such as opinion leaders. These small group discussions provide a rich source of information about the target audience's beliefs, misconceptions, prejudices and practices which provides planners with valuable information that cannot be obtained from quantitative studies.
- Quantitative surveys question a larger sample of the target audience and can provide information on common practices and beliefs that can be generalized to the whole target population. This creates a profile of a population. A standard survey does not generally provide the depth of information obtained through focus group discussions and other qualitative data-gathering methods.

- Market surveys can provide useful information on the price, distribution and type of condoms being sold and the preferences of the individuals who buy condoms. Market surveys are also useful for projects considering commercial outlets for distribution.
- Anecdotal evidence gathered from informal investigations is often disregarded but can provide useful insights into patterns of behaviour, practices and attitudes for which substantiating data is not available.

Methods of gathering information depend on the type of information required and how it will be used. However, the level of expertise required to answer the real questions is frequently underestimated. For example, identification of target and vulnerable groups is more difficult than reporting contraceptive take-up by age and sex. Similarly, assessment of repeat and lapsed use of condoms is more difficult than simply counting the number of condoms sold.

It is important for a manager to identify and use the right expertise to advise about exactly what to measure, how to measure it and how often to measure it. In other words, while a manager should understand the principles of research, he or she is not expected to know everything about how to do research. Rather, the manager should have the skills to build a team of people with the appropriate expertise in operational research techniques.

This team will often include a statistician, an economist, a social anthropologist, a health planner and perhaps a condom manufacturer. The manager must, however, have sufficient knowledge of the issues to be researched to be able to direct and supervise the team effectively. This type of leadership requires direction, which means that the manager must have and must maintain a clear set of programme and research objectives.

# Fact Sheet 7

## Improving Staff Performance



*Photo: Anubhav*





# 7. Improving Staff Performance

## Improving staff performance

The most important asset any programme has is the staff it employs. Their commitment to implementing programme activities effectively and promoting the use of condoms will contribute significantly to convincing people of the health benefits that can be achieved. But staff may not have developed the skills, or even been exposed to sufficient information in their pre-service training, to provide them with enough knowledge, appropriate attitudes and skills to procure, distribute and promote condoms effectively.

For example, a health care provider in a family planning clinic may have some rudimentary knowledge of condoms, but may not have been trained in STD/HIV prevention. The same health care provider may think that condoms are not a very effective method of contraception when compared to the pill or an intrauterine device (IUD) but would not necessarily consider the risk of HIV infection when counselling a client. Other health care providers may believe that adolescents should not receive counselling on reproductive health issues or be encouraged to use condoms. Or a procurement officer may be very good at undertaking the tendering process for contraceptives but may not be aware of the quality assurance measures that must be carried out to procure high-quality condoms.

These factors will affect the quality of staff performance. In order for a programme manager to identify how to improve staff performance in procuring, distributing and promoting the use of condoms, it is important to assess the levels of knowledge, attitudes and skills of the staff in relation to their particular roles in condom programming.

## A programme for staff development

A number of educational techniques and methodologies can be used as part of a continuing process of staff development that will improve competence, change behaviour patterns and attitudes, solve problems and motivate staff. All are to a certain extent learning experiences that need to be applied not in a classroom setting but in the workplace. If the manager builds one or all of these techniques into the workplan, it will initiate a participative process that involves staff in identifying and finding solutions for weak areas of performance.

### *Participative problem-solving process*

A number of tried and tested techniques can be applied to generate a participative process for identifying and solving problems.

Managers work with their programme staff to analyse the problems they are experiencing in order to seek solutions that staff and managers are capable of implementing.

This process may:

- identify specific training needs in areas where the staff feel they do not have enough competence;
- identify organizational, managerial or resource problems that require addressing in order for the staff to function competently;
- become a team-building process as all staff participate in the problem-solving process on an equal basis;
- help managers develop their leadership skills and build a team spirit among their staff.

### *Supervision*

A supervisor should always be a facilitator, not an inspector, since proper supervision assists the learning process and motivates staff.

The supervisor should:

- not generate fear by looking for mistakes (supervisors should encourage and motivate staff by working with them to find solutions to problems and improve their level of competence and confidence);
- help identify the problem, guide staff through the action required to rectify the problem and monitor the progress achieved;
- act as a mentor and teacher of the staff he/she supervises in order to encourage the development of individuals and improvements in overall staff performance.

### *On-the-job training*

The value of on-the-job training is often neglected since it is assumed that it is part of the supervisory process. Effective on-the-job training requires a structured approach which involves:

- assessing the level of competence of individual staff members;
- identifying training needs and planning practical training sessions to meet those needs;
- undertaking a period of supervised practice to ensure that the correct level of competence is reached and maintained.

### *Mentor training*

Mentor training is the training that takes place when an inexperienced staff member is assigned to work, usually side-by-side, with a more experienced staff member. The mentor becomes the guide, supervisor and counsellor of the less experienced individual.

### *Regular study days or study periods*

Regular study days or study periods can be incorporated into the workplan as part of a continuous educational process designed to:

- bring staff up to date;
- provide a forum to discuss performance audits and other issues of general concern;
- respond to a particular training need identified by the programme staff or their supervisors.

### *Training as a managerial tool*

Training is a very powerful managerial tool that can make a substantive contribution to improving the quality of staff performance. It can improve the knowledge, skills and attitudes of the staff, which in turn contribute to improved levels of confidence and competence when performing tasks. Moreover, it can contribute to job satisfaction by motivating staff and creating a happier working environment.

Training is often seen as the vehicle that will create change by improving the quality of work and ultimately the services that are provided. Many managers will immediately write a series of training programmes into their workplans with the good intention of improving performance. But if the manager does not ensure that the infrastructure has the capacity and the resources

to enable staff to use their knowledge and apply their skills, people are neither empowered nor perhaps even motivated to perform effectively.

Training is not a solution to a problem but a tool a manager can use to help solve problems and improve levels of efficiency. Training is often misused since there is a general perception that training should be provided by “experts” in a structured learning environment such as the “classroom”. This is a very narrow view of training because there are many ways to provide an educational and learning experience, particularly in the place of work.

### Training needs assessment

For a manager to choose the right type of training medium required to improve staff performance, it is important to assess the training needs of the staff.

Providing a structured learning experience in the workplace is one way to identify training needs. Managers also have a number of other sources of information to assess the strengths and weaknesses of staff performance, such as periodic audits of staff performance, a community survey to identify gaps in service delivery, questionnaires, focus group discussions with staff and clients, and reports and data generated by the programme.

### Selecting the training medium

Once the training needs have been defined they must be translated into learning objectives. The objectives must be expressed in specific behavioural terms that are measurable and achievable by stating clearly what staff must be able to do, under what conditions and at what level of performance.

This will help to identify the training medium – the teaching methods and assessment tools that must be used to achieve the required objectives. The manager may not be directly involved in the training but must supervise the organization of it, budget for it and be sure that it fulfils its objectives.

### Different training media that can be used to improve staff performance

There are many different types of training media, the most common of which are summarized here:

#### *Overseas fellowships*

Grants may be given for individuals to attend overseas training programmes. This can be a very valuable experience for the individuals involved because they will not only enjoy a structured learning environment but will also be exposed to a variety of different cultures, experiences and perspectives that the other participants bring to the programme.

The problem with this type of programme is that it is generally expensive. Moreover, it may not fully meet the needs of your particular programme or the culture in which you operate. In some instances course organizers can be very flexible and adapt a part of the course programme to meet a particular training need the manager has identified. Universities and training institutes are generally very accommodating and will try to adapt the programme or provide additional study periods in a particular subject area.

### *Day-release programmes*

A day-release programme is far less of a drain on resources since the participant requires only a limited time away from the workplace and generally does not need to stay overnight. Such programmes allow participants to apply their new knowledge and skills as they learn them in the working environment.

### *In-service training programmes*

Expertise can be bought through local or international markets to prepare a training programme to meet your specific requirements.

Training materials that have already been prepared can be adapted for use in your particular environment. This process of adaptation should not be underestimated since it requires considerable expertise to adapt training materials. The manager must identify the right kind of expertise, allow sufficient time to prepare the materials and train the facilitators to teach it.

### *Training trainers*

In general, insufficient attention is paid to training the people who will train others. On occasion, the senior members of staff, or individuals considered more professionally qualified than the people they will teach, will assume the role of trainer purely because of their position and status. Experience and knowledge should always be respected, but not everyone has the skill to guide the learning process.

Everyone has experienced the learned professor or very successful executive director who, when asked to teach their subject, is incapable of presenting the knowledge in a coherent and interesting manner. An individual who can guide a participative learning process must have a number of skills that rarely come naturally. They must first be learned and perfected through practice.

Trainers should be selected for their ability to prepare and facilitate the learning process, and to inspire and motivate people to learn and apply the skills that are taught. Managers should spend time ensuring that they have skilled trainers because they are an invaluable resource that can be constantly employed in a variety of different settings to upgrade the skills of programme staff.

## Evaluation

The manager must ensure that the impact of the training programme is evaluated in the short and longer term. Assessment tools can be developed to monitor the immediate impact of any training experience. But the important aspect of learning is to determine how the new knowledge, skills and attitudes are applied in the place of work.

The manager should build into the supervisory process the capacity to monitor and support staff in performing their new skills. Performance should be audited regularly to ensure that the training has had a lasting impact.

# Fact Sheet 8

## Social Marketing of Condoms



Photo: WHO





# 8. Social Marketing of Condoms

## What is social marketing?

Social marketing means employing commercial marketing principles and techniques to advance a social cause, idea or behaviour. Social marketing has been used to advocate an idea or attitude, such as the importance of breast-feeding, but it is more often associated with the sale of socially useful products such as condoms through commercial and nongovernmental infrastructures at a subsidized price.

## Condom social marketing meets unmet needs

In principle, social marketing is not designed to take over or compete with public sector services but to support them by filling gaps not covered by traditional services. Public sector services may not be easily accessible for many people; they may be overcrowded, intrusive, lack privacy and open at hours that are not convenient. In addition, they generally provide a limited set of services geared to meet the needs of specific sectors of the population, such as married women, while neglecting others such as adolescents, unmarried couples and sex workers.

There is a need for a regular supply of health products which are both accessible and affordable to people with lower incomes. In many countries, products promoted and distributed as commercial goods are affordable only to the more affluent. People may well be aware of the value of condoms, both as contraceptives and as barriers for preventing the transmission of STDs/HIV. They may not, however, be able to afford to buy them at the normal unsubsidized commercial price.

Condom social marketing programmes sell condoms at a subsidized price. They promote the use of condoms through effective communication

techniques and programmes that ensure that condoms are available and affordable by developing extensive distribution networks.

Condom social marketing programmes have sold millions of condoms and can claim success in using innovative sales, distribution and communications to promote the consistent use of condoms.

## Product and price

Research has demonstrated that people tend to place more value on something they pay for than on something they get for nothing. The act of payment implies choice and quality, and people are more likely to use a condom they decide to buy rather than one that is given away free of charge.

Products sold by social marketing programmes are generally heavily subsidized. The subsidies are normally provided by donors, governments or nongovernmental organizations which either supply free condoms or give financial support for programme activities. The subsidy enables the programme to sell the condoms at a fraction of the normal price while still generating sufficient income to provide a small profit margin for the retailer and, sometimes, to offset some of the running costs of the programme.

A condom social marketing programme must determine the price people can afford and are willing to pay. People will only buy a product that they believe is of good quality and meets their needs. The condom offered by the condom social marketing programme must match the quality of those on sale in the commercial sector with design attributes that are acceptable to the target



population. If a socially marketed condom does not meet these criteria, sustained use of the product will not be achieved

### Market research

Market research is essential for successful marketing and promotion of condoms. Carefully planned research gives guidance in product design and selection, package design, advertising and promotion, and distribution. Market research can also help to identify proper pricing – the level at which most people in the target market will be able to afford the condoms, and will value them and use them.

### Packaging

The brand name and packaging speak to the customer at the point of sale and at the time of use, and it is vital that the messages they convey encourage people to buy and use the condoms.

Just as there may be need for different advertising messages for different target groups, different brand names and packaging messages may also be needed in the form of different brands for different target groups. Once again, market research techniques can assist in selecting brand names and package designs.

### Promotion

Experience over the last decade confirms that advertising combined with a well organized condom social marketing programme works. There are many examples of dramatic increases in condom use in countries that have actively promoted the use of condoms as part of STD/HIV prevention programmes. Ethiopia, Thailand, Uganda and Vietnam provide notable examples.

There are also many examples of condom social marketing programmes that have used a variety of innovative promotional techniques to create the recognition of a brand name that is synonymous with good quality.

Mass media advertising, radio, talk-shows, drama, the use of logos, peer group educators, sales agents, puppet shows, traditional storytellers, posters, advertising placards and educational materials are all techniques that contribute to increasing the numbers of consumers who choose to use condoms to protect themselves and their partner.

These promotional techniques are designed not only to promote the acceptability of the product, but also to effect behavioural change. They focus on messages that reinforce positive images associated with responsible sexual behaviour. This in turn can contribute to destigmatizing the use of condoms and making them socially and culturally acceptable.

### Availability

Promotion has no value if the product is not available on the market at a price people are willing to pay. The competent manager of a condom social marketing programme knows that the product must be in stock in at least 90% of the outlets promised in the advertising before a single cent is spent on advertising to the public. Advertising is the most costly way to “buy” distribution.

Condom social marketing programmes tend to take advantage of the multitude of different retail outlets and their traditional suppliers to ensure that the product is accessible to the target population. Retail distribution networks are an established part of society. They are responsible for the distribution of most of life’s necessities to

both rich and poor. As with all commercial transactions, both the retailer and the supplier receive a margin of the profit on the condoms that are sold.

There are numerous examples of condom social marketing programmes combining the use of traditional retail outlets with alternative means of distribution (e.g. community-based distribution and the use of nontraditional outlets such as tea shops, bars, kiosks, cigarette vendors, clubs, factories, mines and other places of work).

The most important aspect of availability is to ensure that a constant supply of condoms is available at an outlet that is acceptable to the target population. Without adequate supplies, retailers and suppliers both lose sales, the condom social marketing programme loses a great deal of credibility, and even more resources are required to regenerate demand for the product.

### Accessibility

Accessibility means not only ensuring a supply of condoms but also ensuring that people have access to condoms when they need them.

Recent experience in marketing condoms for STD/HIV prevention programmes suggests that targeted distribution systems have great potential for reaching specific populations and risk groups.

For example, funds can be allocated to create a special sales force that ensures stocks of condoms in nightclubs, bars and hotels where high-risk sex is negotiated and takes place. Special youth-friendly outlets can be created for adolescents; women's groups can sell condoms and teach women how to negotiate condom use.

Once a market is created it is important to ensure the continuity of supplies; government, donors and programme managers share this responsibility. The key role of government and donors in subsidized condom social marketing programmes is to ensure that the supply and the subsidy are there when needed. The programme manager's responsibility is to ensure that sufficient good-quality condoms are available when people want to use them and at an affordable price.

### Targeted marketing

Targeted marketing goes further than simply designing media messages; it should also foresee and address the implications and consequences of marketing condoms as a commercial product.

For example, adolescents require advertising images that correspond to their perceptions and aspirations. Yet aggressive advertising directed to some special target group might have the perverse effect of drawing negative attention to that particular group, thus making it more difficult for them to have access to condoms.

Targeted marketing involves both the strategic planning of accessible outlets and advertising where and when the product is sold in order to let the target group know the availability of supplies.

The one great advantage of condom social marketing is the relative anonymity of the retail transaction. The retailer offers a product for sale, the customer exchanges money for it, and the deal is done. There is a degree of privacy within social marketing of condoms that should be maintained.

### Monitoring and evaluation

Like any commercial marketing campaign, a condom social marketing programme will be planned with expenditure and revenue budgets, sales targets and forecasts. Professional marketers working within the programme will expect to be rewarded for the success of the programme, as measured by achievement against budgets and targets. A procedure for monitoring progress and evaluating achievement at key intervals will enable managers to make changes and improvements to the campaign as it progresses.

### Who should manage a condom social marketing programme?

When the programme is funded by agreement between a donor and the host government, the host government will in most instances retain overall control over finances and policy. It must be recognized, however, that government ministers and officials are not marketing experts, and the planning and strategy of the campaign should be placed squarely in the hands of marketing professionals.

Serious consideration should be given to entrusting a local marketing company with the planning and execution of the condom social marketing programme. When there are several such companies, they should be invited to present plans and budgets for the programme in a competitive tender.

If no suitable company can be found within the country, there are several nongovernmental organizations in the United States and in some European countries which specialize in managing social marketing programmes. These agencies will create a marketing infrastructure, using both local

personnel and expatriates, and provide training to develop the skills of local staff. They will normally be able to use existing local distribution resources, providing training where necessary to adapt the system to the needs of the programme.

When an international nongovernmental organization manages the condom social marketing programme, it will normally work with a local nongovernmental organization, sometimes one that already exists and sometimes one that is specially created for the purpose. Over time, the aim will be to transfer management completely to the local organization so that the international one can withdraw its personnel and deploy them in some other country where they are needed.

### Can condom social marketing programmes become self-sustaining?

A condom social marketing programme is by definition subsidized and the simple way to eliminate the subsidy is to increase the price to meet the real cost. In theory, it is possible to make a condom social marketing programme self-supporting overnight by raising prices to the full commercial level. However, this would probably undermine the social purpose of the programme because the people the programme wishes to reach would simply not be able to afford the new prices.

In some countries, as sections of the population become more prosperous, so their ability and readiness to pay higher prices for necessities increases. In Barbados, Colombia, Indonesia and Mexico, prices have been raised progressively, enabling donors gradually to withdraw their subsidy and use funds elsewhere. Timing is important and donor cooperation is essential if a seamless transition is to be made from a subsidized to a self-sustaining programme.

With mature condom social marketing programmes, market segmentation may permit product differentiation. In other words, revenue generated from higher-priced brands introduced into the product line can be used to subsidize lower-priced items. Over time, increased sales volumes and improved programme operating efficiencies can also contribute to greater self-sufficiency.



# Fact Sheet 9

## Male and Female Synthetic Condoms







# 9. Male and Female Synthetic Condoms

### What are synthetic condoms?

Synthetic condoms are made from thermoplastic elastomers including polyurethanes. The development of different types of synthetic condom is always a protected, proprietary venture, with the product generally subject to expensive clinical trials before being approved for use. The synthetic condom has a number of design characteristics, including greater sensitivity, greater strength, longer shelf-life, and freedom from allergic reactions, odour and taste. It can also be used with a wider range of lubricants. These attributes should make synthetic condoms an attractive alternative to natural rubber latex condoms.

### Why is it necessary to develop synthetic condoms?

Until recently, the male latex rubber condom has been the only mechanical device available that, if used correctly and consistently, can protect against unwanted pregnancy and the transmission of STDs/HIV/AIDS. In the past decade there has been a marked increase in the use of condoms as a result of the heavy promotion they have received from national family planning and STD/HIV prevention programmes. Yet despite the proven efficacy of natural latex condoms, there is still a major credibility gap when it comes to actual use.

Research has shown that some people have a deep-rooted resistance to using a barrier during intercourse. People believe that it interferes with the pleasure of sex, complaining about loss of penile sensation, product odour and taste. Couples do not use condoms consistently and women experience difficulties in negotiating the use of a condom with their partners. While there is little reason to believe that synthetic condoms will solve these problems, a broader choice of products with

different design features is likely to attract additional users.

In response to public health interest in promoting increased use of condoms, considerable resources have been invested in the research and development of alternatives to latex condoms. Manufacturers have been researching new technologies and materials to develop a more acceptable product.

Although several different types of male and female condom designs are under development the past three years have seen only one female and three male synthetic condoms approved for marketing.

### The female condom

The female condom is manufactured by Chartex International plc, United Kingdom, which is now owned by the Female Health Company located in Chicago, IL, USA. The female condom is marketed in approximately 20 countries under the trade names Femidom, Reality, Femy and Femshield.

The female condom is a strong and soft transparent sheath made of polyurethane and intended for prevention of unwanted pregnancy and STDs, including HIV. The sheath has a flexible ring at each end. The smaller ring at the closed end is used for insertion and helps keep the device at the upper end of the vagina. This ring is removable.

The larger and thinner outer ring remains outside the vagina when the condom is inserted and anchors the condom so that the sheath partially covers the external genitalia as well as the base of the penis during intercourse. It is pre-lubricated with a silicone-based lubricant and extra lubricant is also supplied.

The condom is inserted manually into the vagina before intercourse.

The female condom can be inserted several hours before intercourse and does not have to be removed immediately after intercourse. Neither removal nor insertion requires an erect penis.

### *Can the female condom be used more than once?*

At present, the female condom is marketed for single use but research is currently being undertaken to determine the safety, efficacy and acceptability of re-use.

### *Can the female condom protect against unwanted pregnancy and STDs/HIV?*

Independent studies as well as those carried out by Chartex confirm that the female condom can provide an effective barrier to gases, liquids and organisms smaller than those known to cause STDs, including cytomegalovirus, herpes virus, hepatitis B virus and HIV.

From the limited evidence available it appears that, when used *consistently and correctly*, the female condom can be an effective method of contraception.

It would appear to reduce the exposure of the female genital area to seminal fluid and the polyurethane is stronger and theoretically less likely to break than the latex male condom.

It should be noted that while the female condom provides more protection than the male condom from exposure of the external genitalia to STDs, the area is not totally covered so there is still some potential for exposure and transmission of such STDs as HPV, HSV and syphilis.

More research is needed and is currently being undertaken on the efficacy of the female condom as a contraceptive and barrier to transmission of STDs/HIV.

### *Are couples really using the female condom?*

Acceptability studies in more than 30 countries have demonstrated that the female condom is acceptable to women from different population groups. It can be used at any age, and men reacted positively to it.

Women who continued to use the female condom felt that it increased their contraceptive choice, their sense of being protected, and their sense of control over their own sexual health. Good counselling and other information materials contributed to their satisfaction with the method.

(For full details, refer to the WHO/UNAIDS Information Pack *The Female Condom*, published April 1997.)

## Synthetic male condoms

Working with the London International Group, Apex Technologies has developed and marketed the Avanti Superthin Condom. This condom is made from Duron and looks similar to a straight-sided reservoir-tipped latex condom.

Previously known as Tactyl Technologies Inc., Sensicon Corporation is developing three types of male condom made from a non-latex elastomer formulation of styrene ethylene butylene styrene (SEBS) which can be formulated to mimic the elastic properties of latex. The three designs are similar to a standard condom, a baggy condom and a low modulus standard condom, which is more elastic and has higher elongation.

Carter Wallace Inc. is currently developing two variations of one design, presently called the Trojan Male Condom. Both condoms have a tensile strength and breaking force higher than the latex condom. One will be lubricated with silicone and the other with Nonoxynol-9 and silicone.

Ezon is a synthetic thermoplastic elastomeric condom developed by Family Health International (FHI) but will be manufactured and marketed by Mayer Laboratories. This condom consists of a baggy sheath with a double-layered collar at the open end. This collar is used for gripping and makes it easier to put the condom on; unlike the traditional condom, it can be slipped onto the penis without unrolling in one direction. This reduces the interruption of putting on the condom and the baggy shape may increase sensation for men who feel constricted by a tighter fitting latex condom.

Ortho-McNeil Pharmaceutical of Canada has developed a synthetic elastomeric condom and hold the patent on the manufacturing process, the new condom and the use of the specific polyester polyurethane.

(For full details, refer to the WHO/HRP *Report and Recommendations of a WHO Consultation on Preclinical and Clinical Requirements for Non-Latex Male Condoms, Geneva, 13–15 May 1996.*)

### Are synthetic condoms expensive?

The cost and complexity of developing and manufacturing synthetic condoms and the higher cost of the raw materials means that they are relatively more expensive than the latex condom which may make them unaffordable to poor consumers.

In an effort to overcome this problem, WHO in coordination with UNAIDS has negotiated public sector pricing agreements with the Female Health Company to purchase the female condom for less than US\$1.00.

### What are the advantages of synthetic condoms?

Synthetic elastomeric condoms:

- tend to be stronger than latex;
- tend to be odourless;
- will not deteriorate with oil based lubricants;
- can be used by people who are allergic to latex;
- can be formulated to feel thinner than they actually are;
- are reported to allow more sensitivity than the latex condom.

The female condom is one extra tool, which increases the options women/couples have to control their own fertility and prevent the transmission of STDs, including HIV.

### What are the regulatory requirements?

Non-latex condoms have physical properties different from those of latex condoms. Manufacturers have had to submit detailed information, including a full range of pre-clinical data on the material, its manufacturing process and its safety before conducting clinical studies.

The WHO Consultation on Preclinical and Clinical Requirements for Non-Latex Male Condoms, 13–15 May 1997, reviewed the scientific

evidence and recommended that lengthy and expensive contraceptive efficacy trials are not needed in order to provide assurance that condoms made from the new materials are as safe and effective as latex condoms. If slippage and breakage rates of the new condoms are equivalent to those of conventional latex condoms, there is no reason to expect significantly different rates of contraceptive efficacy.

# Fact Sheet 10

## Bibliography and Further Resources





# 10. Bibliography and Further Resources

The Condom Programming Fact Sheets provide the reader with an introduction to the many facets of condom programming for STD/HIV/AIDS prevention, as well as for family planning. For those interested in studying the subject further, this bibliography lists a selection of recommended further reading that can help those working in country programmes to gain added skills in programme management.

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## Useful Contacts:

*Requests for further information about condom programming may be made to the following organizations:*

DKT, 1120 Nineteenth Street, NW, Suite 600,  
Washington DC 20036, USA  
*Tel.: (1 202) 785 0094; Fax: (1 202) 223 5351*

ENERSOL Consulting Engineers, 127 Trafalgar  
Street, Annandale, NSW, 2038 Australia  
*Tel.: (61 2) 552 1707; Fax: (61 2) 552 1709*

Family Health International (AIDSCAP), 2101  
Wilson Boulevard, Suite 710, Arlington, VA 22201,  
USA  
*Tel.: (1 703) 516 9779; Fax: (1 703) 516 9781*

Futures Group, SOMARC Project, 1050 Seventeenth  
Street, NW, Suite 1000, Washington, DC 20036,  
USA  
*Tel.: (1 202) 775 9680; Fax: 1 202) 775 9694*

International Family Health (IFH), Fifth Floor,  
Parchment House, 13 Northburgh Street, London,  
EC1V 0AH, United Kingdom  
*Tel.: (44 1 71) 336 6677; Fax: (44 1 71) 336 6688*

International Organization for Standardization  
(ISO), 1, rue de Varembe, case postale 56, CH-1211,  
Geneva 20, Switzerland  
*Tel.: (41 22) 749 01 11; Fax: (41 22) 634 0111*

Johns Hopkins University, Center for  
Communication Programs, School of Hygiene and  
Public Health, 111 Market Place, Suite 310,  
Baltimore, MD, 21202-4012, USA  
*Tel.: (1 301) 659 6300; Fax: (1 301) 659 6266*

Joint United Nations Programme on HIV/AIDS  
(UNAIDS), 20 Avenue Appia, CH-1211, Geneva 27,  
Switzerland  
*Tel.: (41 22) 791 21 11; Fax: (41 22) 791 4880*

Marie Stopes International, Marie Stopes  
Consultancy, 153-157 Cleveland St., London W1P  
5PG, United Kingdom  
*Tel.: (44 1 71) 383 2494; Fax: (44 1 71) 388 1884*

Population Services International (PSI), 1120  
Nineteenth Street, NW, Suite 600, Washington DC  
20036, USA  
*Tel.: (1 202) 785 0072; Fax: (1 202) 785 0120*

Program for Appropriate Technology in Health  
(PATH), 4 Nickerson Street, Seattle, WA 98109,  
USA  
*Tel.: (1 206) 285 3500; Fax: (1 206) 285 6619*

United Nations Population Fund (UNFPA), 220  
East 42nd Street, New York, N.Y 10017, USA  
*Tel.: (1 212) 297 5211; Fax: (1 212) 370 0201*

World Health Organization, Family Planning and  
Population, Division of Reproductive Health  
(Technical Support), Avenue Appia, CH-1211  
Geneva 27, Switzerland





## Condom Manufacturers

These lists are provided for the information of the reader and may not be comprehensive.

Appearance on these lists does not imply endorsement by WHO or UNAIDS.

*WHO does NOT maintain a list of pre-qualified suppliers.*

*Experience has shown that manufacturers' quality systems and product quality may vary over time and WHO could not guarantee the accuracy of such a list.*

*WHO conducts a pre-qualification process before each new contract is let.*

*WHO will supply a list of potential suppliers and testing laboratories on request.*

Assistance in compiling this list provided by  
Enersol Consulting Engineers

# Condom Manufacturers

Appearance on these lists does not imply endorsement by WHO or UNAIDS.

Aladan Corporation (manufacturing division),  
4725 Peach Tree Corners Circle, Suite 150,  
Norcross, GA 30092, United States of America

Ansell (America), 1500 Industrial Road, P. O.  
Box 1252, Dotham, Alabama 36302, United  
States of America

Beiersdorf (Malaysia) Sdn Bhd, Karung  
Berkunci No 786, 80990 Johor Baru, Malaysia

Bimacom Perdana Rubber Industry, Wisma  
BCA, 5th Floor, Jalan Jend. Sudiman Kav.  
22-23 Jakarta 12920, Indonesia

Blowtex, Fabrica de Artefaos de Latex Ltd,  
Estrada do Briquituba, 550-Caixa Postal 01,  
18125-000 Aluminio, Sao Paulo, Brazil

Carter Wallace Inc, 1851 Touchstone Road,  
Colonial Heights, Richmond, Virginia 23834  
United States of America

Chinteik Hygiene Products Co. Ltd, 5  
Sukhumvit 3 Road, Bangkok 10110, Thailand

CPR Productions-Und Vertiebs GmbH,  
Im Kirchenfelde 8, 31157 Sarstedt, Germany

Cupid Rubbers Ltd (factory), A68, M.I.D.C.,  
Sinnar, Malegaon, Nashik, India

Da Lian Latex Factory, 188 Ma Lian Bei Jie,  
Sha He Kou district, Da Lian 116021, People's  
Republic of China

Dongkuk Techno Rubber Industries Sbn.  
Bhd, 7th floor, Wisma Manilal, 3 Penang  
Street, 10200 Penang, Malaysia

Dongkuk Trading Co. Ltd, Dongkuk Building  
556-27, Sinsa-dong, S1 Kangam, P.O. Box 270  
Seoul, Korea

Eisai Company Ltd, Overseas Operations, 6-01,  
Kolshikawa, 4-Chome, Bunkyo-ku, Japan

Everts Erfurt GmbH, Tiergartenstr.2, 99089  
Erfurt, Germany

Fuji Latex Co. Ltd., 19-1, 3-chome, Kanda  
Nishiki-cho, Chiyoda-ku, Tokyo 101, Japan

G P Prophylactics SA Pty Ltd, P. O. Box  
22665, Southgate Piertermaritzburg,  
South Africa

Greenmate Medical Supplies Corp, 1143-10  
Seocho Dong, Seocho Ku, Seoul, Korea

Guang Zhou Latex Factory, 90 Gong Ye Da  
Dao Bei, Hai Zhu district, Guang Zhou,  
People's Republic of China

Gui Lin Latex Factory, Jia Shan, Guilin  
541001, People's Republic of China

Hanarum Rubber Tech. Sdn Bhd,  
No 9-12 Jalan Makmur 2, Taman Makmur  
Industrial Area, 09600 Lunas, Kedah, Malaysia

Hankook Latex Gongup Co. Ltd, 406-3  
Shindang 2 Dong, Chung Ku, Seoul 100, Korea

Hatu S.p.A, Divisione Articoli Ingienico  
Sanitari, Via Agresti, 40123 Bologna, Italy

Hindustan Latex Ltd., No 2 Peroorkkada,  
Thiruvananthapuram, Kerala 695 005, India

Hindustan Latex Ltd., Kanagala, Belgaum  
Dist., Karnataka, India

Industria Nacional de Artefatos de Latex Ltd,  
Av. Piracicaba, 137, Caixa Postal 213, 181300-  
000, Marmeleiro-Sao Roque, Sao Paulo, Brazil

J. K. Chemicals Limited, Mahindra Towers,  
B-Wing, 2nd Floor, Pandurang Budhkar  
Marg, Worli, Bombay 400 018, India

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Johnson and Johnson deo Brasil, Industria e Comercio Ltda, Rod. Pres. Dutra, dm 157, Caixa Postal 184, 12240-420 Sao Jose dos Campos-SP, CEP: 12237-350, Brazil

Karex Industries Sdn Bhd, PTD 7906 & 7907 Taman Pontian Jaya, Bt 34, Jalan Johor, 82000 Pontian, Johor, Malaysia

Laboratorios Hispano-ICO SA, Puerto Principe 68, 08027 Barcelona, Spain

L.A. Falcao Bauer, Rue Aquinos, 111, 05036-070 Sao Paulo SP, Brazil

Latex Surgical Products (PTY) Ltd, Pieterwessels St., Stafford Ext, 4 Gauteng, P.O. Box 57037, Springfield, 2137, South Africa

London International Group plc, 35 New Bridge Street, London EC4V 6BJ

London International Group plc, P. O. Box 8308, Dothan, Alabama, 36304, United States of America

London Royal Consumer Products, Wellgrow Industrial Estate, 100 Moo5, Bangna-Trad KM36, Bangpakong, Chachoengsao 24130, Thailand

Lord Hygiene-Curafam GmbH, Im Schlangengarten, 76877 Offenbach/Landau, Germany

MAPA GmbH, Postfach 1260, D27392 ZEVEN, Germany

Mayer laboratories Inc, 646 Kennedy Street Building C, Oakland, California, 94606, United States of America

Medilatex Sdn Bhd, Lot PTB 500, Kawasan Perindustrian, Pkt. 2, Bandar Tenggara, 81000 Kulai, Johor Darul Takzim, Malaysia

Merufa, 38 Truing Quoc Dung Street, Phu Nhuan District, Ho Chi Minh City, Viet Nam

MPA Darmstadt, Staatliche Materialprüfungsanstalt Darmstadt, Grafenstr. 2, 64283 Darmstadt, Germany

Okamoto Industries, Inc., No 1 Aza Nishiyama, Itabashi-cho, Ryugasaki-shi Ibaraki-ken, Japan

Pashupati Seohung, 15/1A Loudon Street, Calcutta 700 017, India

Polar Latex Ltd, Poddar Point, 113 Park Street, Calcutta 700 016, India

Profilatex, No. 4 Febrero de 1917, No 4 Chalco, Edo, Mex, Mexico C.P. 56600

Qing Dao Latex Factory, 103 Taidong 1st Road, Qing Dao 266022, People's Republic of China

Reddy Medtech Health Products, 8 Park View Road, United India Colony, Kodambakkam, Madras, India

Remed S.A., Chaussée d'Alseberg 1001, B-1180 Brussels, Belgium

RFSU, Bergvagen 8 A, S-186 41, Vallentuna, Sweden

Ritex Gummiwarenfabrik GmbH, Postfach 180 182, 33691 Bielefeld, Germany

Sagami Industries (Malaysia) Sdn (Berhad), P. O. Box 387, Ipoh 30750, Malaysia

Sagami Rubber Industries Co. Ltd, 2-1 Moto-cho, Atsugi-shi, Kanagawa-Ken 243, Japan

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Vista, California 92083, United States of  
America

Seohung Industrial Co. Ltd., Songpa, P. O.Box  
88, Seoul, Korea

Shang Hai Latex Factory, 1700 Huang Xing  
Road, Shang Hai, People's Republic of China

Shangrila Latex Industries, Munshi Manor,  
20 Altamount Road, Bombay 400 026, India

Shen Yang Latex Factory, 67 He Ping Bei Da  
Jie, He Ping district, Shen Yang, People's  
Republic of China

Shinheng Corporation, Yeongdong, P. O. Box  
371, Seoul, Korea

Sime Healthcare Sdn Bhd, 3rd Floor, Wisma  
Consplant, No 2 Jn SS 16/4 Subang Jaya, 47500  
Petalong Jaya, Senglor DE, Malaysia

Suretex Ltd., 71 Sap Road, Sipraya, Bangrak,  
Bangkok, Thailand

Suretex Prophilatex (India) Ltd, No 1483,  
40th Cross, 18th Main, 4th T Block, Jayanagar,  
Bangalore 560 041, India

Takaso Rubber Products Sdn Bhd, No 4 & 5,  
Lorong Jelawat (2), Taman Sungai Abong,  
84000 Muar, Johor, West Malaysia, Malaysia

Thai Nippon Rubber Industries, 1  
91-193 Jarusmuang Road, Soi Chula 16,  
Patumuang, 10330 Bangkok, Thailand

Teenilatex, Fraguas 2, 28923 Alcorcón, Madrid,  
Spain

Tian Jin Latex Factory, 240 shan Mar Road,  
Hebei district, Tian Jin, People's Republic of  
China

TTK-LIG Limited, 6 Cathedral Road,  
Chennai 600 086, India

UNIMIL Co. Ltd, ul. Gesia 8, 31-535 Krakow,  
Poland

UNIMIL Co. Ltd, ul. Towarowa 8, 32 410  
Dobczyce, Poland

Vonix P.T, Jl Balik Papan 21 E., Jakarta,  
Pusat, Indonesia

Vulkan Akciova Spolecnost, 46334 Hrádek  
nad Nisou, Czech Republic

The Female Condom,  
1 Sovereign Park Coronation Road,  
Park Royal, London NW 10 7QP

*Note:* The mention of specific companies or products from certain manufacturers does not imply that they endorsed or recommended by WHO and UNAIDS in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

If there are any inaccuracies in the names and address of companies, or the name of your company has not been included in the list please contact WHO, Family Planning and Population, Division of Reproductive Health Technical Support, Avenue Appia, 1211 Geneva 27, Switzerland. The list will be updated and amended at periodic intervals.

# Testing Laboratories and other Services

Appearance on these lists does not imply  
endorsement by WHO or UNAIDS.

Akron Rubber Development Laboratory  
2887 Gilchrist Road, Akron, Ohio 44305  
United States of America

Apoteksbolaget, AB, Centrallaboratorlet  
(ACL), 105 14 Stockholm, Sweden

Crown Agents, St Nicholas House, Sutton,  
Surrey SMI 1EL, United Kingdom

Enersol Consulting Engineers,  
127 Trafalgar Street, Anmandale, New South  
Wales 2038, Australia

Family Health International (FHI),  
2224 East Chapel Hill-Nelson Hwy, Durham,  
North Carolina 27713, United States of America

Instituto Nacional de Tecnologia, Avenida  
Venezuela n<sup>o</sup>82 sala 108, Rio de Janeiro RJ,  
CEP 20081-310, Brazil

Institut National de la Consommation,  
80, rue Lecourbe, 75732 Paris Cedex 15, France

Laboratoire National d'Essai (LNE),  
1, rue Gaston Boissier, 75724 Paris Cedex 15,  
France

PATH, 4 Nickerson St., Seattle, WA 98109,  
United States of America

Rubber research Institute of Malaysia,  
Department of Chemistry & Technology, 260  
Jalan Ampang, 50450 Kuala Lumpur, Malaysia

SGS India Ltd., General Laboratory,  
SGS Lab House, 21 New Street, Kottur,  
Chennai, 600 085, Madras, India

Singapore Productivity and Standards Board,  
PSB Building, 2 Bukit Merah Central,  
Singapore 159835

Smithers Scientific Service, Inc., 425 West  
Market Street, Akron, Ohio 44303,  
United States of America

Societe Generale de Surveillance, 1 Place des  
Alpes, P. O. Box 2152, 1211 Geneva,  
Switzerland

Swiss Federal Laboratories for Materials  
Testing and Research (EMPA),  
Unterstrasse 11, 9001 St Gallen, Switzerland

Tanda Associates, P. O. Box 91091, Bayview  
Village post office, North York, Ontario,  
M2K 2Y6, Canada

Thai Industrial Standards Institute, Stand-  
ards Bureau 3, Rama VI Street,  
10400 Bangkok, Thailand

Zimbabwe Regional Drug Control Laboratory  
(ZRDCL), 106 Baines Avenue, P.O. Box UA  
319 Union Avenue, Harare, Zimbabwe

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