

Condom and lubricant programming in high HIV prevalence countries

Resource kit for high-impact programming

This Guidance Note is part of the resource kit for high-impact programming that provides simple, concise and practical guidance on key areas of the AIDS response. The resource kit is developed by the Joint United Nations Programme on HIV/AIDS. The resource kit can be accessed at <http://www.unaids.org/en/ourwork/programmebranch/countryimpactsustainabilitydepartment/globalfinancingpartnercoordinationdivision/>.

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The development of this guidance note was led by United Nations Population Fund (UNFPA) in close collaboration with UNAIDS Secretariat and with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). This guidance note provides simple, concise and practical guidance on condom and lubricant programming. References and links to full guidelines are provided in the last section of the Guidance Note.

WHAT IS NEW?

- *Ending HIV and AIDS in Adolescents: Programmatic and Implementation Science Priorities, 2014* (<http://journals.lww.com/jaids/toc/2014/07011>).
 - WHO launched their consolidated guidance for key populations (2014) which includes information on condom and lubricant programmes for men who have sex with men, sex workers and transgender populations (<http://www.who.int/hiv/pub/guidelines/keypopulations/en>).
 - In July 2012, a new design, the *Cupid Female Condom*, was prequalified by UNFPA/WHO in addition to the FC2 by Female Health Company. Other new designs are expected to be reviewed and possibly proceed to the inspection stage of prequalification in 2014.
 - In 2013, the Gates Foundation launched the Condom Grand Challenges Explorations (GCE) for the development of the *Next Generation of Condoms*. Hundreds of selected projects received US\$100 000 each in funding to develop further their ideas for about six months. The second phase will award the best ideas with US \$1 million to complete the research and development, as well as clinical studies of the new condoms.
 - *Condom use and problems: a global view*. Systematic literature review of 50 articles on condom use failures, 14 countries and a diverse set of populations (<http://www.ncbi.nlm.nih.gov/pubmed/22348636>).
 - *Total market approach case studies (UNFPA/PSI) 2013*. These case studies describe the condom market for male condoms in six Sub-Saharan countries (Botswana, Lesotho, Mali, South Africa, Swaziland and Uganda) and the role of public, social marketing and commercial sectors (<http://unfpa.org/public/home/publications/pid/16089>).
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Introduction

This guidance note is primarily targeted at high HIV prevalence countries and should be read in conjunction with the guidance note on social and behaviour change, and other guidance on voluntary medical male circumcision, and treatment for HIV. Condom promotion and distribution in epidemics should be part of holistic and integrated programmes for key populations. This is elaborated in separate guidance notes for key populations.

Condom and lubricant programming is highly effective in preventing sexual transmission of HIV. The consistent and correct use of the male condom significantly reduces HIV during vaginal (80%)¹ and anal sex (70%).² Female condoms can provide protection by approximately 97%,³ making them among the most effective prevention technology available today, exceeding consistent use of antiretroviral therapy (ART) in reducing HIV transmission (86–96%)⁴ and pre-exposure prophylaxis (up to 92%).⁵

Condoms are far from a new phenomenon. Historically, barrier methods to prevent fluid exchange started with the ancient Egyptians and Chinese, with the oldest-ever condoms dating back to 1640. Condoms have had a transformative impact on the trajectory of the HIV epidemics worldwide. Even before it was known that HIV was the causative agent of AIDS, men who have sex with men pioneered condom use in the US in the early 1980s. Condoms played a key role in curbing the early epidemics in Brazil, India, Thailand, South Africa and to some extent Uganda and Zimbabwe.

Despite progress made towards prevention of HIV over the past three decades and promising new prevention technologies becoming available, insufficient levels of condom use continue to drive the epidemic in many locations. Intensified efforts are urgently needed to increase condom programming in high prevalence countries. In 2012 the donor community supplied a mere 3 billion male condoms and 32 million female condoms.⁶ This translates into eight male condoms per man per year and one female condom for every eight women in these high HIV prevalence countries. Information on the purchase of condoms by the domestic public sector or through commercial channels is not available.

Female and male condoms are a familiar and convenient prevention method to most people and, for many, the only viable option to prevent HIV and unwanted pregnancy. Female and

- 1 Weller S and Davis K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database Syst Rev* 2002, (1). Hearst N and Chen S. Condoms for AIDS prevention in the developing world: A review of the scientific literature. San Francisco CA: University of California; 2003 Pinkerton SD and Abramson PR. Effectiveness of condoms in preventing HIV transmission. *Soc Sci Med*, 1997,44(9):1303–1312. Holmes KK, Levine R and Weaver M. PhD. Effectiveness of condoms in preventing sexually transmitted infections. *Bulletin of the World Health Organization*, 2004, 82(6): 454–461.
- 2 Smith D et al. Condom efficacy by consistency of use among men who have sex with men: US 20th Conference on Retroviruses and Opportunistic Infections (CROI 2013), Abstract 32. Atlanta GA, 3–6 March, 2013.
- 3 Trussel J et al. Comparative contraceptive efficacy of the female condom and other barrier methods. *Family Planning Perspectives*, 1994, 26(2): 66–72.
- 4 Cohen MS et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*, 2011, 365(6):493–505.
- 5 CDC. *HIV/AIDS: Pre-exposure Prophylaxis (PrEP)*. CDC, Atlanta; 2014 Available from: <http://www.cdc.gov/hiv/prevention/research/prep>.
- 6 DFID, Global Fund, IPPF, KfW, MSI, PSI, UNFPA, USAID (DKT data on male and female condoms were unavailable for 2012).

male condoms are easy to use and store, do not require medical prescriptions or health-care personnel/facilities and can be utilized by anyone who is sexually active, subject to availability. Effective condom programming requires investments into commodities but also demand-generating efforts to sustain their correct and consistent use.

Female and male condoms are inexpensive and cost-effective. They reduce incidence, morbidity, mortality and unwanted pregnancy and may result in cost savings for the health-care and social sectors. With further proven impact on reducing sexually transmitted infections (STIs),⁷ condoms are an essential public health investment to enable countries to achieve global health and development goals. Condom and lubricant programming is a basic programme area in the UNAIDS Investment Framework, and female and male condoms and lubricants should be a key component of all HIV prevention and care packages.

1. Key elements

Comprehensive condom programming (CCP) involves the development, implementation and monitoring of strategic collection of activities to increase distribution and expand access and consistent, correct and sustained use of female and male condoms in low- and middle-income countries. (See Annex 1 for more details on the CCP framework.)

Leadership and coordination

National AIDS coordinating authorities coordinate and manage HIV prevention activities and strengthen their decentralized structures to play the same managerial role at the district and community levels. Their role includes ensuring that condom and lubricant programming efforts are strategic, efficient through continued coordination with relevant national and international partners and donors, and that earmarking for condoms and lubricants exists in STI, sexual and reproductive health (SRH) and HIV budgets. Besides good coordination, condom programmes require policy analysis and routine monitoring and evaluation to ensure quality and coverage. Situation analysis as well as market and social research need to be repeated periodically to track changes in demand and progress on knowledge, attitudes, norms and use. Condoms must be included in national essential Drug Lists, and taxes and tariffs on condoms and lubricants removed to ensure greater availability.

⁷ 70% against gonorrhoea, 50–66% against syphilis, from 26%– 85% against chlamydia and trichomoniasis and approximately 73% against HPV acquisition for women. Estimates of efficacy against HSV-2 (genital herpes) infection vary considerably; a meta-analysis has estimated that using condoms more than three-quarters of the time halves the chance of acquiring HSV-2, and may reduce the chances of genital infection with the cold sore virus (HSV-1)

Condom promotion and distribution

Experience has shown that condom distribution and private sector efforts alone are inadequate to ensure robust condom uptake and use. Even in countries where condom use is relatively high, consistent use may be low, emphasizing the continued importance of demand generation. Demand-generation activities increase awareness and stimulate demand for female and male condoms among a particular target audience through focused social and behaviour change communication, social marketing efforts and community mobilization.

Social and behaviour change communication

Individuals must be motivated to use condoms, and have the information and knowledge to use them consistently and correctly. Social norms shape the means people take to protect themselves from HIV or pregnancy, including their uptake and use of female and male condoms. Through awareness, sexuality education, social and behaviour change communication and community mobilization, knowledge levels may be improved and maintained among both clients and service providers as well as increasing and sustaining female and male condom uptake. Activities to promote female and male condoms, knowledge, skills building and favourable social norms in order to achieve behaviour change are often neglected and underfinanced. Campaigns, information materials (both print and digital), mass and traditional media, edutainment and arts-based activities in community settings, interpersonal/group communication, mass communication and mHealth applications must be developed specific to the target audiences and in suitable languages to support promotional efforts. Similarly, training of journalists, community workers and peer educators must be ensured together with access to penis and pelvic models for condom demonstrations.

Free distribution

Condom distribution allows condoms to be readily available to individuals either for free or at highly subsidized prices. Condoms should be made available at all sites where casual and commercial sex may occur. In addition, strategic locations for distributing condoms may include prisons, bars, brothels, schools, universities, military locations, workplaces, hotels, taxis, petrol stations, ports and other transport hubs, pharmacies, vending machines etc., depending on the local epidemic.

Social marketing

Condoms must be available at convenient places and be commensurate with user preferences and needs in terms of types, brands and sizes as well as willingness and ability to pay. Social marketing helps create access to a variety of condoms and brands at different price points. Social marketing is the application of marketing concepts and techniques including advertisement to influence behaviour among a target audience in order to benefit themselves and

their communities. It helps increase demand, access to and use of products. In this way, social marketing can help saturate coverage of high-risk areas, and encourage expanded access in rural and remote communities.

Total market approach

A total market approach ensures that male and female condoms for all population segments are available at affordable prices through effective coordination and collaboration between government and private sector companies. A total market approach is particularly critical when resources are becoming scarce and must be allocated as efficiently as possible in order to maximize coverage and health impact, and to strengthen the market for greater sustainability and equity in the long term. Best practice entails wide government distribution of free condoms for low income and vulnerable individuals, social marketing condoms for those with some but limited dispensable income, and private sector condoms for those with higher earnings.

Lubricants

Programmes should always make water- or silica-based lubricants available with condoms, particularly ensuring availability close to clients, and these are particularly recommended for use during anal intercourse to prevent condom breakage. Lubricants are highly important for men who have sex with men, sex workers and post-partum women. Little normative guidance exists on lubricants and they are not regulated like condoms and not all lubricants are safe. Oil-based lubricants weaken condoms and spermicide lubricants may irritate rectal and vaginal tissues. Providing lubricants in countries where anal sex is criminalized is difficult but is nevertheless an essential part of HIV prevention.

Procurement and supply management (PSM)

Programmes should purchase products that meet the diverse needs of clients. To ensure that the supply of condoms is matched with demand, countries need to accurately forecast condom needs. Different methods exist for forecasting. Condoms should always be procured according to national and international standards and specifications for quality assurance. Many varieties of fun and affordable female and male condoms have been prequalified by World Health Organization WHO/UNFPA and are available for procurement. Managing the PSM pipeline is important to ensure and maintain a regular supply of condoms.

Monitoring and evaluation (M&E)

Programmes must monitor and measure performance and incorporate regular quality appraisals and evaluations. A complete monitoring and evaluation system measures inputs (i.e. the number of people trained in condom counselling and distribution), outputs (e.g. the availability and quality of condoms), outcomes (i.e. changes in behaviour and key determinants of behaviour) and health impact (e.g. HIV infections, maternal deaths and STIs averted). Process evaluations are also essential to ensure that a particular programme is optimally delivered vis-à-vis its objectives (feasibility, coverage and acceptability) among different populations and assessed for its transferability with a view to bring successful programmes to scale.

M&E is an integrated part of comprehensive condom and lubricant programming and may be used for informing management, reporting and accountability, advocacy, learning and resource mobilization. Condom indicators are used to set targets, aims and objectives of the programme as well as planning activities. Baseline measurements should always be established to measure changes over time and to assess programme impact.

2. Focus populations

Female and male condoms are life-saving commodities that should be available to all sexually active women and men regardless of age, culture, economic or education, gender, marital status, religion or sexual orientation. Yet, focused and dedicated efforts are required to ensure that condoms are used by populations at higher risk and their sexual partners. National strategic plans must prioritize locations of high HIV prevalence and ensure that condom and lubricant programmes are intensified there to accommodate the HIV prevention needs in these communities.

Focus populations, priority locations and settings for intensified condom programming will vary according to the local epidemiological and response context. Providing epidemiological descriptions, drawing on available epidemiological and modes of transmission and behavioural and programming data will help inform efforts to scale up condom programming for maximal impact and efficiency. Where available, district level data might be more useful than national level data to identify unmet need and programmatic gaps. Target populations should always be involved in designing, pre-testing, validating, implementing and monitoring condom and lubricant programmes.

Below is a list of populations in which condom and lubricant programming have been effective in preventing HIV and should be promoted.

Persons having casual sex

Condom and lubricant programming is particularly relevant for populations who engage in risky sex acts. These include short-term sexual partnerships such as casual sex, relationships with two or more sexual partners, sex under the influence of drugs or alcohol, sex with an HIV-positive partner and anal sex with a partner whose HIV status is unknown.

Sex workers (female/male)

Condom and lubricant programming for sex workers and their clients has proven to be an effective tool for preventing HIV transmission.^{8,9} Meaningful engagement with sex workers helps to determine the types, designs and prices of condoms that are preferred and in identifying suitable access and distribution points and quantities needed. An enabling environment for condom programming is critical for addressing legal and policy barriers that penalize the possession of condoms and thereby limit populations' access and usage. The female condom has been well-received by female sex workers as a woman-controlled device that does not rely on the cooperation of their male clients and can be inserted in advance. For the same reason some gay men also advocate off-label promotion of the female condom for anal sex although so far it has only been prequalified by WHO/UNFPA for vaginal use.

Clients of sex workers

Clients of sex workers are diverse, and multi-layered strategies and approaches are needed to meet their respective HIV prevention needs. The efforts to reach the general population might often be inadequate for reaching these groups and these need to be amplified by the use of outreach activities targeted at locations where clients meet with sex workers (bars, brothels, parks, transport hubs, motels, etc.) as condom use in different locations tends to differ.

Partners of sex workers

Partners of sex workers are often overlooked in condom and lubricant programming. Successful integrated programmes for key populations with strong condom and lubricant

8 Shahmanesh M et al. Effectiveness of interventions for the prevention of HIV and other sexually transmitted infections in female sex workers in resource poor setting: a systematic review. *Tropical Medicine & International Health*, 2008, 13(5): 659–679.

9 Foss AM et al. A systematic review of published evidence on intervention Impact on condom use in Sub-Saharan Africa and Asia, *Sexually Transmitted Infection*, 2007, 83(7): 510–516.

components, such as the Avahan project,^{10,11} have emphasized the importance of multi-layered interventions to also address the vulnerabilities and risks faced by sex workers in their private relationships, where condom use may be more difficult to sustain.

Gay men and other men who have sex with men (MSM)

Condoms and condom compatible lubricants are recommended for preventing HIV in gay men and other men who have sex with men.¹² However condoms are not always available for gay men and other men who have sex with men in low- and middle-income countries, nor are they distributed in the locations/settings where sexual encounters take place. Laws that penalize possession of condoms and lubricants limit promotion and distribution efforts with implications on HIV incidence for this group. Modelling scenarios have confirmed that without condom use, HIV incidence in this group would be much elevated.¹³ Treatment optimism, fatalism and fear of infection in this group, which is, on average, up to 19 times more likely than the general population to be living with HIV, warrants tailored condom distribution, dedicated social mobilization and continued demand-generation efforts to reach these men.

Young people

It is a common misconception that condom promotion and distribution efforts incite young people to have more and riskier sex. However, evidence has firmly concluded that this is not the case. Rather, data from Sub-Saharan Africa have confirmed the effectiveness of condom use in young men.¹⁴ For many young women, using condoms is the only viable prevention option to protect themselves against HIV infection. Policy limitations that infringe on promotional efforts or laws that restrict free access to female and male condoms for young people should be reviewed and access to condoms ensured through youth-friendly community access points, special outreach and social events.

10 Deering KN et al. Condom use within non-commercial partnerships of female sex workers in southern India. *BMC Public Health*, 2011, 11(Suppl 6): S6–S11.

11 Piot B et al. Lot quality assurance sampling for monitoring coverage and quality of a targeted condom social marketing programme in traditional and non-traditional outlets in India. *Sex Transm Infect*, 2010, 86(Suppl 1): i56–i61.

12 Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (WHO 2014)

13 See for instance Phillips AN, Cambiano V, Nakagawa F, Brown AE, Lampe F, et al. (2013) Increased HIV Incidence in Men Who Have Sex with Men Despite High Levels of ART-Induced Viral Suppression: Analysis of an Extensively Documented Epidemic. *PLoS ONE* 8(2): e55312. doi:10.1371/journal.pone.0055312.

14 Michielsen, K., Chersich, MF., Luchters, S., Koker, PD., Rossem, RV and Temmerman, M. (2010) Effectiveness of HIV prevention for youth in Sub-Saharan Africa: systematic review and meta-analysis of randomized and non-randomized trials, *AIDS* 2010, Vol 24 No 8.

People living with HIV

Easy access and adequate supply of condoms for people living with HIV is a critical element of ensuring their positive health, dignity and the prevention of infection.¹⁵ Male and female condoms must be routinely available at HIV-care locations and these should ensure a supply of minimum 12 condoms per month for every person living with HIV. Evidence since the 1990s has confirmed that condom and lubricant interventions can be highly impactful among people living with HIV. Addressing the full reproductive needs of people living with HIV and their partners within health-care services also includes support to safely conceive.¹⁶

Stable heterosexual couples

Condom and lubricant programming is relevant to stable heterosexual couples,¹⁷ especially sero-discordant couples (i.e. couples in which one partner is HIV-positive and the other HIV-negative), or where condoms are used for dual protection or to boost other primary prevention methods such as voluntary medical male circumcision and pre-exposure prophylaxis.

3. Data requirements

- Legal and policy data help to identify the policy obstacles and human rights barriers to effective and meaningful condom and lubricant programming. This type of data can be collected through the National Commitments and Policy Index (NCPI). Where legal, gender and youth assessments have been carried out, they may provide additional information.
- Epidemiological data are essential to know where the HIV prevalence rate is high and the numbers of people living with HIV in these areas. Subnational estimates may be preferred to national level data since condom promotion and distribution is often uneven and unmatched with need¹⁸.
- Modes-of-transmission data enable analysis of the pattern of the epidemic and gives an overview of where new infections are occurring.
- Behavioural data are essential to identify trends in knowledge, motivation and use of condoms and to identify changes in knowledge, attitude and practices over time.

15 Available from: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110701_phdp.pdf

16 Steiner R et al. Pre-conception care for people living with HIV: recommendations for advancing implementation. *AIDS* 27: S113–9, 2013.

17 Weller SC and Davis-Beaty K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database of Systematic Reviews* 2007, 4.

18 Local epidemics, Issues Brief. Geneva: UNAIDS; 2014 (Available from: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2014/JC2559_local-epidemics_en.pdf).

- Social and ethnographic data provide information about the health contexts and sexual practices that place within specific populations at risk for HIV, as well as condom acceptability, use and uptake. Such research can help identify barriers and opportunities for acceptability together with expanded access and uptake within a particular target group or community.
- Market research data identify the types of condoms available and the preferred and desirable brands as well as opportunities for product diversification, innovation and branding together with pricing (as applicable). Market research on female condoms is a critical priority, given the appeal of the product to women. Ideally, users' preferences should be assessed periodically to optimize the purchase of condom types and brands favoured by the target populations.
- Programme monitoring data generate information that allows for continuous tracking and enhancing of programmatic performance and helps inform decision-making and management processes. Such data may be used to inform forecasting and identify problems such as uneven distribution and supply of condoms and capacity gaps that may require evaluation. Routine monitoring is an integral part and not an end of programme activity, but can also serve as the basis for surveys to assess providers, for observation and for follow-up studies. Given that condom programmes involve multiple activities carried out by multiple partners, it is always essential to ensure that data sources are geocoded and indicate the numbers of male and female condoms respectively.
- Costing data helps ensure that condoms are competitively priced. Commodity unit costs may be benchmarked against international standards, and more comprehensive costing data that indicates price per condom promoted may also help identify opportunities for cost savings.

Figure 1 below provides an illustrative overview of data requirements as they pertain to need, use, distribution, market trends and cost.

Metric	Definition	Indicator
Universe of need	The number of products or services needed to reach universal coverage in the market.	HIV: Male population 25-64 multiplied by average number of risky sex acts per man per year.
Use	The percentage of the population at risk using a product or service, or adopting a behaviour.	Percentage of males and females reporting condom use at last sex (geographic differences).
Market volume	The number of products sold, distributed or provided in a given market.	Total number of condoms distributed in the public, social market and commercial sectors.
Market value	The dollar value of the total number of products or services sold, distributed or provided in a given market.	Average consumer price multiplied by market volume.
Number of brands	The number of distinct brands for a product in a given market.	Total number of condom brands on the market.

Source: Adapted from Population Services International.

4. Approaches to forecasting

Forecasting exercises help quantify the number of condoms needed for procurement. Three sources of data inform forecasting of condom needs:

- **Logistics-based forecasts** are most accurate when good historical data exist on the quantities of products dispensed to users.
- **Service statistics data** recorded at clinics and other delivery sites can be used to forecast condom need in any programme where client visits are methodically counted and standard protocols are used for dispensing supplies.
- **Population-based estimates** are useful for new programmes that have little or no historical data on which to base forecasts.

Each of these three forecasting methods has advantages and disadvantages.¹⁹ The choice of method should be based on the type of programme at issue, how recently it was established, and the types and quality of data that are available. If possible, more than one method should be used, with results compared.

The estimated number of risky sex acts that occur each year may serve as a rough approximation of the number of condoms needed annually. In the case of HIV prevention, risky sex acts include:

- casual sex;
- paid/commercial sex;
- sex between men;
- marital contacts of those engaged in casual sex;
- sex between transgender people and their partners;
- sex between people who inject drugs and their partners;
- sex among sero-discordant couples.

The number of sexual acts per year in each of these categories should be estimated based on the most recent health and behavioural data or mathematical models. Using this combined figure, planners should estimate the proportion of the sex acts where a condom should be used (total coverage = condom use target) and the proportion when a condom is used (actual coverage). To determine the annual number of condoms recommended in a country with an aggressive campaign to promote condom use, actual coverage should be subtracted from total coverage. If the country desires to generate a single estimate of condom needs, the number of condoms needed for family planning should be added to the number required for HIV prevention programmes.

¹⁹ See for instance Meekers D. Explaining inconsistencies between condom use and condom sales. *BMC Health Services Research*, 2005, 5(5).

5. Approaches to costing

Funding must be systematically earmarked for female and male condoms and lubricants across HIV prevention, STI, SRH (sexual and reproductive health) and HIV care budgets. Comparing unit costs with comparable countries may be a useful method to identify reasons why they may be lower or higher than the comparison settings. Care should be taken to ensure that like is being compared with like—different definitions of the scope of an activity, for example whether the costs of support or management staff are included or not, can have a major impact on reported costs. Attention should also be given to the quality of a service, so unit costs should be assessed in relation to results—if a programme has higher unit costs but delivers better results than a lower cost programme it may still represent good value of money. There may also be differing external factors between countries that explain differences in cost.

- Indicatively, unit commodity costs should be within the range US\$0.031–0.032 for a male condom (including plain and specialty condoms), and female condoms cost US\$0.55.
- Procurement costs plus the costs of shipping the condoms to a country warehouse brings the average total cost to US\$0.038 per male condom and US\$0.62 per female condom.
- A more complete unit cost estimate including procurement, shipping, distribution, and marketing may range from US\$0.10 (in 2012) for condoms marketed with fewer marketing procedures and US\$0.28 for condoms that are heavily branded and marketed.

It is recommended that for intensified condom and lubricants programmes in key locations (with very high transmission and strong condom markets) a unit cost close to US\$0.28 should be used.

Often budgeting for condoms tends to only cover procurement costs and fails to take into account additional costs incurred for shipping and marketing/distribution.

Various methods and tools are available to estimate the resource needs for optimized condom programming. Relevant modelling tools, especially the Goals and Resource Needs Models of Futures Institute are available from: <http://www.futuresinstitute.org/spectrum.aspx>.

Resource needs should be estimated for the optimized condom package of interventions agreed upon and taking into account unit costs that reflect efficiency gains identified. Partners, including UNAIDS, can assist with support for modelling exercises.

6. Programmatic and implementation challenges

Stock-outs

Programmes often experience challenges in ensuring that a ready supply of condoms is available for all focus populations at all times. Stock-outs are common and may last for months, with negative individual and public health implications. Stock-outs diminish confidence in condom programmes, undermine the effectiveness of promotional efforts, and may result in emergency orders, a costly and time-consuming process. Stock-outs are commonly the result of poor forecasting, delays in procurement and bottlenecks in the supply and distribution pipeline.

Where stock-outs occur, they should be carefully documented to enable programmes to address the underlying procurement and supply-management deficiencies. A valuable measure to prevent stock-outs is a survey of distribution outlets to determine where condoms are currently being provided and dispensed, where distribution is low and where new distribution channels and service providers may be needed.

Limited condom outlets

In many developing countries, public-sector condoms are mainly supplied to health facilities, which have strict operating hours. This is one of the most challenging issues with condom accessibility. Than at the time most couples plan sex, most facilities are closed, and few community distribution points have condoms available. Obtaining condoms in health facilities may also be embarrassing for some people, especially young people and women, further underscoring the importance of alternative community outlets. Access through public health facilities may also be undermined by staff attitudes and judgement, lack of choice of condom brands and sizes, and long distances required to access condom outlets. Hence, there is need to make condoms available in places where they are easily and readily accessible outside of medical settings.

Lack of quality assurance

If local regulatory requirements do not insist on compliance with good quality standards, clients may obtain condoms of poor or variable quality, especially in the open market. In addition to potentially exposing clients to HIV, STIs or unintended pregnancy, sub-optimal condoms also undermine users' confidence, potentially deterring them from using condoms in the future. Condoms should always be procured according to national and international standards and specifications. WHO/UNFPA for Specification, Prequalification and Guidelines for Procurement (2010) provide normative guidance on procurement of condoms and quality assurance.

Post-shipment testing

Countries are increasingly requiring post-shipment testing of all medical products, including condoms. While such regulations reflect a laudable vigilance regarding the safety of medical products to be used, such rules may result in considerable delays in condom access. In settings without labs accredited by an international body, proper equipment and a sufficient number of skilled lab technicians, these provisions may also result in the rejection of quality commodities. While maintaining inspection protocols for medical products generally, countries are advised to exempt commodities procured by recognized international groups (e.g. United Nations Population Fund (UNFPA), United States Agency for International Development (USAID), etc.) from post-shipment testing requirements.

Social, economic and political obstacles

Social, economic and political pressures sometimes constrain the efforts of HIV prevention and family planning programme workers to promote the use of condoms. These pressures, sometimes manifested in government regulations, often stem from social, cultural or religious rules regarding what is acceptable in the community. In some cases, these barriers can seriously obstruct the ability of the programme to implement effective activities at scale, with negative health impacts on the individual, their families and sexual partners as a consequence. Strong political leadership is often required to educate societies regarding the public health importance of condom and lubricant programming in the face of such social, economic and political issues.

Policy regulations

Policy regulations may diminish the individual and public health impact of condoms. For example, regulations in some settings restrict provision of condoms to married couples. Distribution of condoms may be permitted only through certain outlets, which may limit the access due to stigma and unsuitable opening hours. Promoting or possessing condoms may be banned to prevent inciting sex. In some countries, age restrictions and criminalization laws limit access to condoms for key populations such as gay men and other men who have sex with men (MSM) and sex workers. Restrictions may be placed on the content of advertising and promotional messages, or on the media outlets in which condom-related content may 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. Overcoming policy challenges to effective condom and lubricant programming requires understanding and addressing the policy barriers that limit comprehensive condom and lubricant programming, and ensuring revisions as needed.

Price

Condoms may cost more than target audiences can afford or are willing to pay for them. Limited supplies or stock-outs may result in even higher prices. Programmes need to ensure the distribution of free condoms and affordable pricing for commercial condoms for focus populations. Countries are advised to benchmark their condom related costs and may consult the UNFPA Procurement Guide, which describes available suppliers and prices, in order to optimize prices for condoms.

Myths and misconceptions

Various sociocultural misconceptions about condoms undermine the public health impact of condom programming by discouraging at-risk individuals from using them. Although condoms promote sexual health and prevent unwanted pregnancy, condom use may be mistakenly associated with disease, extramarital sex, promiscuity, selling sex or being too sexually experienced. Misperceptions that condom use increase sexual activity of young people is a persistent challenge, with implications for their demand and use. To avoid and overcome misconceptions about condoms, programmes should provide accurate information, dispel myths, challenge social beliefs and misconceptions about condoms (effectively and evidentially) and remain attentive to such issues in the development of social marketing strategies and promotional materials. Governments, community-based organizations and networks, educational and health-care institutions, workplaces and traditional leaders have a role to play in overcoming cultural resistance to condoms.

Relationship building

Some people regard safe sex as incompatible with building and maintaining a romantic relationship. Some couples seek to manage risk through monogamy or always using condoms with “other people”. Once these rules are in place, whether verbalized or assumed over time, suggesting the introduction of condoms may infer infidelity or lack of love and trust, prompting suspicion regarding this change in the relationship’s ground rules. HIV programmes need to actively address these issues, linking condoms to intimacy, romantic relationships and the experience of love and social closeness. Furthermore, they need to promote male involvement in HIV prevention and develop locally available activities in support of this aim.

Bringing the female condom to scale

The female condom has experienced design improvement and cost reductions in recent years and until today the female condom is the only approved primary prevention method for HIV designed for the female body. The United Nations Commission on Life-saving Commodities for Women and Children have identified the female condom as one of 12 high impact tools that, combined, could save the lives of more than 6 million women and children. Yet it is far from universally available to women to use and promote, and not systematically supported by public health programmes, with some reporting very small numbers distributed. Despite its inherent importance for women, the female condom is still considered a niche product due to its higher cost relative to male condoms and lack of capacity of service providers to provide information and advice on utilization.

7. Main activities

The Table below summarizes activities under each of the key elements of condom and lubricant programming to be considered for national programme managers in their efforts to expand condom use.

Male and Female condom promotion and distribution		
	Main activities	Area of intervention
Situation assessment	<ul style="list-style-type: none"> Undertake a situation analysis to identify focus populations, their respective needs and demands, barriers and opportunities for programmatic action. Conduct an appraisal of programme capabilities (gap analysis, supply and distribution; providers' attitudes, skills and practices; quality of services delivered and existing condom promotion in the community) to identify opportunities for programme enhancement. 	<ul style="list-style-type: none"> Assessing current condom and lubricant programming options and making recommendations for programmatic scale-up.
Market and social research	<ul style="list-style-type: none"> Conduct special bio-behavioural knowledge, attitudes and practices (KAP) surveys. Conduct qualitative research on norms and practices (including longitudinal panel designs for tracking progress over time including any unintended consequences of messages). Conduct formative research on messages, brands, user values and product preferences. 	<ul style="list-style-type: none"> Determining the status of knowledge, attitudes, risk perceptions, demand, user preference norms, access and perceived service quality.

Male and Female condom promotion and distribution		
	Main activities	Area of intervention
Awareness and education	<ul style="list-style-type: none"> Design and implement entertaining educational activities (websites, social media challenges, and infographics and arts-based activities). Commission and evaluate arts-based projects including theatre project through collaboration with local community and link it with interactive workshops/activities to meet educational and skills building objectives through a range of methods such as forum theatre, street theatre, monologues, spoken word poetry, interactive role play, cops in the head, image theatre, etc. 	<ul style="list-style-type: none"> Creating greater awareness, knowledge and open conversation about condoms, risk and safe sex.
Integration of female and male condoms and lubricants into existing HIV and SRH services	<ul style="list-style-type: none"> Map service delivery points and ensure contraceptive choice includes both female and male condoms for dual protection in SRH encounters and make them available at scale in public sector health facilities. Promote female and male condoms through interpersonal communication as part of HIV and broader SRH services, to help new users/ensure continuity of support and motivate ongoing use. Training sessions to reinforce competency with the female condom among health and community workers and with opportunities to practice inserting/putting on condoms on pelvic/penis models. 	<ul style="list-style-type: none"> Integrating male and female condom as a dual protection method into a wide range of non-HIV-related service delivery points to ensure that condoms are consistently available and on the menu of contraceptive options in SRH services, STI clinics, ANC and youth serving clinics.
Social and community mobilization	<ul style="list-style-type: none"> Condom awareness campaigns in and out school programmes, at workplaces, at festivals, in rural communities, concerts, football matches and other social events. Design social network based condom promotion activities (using networks as defined by participants themselves). Mobilize, engage and train traditional and religious leaders in condom promotion and distribution to address religious and cultural norms and stigma that limits acceptability and uptake of female and male condoms. Intensify condom promotion and distribution in key locations via community distribution points (places of worship, taxi and motorcycle drivers, taverns, grocery stores, hairdressers, pharmacies, petrol stations, vending machines) and mobilize community groups and community-based systems to reach key and vulnerable populations with male and female condoms. Partner with youth and women's movement, networks of women living with HIV and family planning advocates to undertake political lobbying, manifestations/demonstrations and media advocacy activities including creative epidemiology, agenda setting, framing, petitions to generate demand and ensure all women their right to available and adequate supply of female condoms. 	<ul style="list-style-type: none"> Intensifying condom promotion and distribution in key locations and among communities at higher risk including in communities where local leadership for condoms is weak and inadequate.

Male and Female condom promotion and distribution		
	Main activities	Area of intervention
Social and behaviour change communication	<ul style="list-style-type: none"> Identify interpersonal communication (IPC) providers and develop their capacity in managing evidence-informed, quality IPC for peer education, outreach activities and peer counselling. Identify and develop materials for peer education, outreach activities, peer counselling. Conduct IPC (such as group talks, short community courses, dramatized information sessions, road shows and home visits). Design high-quality evidence-based communication campaigns relevant to the target populations using various formats (individual, group, peer, etc.). Commodity security for people in care as well as outreach/ Behavioural Change Communication (BCC) support for discordant couples and link them with efforts to challenge stigma and discrimination and support groups. Undertake systematic and regular quality assurance of social and behaviour change communication through support in sessions, progress monitoring and qualitative research. 	<ul style="list-style-type: none"> Nudging of core social and gender norms for HIV prevention (including barriers). Enhancing self-efficacy and key prevention skills (e.g. communication and consistent condom use) for key audiences. Ensuring that referral to HIV prevention, testing and treatment services are in place.
Social marketing	<ul style="list-style-type: none"> Develop a social marketing plan for female and male condoms. Conduct market analysis (competition, segmentation and targeting) and consumer research to understand the priority populations and their preferences (brand, price and outlet) and preferred channels of communication. Select channels and materials and identify opportunities for distribution (product, price, promotion and placement) to develop branding and strategy for communicating cost/benefit relationships of using condoms. Expand female and male condoms through supply and demand generation exercises focusing on key populations (sex workers, people who use drugs, gay men and other MSM and other sexual minorities) using evidence-based approaches relevant to each group. 	<ul style="list-style-type: none"> Identifying user preferences and opportunities to segment condom audiences and serve the total market with multiple brands. Promoting brand harmonization and consolidation, as well as new brand development opportunities and campaigns targeting specific users including priority populations.

Male and Female condom promotion and distribution		
	Main activities	Area of intervention
Mass media	<ul style="list-style-type: none"> Develop media campaign plans and the overall plan for strategic behaviour communication. Produce and place print materials and electronic media campaigns (including radio, television, internet and/or social and mobile-phone elements) as appropriate for target population. Train journalists and media producers on HIV prevention and establish a network of HIV prevention experts in the media sector. Secure media coverage for popular opinion-leaders who are prevention advocates and role models. 	<ul style="list-style-type: none"> Reinforcing local efforts to change social norms, raising awareness and generating new knowledge about HIV through simple, repetitive and well framed messages. Marketing of innovation in HIV prevention services including condom brands and female condom options. Identifying condom champions for diffusion acceleration.
Procurement and supply management	<ul style="list-style-type: none"> Assess PSM system and identify opportunities to enhance female and male condom supply-chain initiatives to minimize condom stock-out and ensure the availability of condoms as and when demand is generated. Develop a multi-year procurement plan for condoms (reproductive health commodity security plan). Motivate, engage and train suitable partners (private sector, NGO and faith-based organization) partners to map condom distribution outlets and stock-outs in local communities and leveraging mHealth applications and mobile devices with a view to building real-time digital maps for local authorities. 	<ul style="list-style-type: none"> Ensuring commodity security by preventing stock-outs and resolving PSM bottlenecks to ensure that procured condoms reach intended audiences.
Capacity-building	<ul style="list-style-type: none"> Train (orient, sensitize and build skills) of peer-educators, nurses, lay counselors, pharmacists, and health and outreach workers. Identify and train credible community-level facilitators of IPC with the potential to be opinion leaders (staff or community-based workers). 	<ul style="list-style-type: none"> Reducing bias and increasing acceptability towards female and male condoms, ensuring accurate information and access to sub-populations who need them.

Male and Female condom promotion and distribution		
	Main activities	Area of intervention
Partnerships with the private sector	<ul style="list-style-type: none"> Define non-traditional condom outlets such as bars and other outlets frequented by target audiences and partner with the private sector²⁰ (to reach out to hard to reach populations to actively promote and distribute condoms in key locations. Train truck drivers to distribute condoms and refill vending machines along their travel routes. 	<ul style="list-style-type: none"> Providing non-clinical, easily accessible and user-friendly, distribution outlets, expanded for female and male condoms and moving excess stock across provincial lines at low or no cost for greater equity.

²⁰ Cooperatives, informal economy, grocery stores, hairdressers/barbers, pharmacists, unions, Community Based Organizations (CBO), men, women and young people's associations.

8. Key indicators

Below is a compiled list of condom-related indicators. For sound M&E, select indicators that are objective, relevant to what is being measured and responsive to programme changes/intervention activities.

More details on indicators (including mechanism for data collected) can be found at: <http://indicatorregistry.unaids.org>.

	Indicator definition		Data source	Disaggregation by
	Indicator	Numerator/Denominator		
HIV	HIV prevalence among members of a defined sub-population at higher risk of contracting or spreading HIV	<p>N: Number of members of the at-risk sub-population testing positive for HIV at sub-population sentinel sites</p> <p>D:Total number of members of the at-risk sub-population tested for HIV</p>	Global AIDS response progress reporting (GARPR), special surveys	Population, sex and age
	Percentage of young people aged 15–24 years who are living with HIV	<p>N: Number of antenatal clinic attendees (aged 15–24 years) tested whose result was positive</p> <p>D: Number of antenatal clinic attendees (aged 15–24 years) tested for their HIV infection status</p>	GARPR, special Surveys	
	HIV incidence rate	<p>N: Number of new infections cases per population at risk in a given time period</p> <p>D: the sum of the person-time of the at-risk population</p>	UNAIDS	By population, sex and age group, and location
	STI prevalence (the proportion of young people with STIs detected during diagnostic testing)	<p>N: The number of diagnostic tests carried out for persons aged 15–24 years confirming the existence of an STI; NOTE: the type or types of STI taken into account should depend on what is locally important; if more than one type of STI is considered the results should be given for each separately, as well as the aggregated total</p> <p>D: The total number of persons aged 15–24 years who had diagnostic tests for STIs</p>	Sentinel surveys Programme data	By population, sex and age group

	Indicator definition		Data source	Disaggregation by
	Indicator	Numerator/Denominator		
Leadership	Number of districts with budget allocation to condom programming	<p>N: Number of districts with a total budget allocation to condom programming</p> <p>D: Total number of districts surveyed</p>	District government	By district, male and female condom
	Total amount of funding on condoms contributed by donor communities	Total amount in US\$ by donor on condoms by condom type/brand promoted	UNFPA, Ministry of Health (MOH)	Male and female condoms
	Percentage of condoms supplied by the donor community	<p>N: Number of donor-supplied condoms reported</p> <p>D: All condoms available for distribution nationwide in the last 12 months</p>	UNFPA , MOH	Male and female condoms
	Percentage of men and women who know a place to obtain condoms and who report they could get them on their own if they wanted	<p>N: Number of men and women who know a place where they can obtain condoms and who report they could get condoms on their own if they wanted</p> <p>D: The number of respondents surveyed</p>	UNAIDS and civil society organizations (CSOs)	Age, sex

	Indicator definition		Data source	Disaggregation by
	Indicator	Numerator/Denominator		
Demand generation	Percentage of respondents who believe that, if her husband has an STI, a wife can either refuse to have sex with him or propose condom use	<p>N: Number of respondents who believe that, if her husband has an STI, a wife can either refuse to have sex with him or propose condom use</p> <p>D: All respondents having heard of STIs</p>	UNAIDS and CSOs	Age, male and female condoms
	Percentage of adults who are in favour of young people being educated about condoms	<p>N: number of adults who are in favour of young people being educated about condoms</p> <p>D: total number of respondents</p>	Demographic and health surveys (DHS)	
	Percentage distribution of currently married women who are not using a contraceptive method and who do not intend to use in the future, by main reason for not intending to use	<p>N: Number of currently married women who do not currently use a method of contraception and who do not intend to use any I the future, by main reason for not intending to use in the future</p> <p>D: Total number of currently married women who do not currently use a method of contraception and who do not intend to use at any time in the future</p>	DHS	Age
	Percentage distribution of currently married men and women who are not using a contraceptive method but who intend to use in the future by preferred method, according to whether they intend to use in the next 12 months or later	<p>N: Number of currently married men and women who do not currently use a method of contraception method and who intend to use at some time in the future by preferred method to use in the future</p> <p>D: Total number of currently married women who do not currently use a method of contraception and who intend to use at some time in the future</p>	DHS	Sex, male and female condom
	Percentage of respondents reporting that HIV can be prevented by consistent and correct use of condom or having sex only with one faithful, uninfected partner	<p>N: Number of respondents who report HIV can be prevented by consistent and correct use of condom.</p> <p>D: Total number of respondents</p>	UNAIDS and CSO	Sex, age

	Indicator definition		Data source	Disaggregation by
	Indicator	Numerator/Denominator		
Utilization	Percentage of women and men aged 15–49 years who had sexual intercourse with more than one partner in the past 12 months and who used a condom during their last sexual intercourse	<p>N: Number of the respondents (aged 15–49 years) who reported having had more than one sexual partner in the last 12 months and who also reported that a condom was used last time they had sex</p> <p>D: Number of respondents (aged 15–49 years) who reported having more than one sexual partner in the last 12 months</p>	GARPR	Sex, age
	Percentage of MSM reporting the use of a condom the last time they had anal sex with a male partner	<p>N: Number of MSM who report they used a condom the last time they had anal sex</p> <p>D: Number of men who reported having anal sex with a male partner in the last six months</p>	GARPR	Age
	Percentage of sex workers reporting the use of a condom with their most recent client	<p>N: The number of sex worker respondents who reported that a condom was used with their last client</p> <p>D: Number of sex workers who reported having commercial sex in the last 12 months</p>	GARPR	Sex, age
	Percentage of men reporting condom use the last time they had sex with a sex worker, of those who report having had sex with a sex worker in the last 12 months	<p>N: Number of men who report they used a condom at last sex with a sex worker</p> <p>D: Number of men who say they have had sex with a sex worker in the last 12 months</p>	Behavioural Surveillance Survey (BSS), DHS	Sex, age
Quality control	Performed condom quality control in the past 12 months	Yes/no		

	Indicator definition		Data source	Disaggregation by
	Indicator	Numerator/Denominator		
Procurement and supply management	Total number of male and female condoms available at the warehousing for distribution nationwide during the last 12 months per person aged 15–49 years	N: Number of male and female condoms available for distribution nationwide in the last 12 months D: Total population aged 15–49 years	Condom type (male, female) by district	
	Percentage of storage facilities that experienced a stock-out of condoms at any given time period	N: Number of storage facilities distributing or issuing condoms assessed that experienced a stock-out of condoms D: Total number of facilities assessed that distribute or issue condoms and that have data available	USAID Deliver	Condom type (male, female)
	Number of condoms stocked-out in the past 12 months at the central warehouse	N/A	UNFPA	Condom type (male, female)
	Percentage of condoms that expired at the central warehouse in the past 12 months	N: Total number of condoms that expired in the past 12 months D: Total number of condoms available at the central warehouse during the time of the assessment	UNFPA	Condom type (male, female)

Adapted from UNFPA

9. Addressing gender, human rights and equity issues

The following are key actions to address gender, human rights and equity issues in the context of condom and lubricant programming.

- Create and/or augment gender-sensitive condom programmes focusing on women and incorporating female condom programming, and encourage male participation and involvement. Create awareness of women and men about SRH, HIV, and other STIs, ways to protect themselves using condoms, and female and male condom options.
- Promote skills building for negotiating safer sex as part of broader programmes.
- Partner with organizations working with and serving key populations (e.g. young people, men who have sex with men, sex workers, transgender people) to develop focused, community-centred and culturally appropriate prevention programmes that distribute free condoms and encourage their correct and consistent use.

- Challenge socially shared beliefs that undermine condom and lubricant programming, including notions of “uncontrollable male sex drive“ and reinforcing notions that “being under the influence“ necessarily impact condom use.
- Review and, where indicated, repeal or revise laws or regulations that may affect condom access for potential focus populations, including women, young people, men who have sex with men, people who inject drugs, sex workers and transgender people.

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Annex 1: Ten key steps in effective condom programming

Step 1: Establish a national condom support team

Assemble a team—including representatives from government, civil society, donors, the private sector and researchers—to guide and support in development and monitoring of a national condom strategy and operational plan. Ideally, the team will be selected from an existing reproductive health commodity security working group or HIV prevention committee.

Step 2: Undertake a situation analysis

Undertake a desk review of available background information—and field research, as necessary—to assess the current situation regarding HIV prevention and sexual and reproductive health as well as the status of national condom programming efforts. Convene a stakeholders meeting to share findings, build consensus and formulate a roadmap for scaling up condom programming efforts.

Step 3: Develop a national strategy for male and female condoms

Develop an integrated condom strategy with all stakeholders and partners. The strategy should address leadership and coordination; demand, access and utilization; supply and commodity security; and overall support.

Step 4: Develop a five-year operational plan and budget

For each component of the national condom strategy, create an operational plan that includes activities to be undertaken, division of labour for each partner, time frame, cost, and process indicators. Above all, ensure the buy-in of key stakeholders by including them in key decisions.

Step 5: Link the multi-year operational plan with the national commodity security plan

Leverage existing systems and strategies for forecasting, procurement, distribution and warehousing for key commodities. If no reproductive health commodity security committee is in place, the national condom support team should advocate for one to be established.

Step 6: Mobilize financial resources

Identify available, committed and potential resources for implementing the operational plan; determine funding gaps; advocate for and secure the necessary funds; and develop a reporting system to provide routine feedback to all stakeholders. Resource mobilization for condom promotion will be most effective if it is part of the development of a broader national HIV investment case that identifies an optimal mix of priority interventions, focuses programmes where they are most needed, identifies programming efficiencies and sets forth specific strategies to mobilize sustainable resources.

Step 7: Strengthen human resources and institutional capacity

Identify the strengths and gaps in human resource and institutional capacity and determine how such gaps can be filled; develop, obtain or adapt existing training materials; train trainers, drawing from the public and private sectors, civil society and social marketers; and cascade training to service providers at various levels. Particular attention should be paid to systems for forecasting and quality control for procured condoms, as well as systems for managing inventory, storage and transportation to maintain product quality and avoid stock-outs.

Step 8: Create and sustain demand for condom use

Conduct research on male and female condom use and factors that influence use; develop a communication strategy for stimulating and sustaining demand; define a total market approach, including non-traditional outlets for promoting and distributing condoms; and stimulate social mobilization to ensure a supportive environment for male and female condoms.

Step 9: Strengthen advocacy and engage the media

Initiate policy analysis and dialogue; identify condom champions and reinforce their skills; build coalitions and partnerships; and coordinate media outreach and capacity-building.

Step 10: Monitor programme implementation, conduct research and evaluate outcomes

Incorporate the comprehensive condom programming monitoring and evaluation (M&E) framework into the national M&E framework; review and update operational plan indicators; identify and conduct research to support programme implementation; establish baselines; monitor programme implementation; and conduct annual, mid-term and final evaluations, including of the overall impact of the national strategy.

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