

WHO Consolidated Guideline on Self-Care Interventions for Health

Sexual and Reproductive Health and Rights



World Health
Organization

human
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WHO consolidated guideline on self-care interventions for health: sexual and reproductive health and rights

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PREFACE

I am driven by the conviction that everyone should be able to realize their right to health. But today, at least half the world's people have no access to essential health services, including 214 million women of reproductive age in developing countries who want to avoid pregnancy but do not use or cannot access modern contraceptive methods. On top of that, an estimated 22 million unsafe abortions occur worldwide each year, more than 1 million sexually transmitted infections are acquired every day and, worldwide, the number of new HIV infections among young people is not declining.

People have been practising self-care for millennia, but new products, information and technologies are changing how health services are delivered. People can access services for a range of health needs – if they want them, when they want them and how they want them. We cannot continue to promote vertical approaches that do not benefit people who need health care the most. Fragmented services for individual diseases or health issues is not the way forward, as we have seen that quality interventions sometimes do not reach people who cannot access formal health systems.

A clear solution is to work together towards universal health coverage (UHC), which not only improves health outcomes, but can help to reduce poverty, promote gender equality and protect the most vulnerable populations. UHC includes a people-centred approach to health that views people as active decision-makers in their own health, not merely passive recipients of health services.

The provider-to-receiver model that is at the heart of many health systems must be complemented with a self-care model through which people can be empowered to prevent, test for and treat disease themselves. Many health issues can already be dealt with through self-care and the list continues to grow.

A people-centred approach supports health literacy so that people can take charge of their own health with evidence-based self-care interventions. When people have agency and autonomy, they can make and enact decisions in all aspects of their lives, including in relation to sexuality and reproduction.

Self-care interventions also offer exciting new opportunities to reach WHO's "triple billion" goals. These interventions

should be given within a safe and enabling environment to people who seek health care. Without this requirement, stigma, discrimination, coercion, violence and poor mental health outcomes will remain an impediment to access to and uptake of quality health services.

Continued meaningful engagement of communities, and strengthened partnerships can give us the platform to reach the Sustainable Development Goals – not just to improve health outcomes, but to transform the health systems on which billions of people depend.

This first consolidated guideline on self-care interventions is a milestone for WHO. It is an important paradigm shift in normative guidance from WHO and paves the way for the years ahead in the links between primary health care, communities and health systems.

The partnerships and experts who have contributed to the development of this guideline will also be important for its dissemination and implementation. By working together, we can accelerate attainment for UHC, create the opportunities to move from aspirational to achievable health goals for all and, most importantly, make a positive impact in the lives of the most vulnerable populations.

I hope you will join me to promote this important guideline.



Dr Tedros Adhanom Ghebreyesus
Director-General

A handwritten signature in black ink, which appears to read "Tedros Adhanom". The signature is written in a cursive, flowing style.

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral therapy
CESCR	United Nations Committee on Economic, Social and Cultural Rights
CSE	comprehensive sexuality education
DMPA	depot medroxyprogesterone acetate
DMPA-IM	DMPA in its intramuscular form
DMPA-SC	DMPA in its subcutaneous form
DOI	declaration of interest
ERG	External Review Group
GDG	Guideline Development Group
GPS	good practice statement
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRC	Guidelines Review Committee
GVPS	Global Values and Preferences Survey
HIVST	HIV self-testing
HPV	human papillomavirus
HPVSS	HPV self-sampling
HRP	The UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction
IPCHS	Integrated People-Centred Health Services framework
MEC	<i>Medical eligibility criteria for contraceptive use</i> (WHO publication)
OCP	oral contraceptive pill
OPK	ovulation predictor kit
OTC	over the counter
PHC	primary health care
PICO	population, intervention, comparator, outcome(s)
RCT	randomized controlled trial
REC	recommendation
SCS	self-collection of samples
SDG	Sustainable Development Goal
SG	WHO Guideline Steering Group
SRH	sexual and reproductive health
SRHR	sexual and reproductive health and rights
STI	sexually transmitted infection
UHC	universal health coverage
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
WHO	World Health Organization

EXECUTIVE SUMMARY

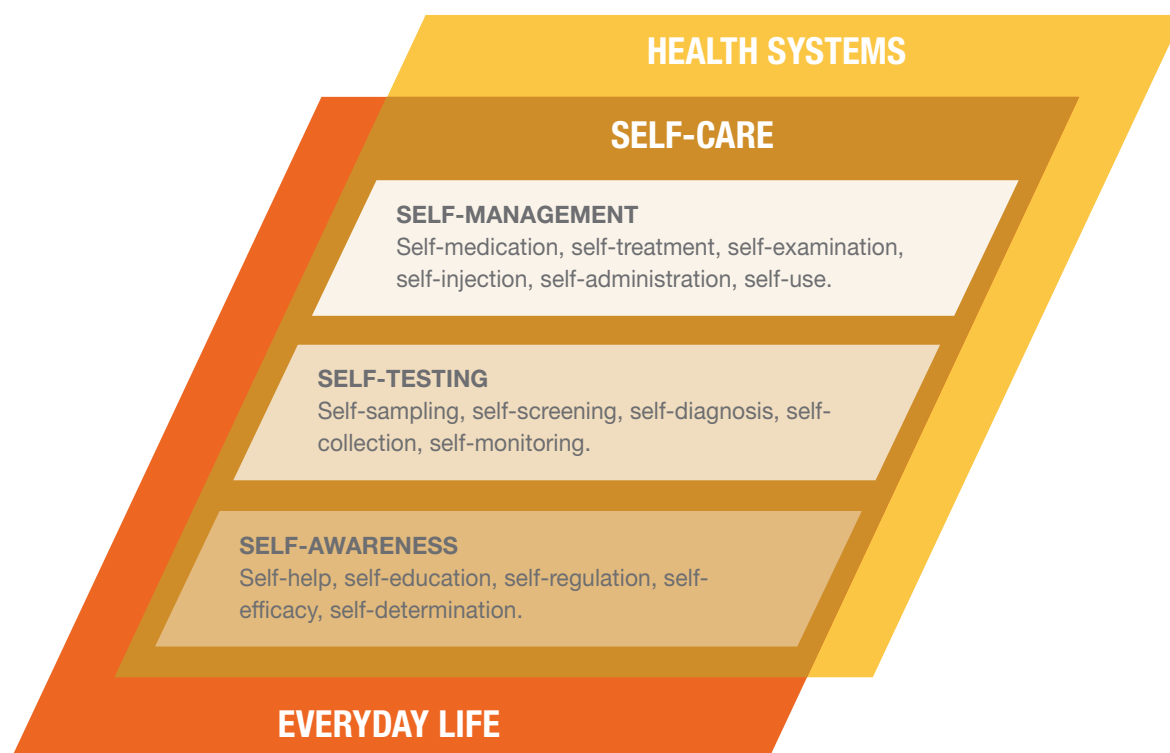
BACKGROUND

Self-care interventions are among the most promising and exciting new approaches to improve health and well-being, both from a health systems perspective and for people who use these interventions. The World Health Organization (WHO) uses the following working definition of self-care: Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health-care provider. The scope of self-care as described in this definition includes health promotion; disease prevention and control; self-medication; providing care to dependent persons; seeking hospital/specialist/primary care if necessary; and rehabilitation, including palliative care. It includes a range of self-care modes and approaches. While this is a broad definition that includes many activities, it is important for health policy to recognize the importance of self-care, especially where it intersects with health systems and health professionals (Figure 1).

Worldwide, an estimated shortage of 18 million health workers is anticipated by 2030, a record 130 million people are currently in need of humanitarian assistance, and disease outbreaks are a constant global threat. At least 400 million people worldwide lack access to the most essential health services, and every year 100 million people are plunged into poverty because they have to pay for health care out of their own pockets. There is an urgent need to find innovative strategies that go beyond the conventional health sector response.

While “self-care” is not a new term or concept, self-care interventions have the potential to increase choice, when they are accessible and affordable, and they can also provide more opportunities for individuals to make informed decisions regarding their health and health care. In humanitarian settings, for example, due to lack of or limited health infrastructure and medical services in the crisis-affected areas, self-care could play an important role to improve health-related outcomes. Self-care also builds upon existing movements, such as task sharing and task shifting, which are powerful strategies to support health systems.

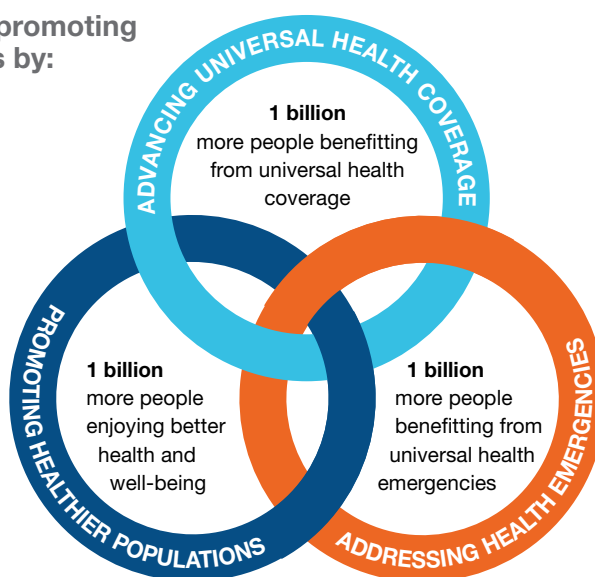
FIGURE 1: SELF-CARE IN THE CONTEXT OF INTERVENTIONS LINKED TO HEALTH SYSTEMS



Source: adapted from Narasimhan M, Allotey P, Hardon A. Self-care interventions to advance health and well-being: a conceptual framework to inform normative guidance. *BMJ*. 2019;365:l688. doi:10.1136/bmj.l688.

FIGURE 2: WHO STRATEGIC PRIORITIES AND “TRIPLE BILLION” GOALS FROM THE 13TH GENERAL PROGRAMME OF WORK (GPW13)

Ensuring healthy lives and promoting well-being for all at all ages by:



Source: Director-General of the World Health Organization. Thirteenth general programme of work 2019–2023 (Draft 5 April). Seventy-first World Health Assembly. Geneva: World Health Organization; 2018 (A71/4).

Self-care interventions represent a significant push towards new and greater self-efficacy, autonomy and engagement in health for self-carers and caregivers. At the same time, a key consideration in the development of health policy and guidance is that the availability of self-care interventions should not lead to care being disconnected from health services. Therefore, while risk and benefit calculations may be different in different settings and for different populations, with appropriate normative guidance and a safe and supportive enabling environment, self-care interventions offer strategies that promote active participation of individuals in their health and an exciting way forward to reach a range of improved outcomes, including:

- increased coverage and access;
- reduced health disparities and increased equity;
- increased quality of services;
- improved health, human rights and social outcomes; and
- reduced cost and more efficient use of health-care resources and services.

Self-care has the potential to contribute to all aspects of WHO’s strategic priorities and “triple billion” goals (Figure 2) and is increasingly being acknowledged in global initiatives, including for advancing primary health care (PHC) with the new Declaration of Astana, to advance the health and well-being of people most effectively, equitably, efficiently and sustainably through PHC. The new Declaration calls for the mobilization of all stakeholders – health professionals, academia, patients, civil society, local and international

partners, agencies and funds, the private sector, faith-based organizations – to include a focus of efforts around empowering individuals, families and communities to optimize their health as advocates for policies that promote and protect health and well-being, as co-developers of health and social services and as self-carers and caregivers.

PURPOSE AND OBJECTIVES OF THE GUIDELINE

The purpose of this guidance is to develop a people-centred, evidence-based normative guideline that will support individuals, communities and countries with quality health services and self-care interventions, based on PHC strategies, comprehensive essential service packages and people-centredness.

The specific objectives of this guideline are to provide:

- evidence-based **recommendations** on key public health self-care interventions, including for advancing sexual and reproductive health and rights (SRHR), with a focus on vulnerable populations and settings with limited capacity and resources in the health system; and
- **good practice statements** on key programmatic, operational and service-delivery issues that need to be addressed to promote and increase safe and equitable access, uptake and use of self-care interventions, including for advancing SRHR.

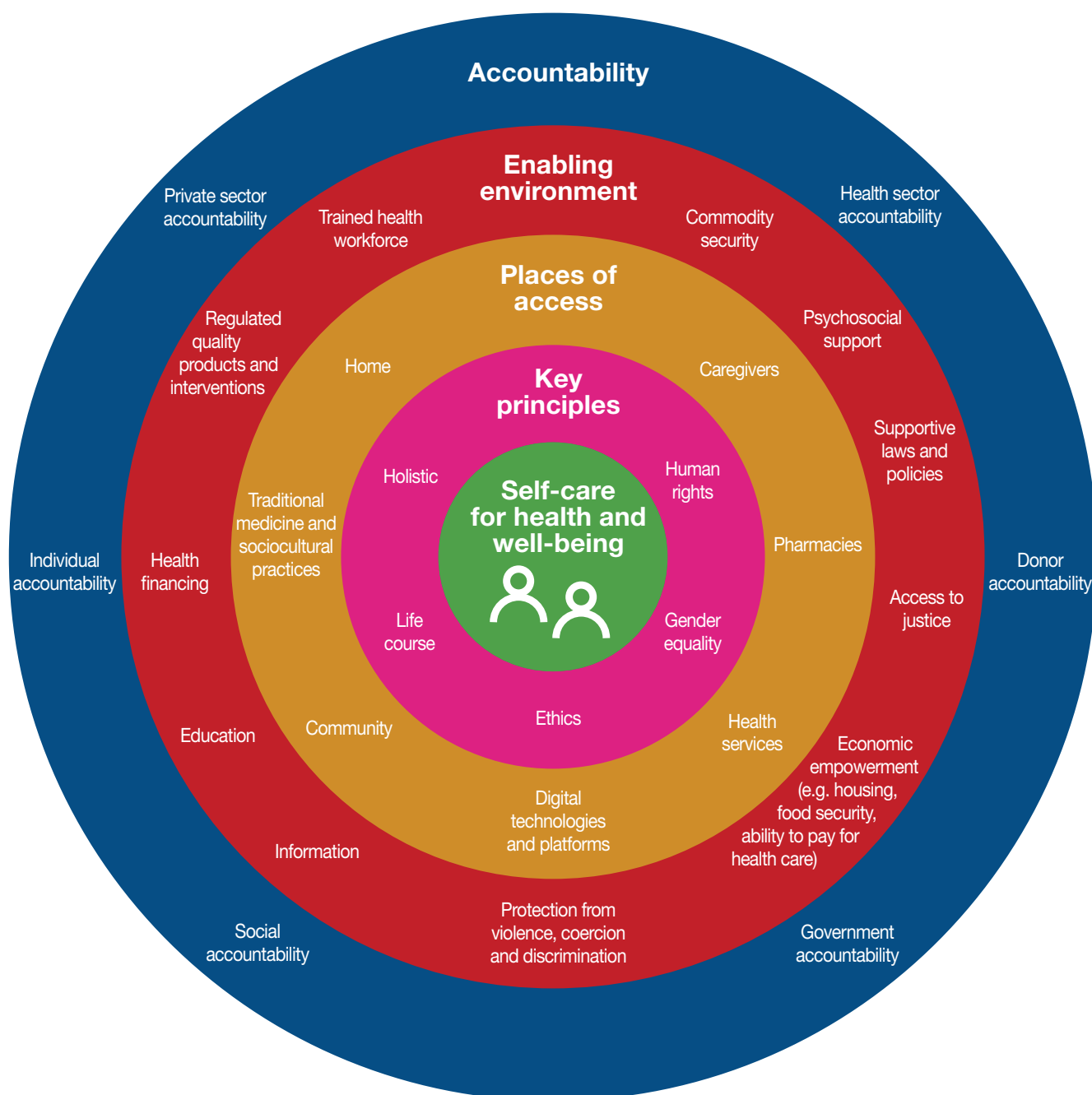
CONCEPTUAL FRAMEWORK FOR SELF-CARE INTERVENTIONS

The conceptual framework provides a starting point for tackling the evolving field of self-care and for identifying self-care interventions for future updates. The conceptual framework illustrates core elements from both the “people-centred” and “health systems” approaches, which can support introduction, uptake and scale-up of self-care interventions. The people-centred approach to health and well-being lies at the core of this framework and is underpinned by “key principles”, as shown in Figure 3.

APPROACH AND KEY PRINCIPLES

This guideline is grounded in and advocates for a strengthened, comprehensive, people-centred approach to health and well-being, including for SRHR. This approach is underpinned by the key principles of human rights, ethics and gender equality. People-centredness requires taking a holistic approach to the care of each person, taking account of their individual circumstances, needs and desires across their whole life course, as well as the environment within which they live.

FIGURE 3: CONCEPTUAL FRAMEWORK FOR SELF-CARE INTERVENTIONS



Source: adapted from Narasimhan M, Allotey P, Hardon A. Self-care interventions to advance health and well-being: a conceptual framework to inform normative guidance. *BMJ*. 2019;365:l688. doi:10.1136/bmj.l688.

SCOPE OF SELF-CARE INTERVENTIONS

While self-care is important in all aspects of health, it is particularly important – and particularly challenging to manage – for populations negatively affected by gender, political, cultural and power dynamics and for vulnerable persons (e.g. people with disabilities and mental impairment). This is true for self-care interventions for SRHR, since many people are unable to exercise autonomy over their bodies and are unable to make decisions around sexuality and reproduction.

The use and uptake of self-care interventions is organic and the shift in responsibility – between full responsibility of the user and full responsibility of the health-care provider (or somewhere along that continuum) – can also change over time for each intervention and for different population groups. In addition, not all people require the same level of support, and vulnerable populations in particular may require additional information and/or support to make informed decisions about their uptake and use of self-care interventions. Safe linkage between independent self-care and access to quality health care for vulnerable individuals is critically important to avoid harm. Where self-care is not a positive choice but is prompted by fear or lack of alternatives, it can increase vulnerabilities.

TARGET AUDIENCE

The primary target audience for this guideline is national and international policy-makers, researchers, programme managers, health workers (including pharmacists), donors and civil society organizations responsible for making decisions or advising on delivery or promotion of self-care interventions. The secondary target audience is product developers. This new guideline is also expected to support persons affected by the recommendations: those who are taking care of themselves, and caregivers.

Health services and programmes in low-resource settings will benefit most from the guidance presented here, as they face the greatest challenges in providing services tailored to the needs and rights of vulnerable populations. However, this guideline is relevant for all settings and should, therefore, be considered as global guidance. In implementing these globally relevant recommendations, WHO regions and countries can adapt them to the local context, taking into account the economic conditions and the existing health services and health-care facilities.

AN ENABLING ENVIRONMENT FOR SELF-CARE

Self-care interventions, if situated in an environment that is safe and supportive, constitute an opportunity to help increase people's active participation in their own health, including patient engagement.

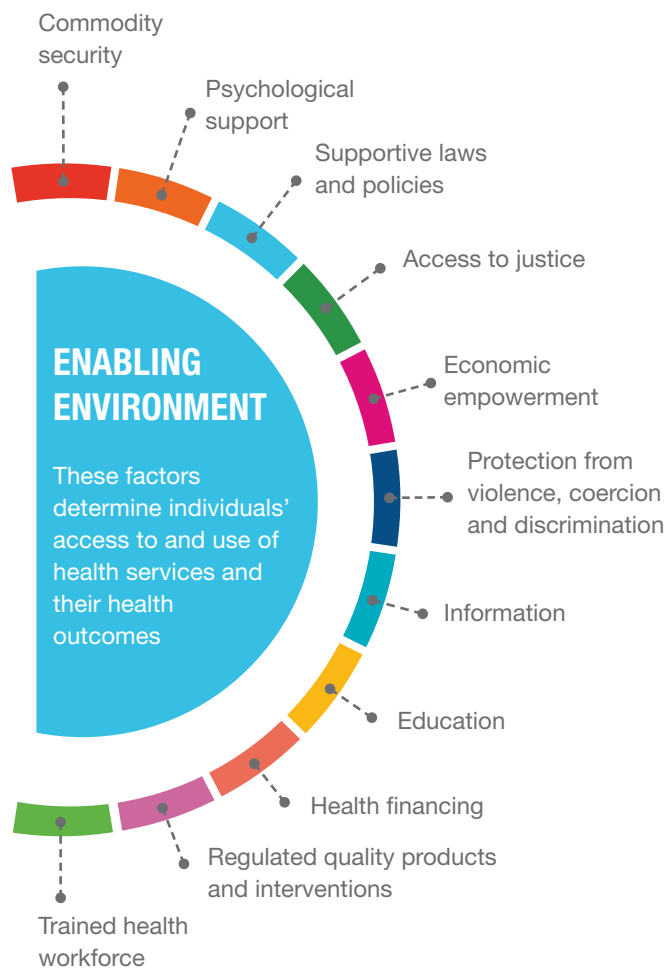
A safe and supportive enabling environment is essential to facilitate access to and uptake of products and interventions that can improve the health and well-being of vulnerable and marginalized populations (Figure 4). Assessing and ensuring an enabling environment in which self-care interventions can be made available in safe and appropriate ways must be a key initial piece of any strategy to introduce or scale-up these interventions. This should be informed by the profile of potential users, the services on offer to them, and the broader legal and policy environment and structural supports and barriers.

GUIDELINE DEVELOPMENT METHODS

The WHO Department of Reproductive Health and Research led the development of this consolidated guideline, following procedures in the *WHO handbook for guideline development*. The Department set up three working groups to perform specific guideline development functions: the WHO Guideline Steering Group (SG), the Guideline Development Group (GDG) and the External Review Group (ERG). Members of the groups were selected to ensure a range of expertise and experience, including appropriate representation in terms of geography and gender.

The SG led the guideline development process. They drafted the initial scope of the guideline; identified and drafted the priority questions in PICO (population, intervention, comparator, outcome) format; and recruited the guideline methodologist and members of the systematic review teams, the GDG and the ERG. The SG oversaw the process of screening WHO guidance documents and identifying existing self-care-related recommendations and good practice statements for sexual and reproductive health. The SG also finalized and published the guideline document, will oversee dissemination of the guideline and be involved in the development of implementation tools. The GDG members were involved in reviewing and finalizing key PICO questions and reviewing evidence summaries from the commissioned systematic reviews. They were also responsible for formulating new WHO recommendations and good practice statements at the GDG meeting in January 2019, as well as for achieving consensus on the final content of the guideline

FIGURE 4: CHARACTERISTICS OF THE ENABLING ENVIRONMENT TO SHAPE ACCESS TO AND USE OF SELF-CARE INTERVENTIONS



document. The ERG members were asked to review the draft of the guideline to provide technical feedback, identify factual errors, comment on the clarity of the language, and provide input on considerations related to implementation, adaptation and contextual issues. The Group ensured that the guideline decision-making processes had considered and incorporated the contextual values and preferences of persons affected by the recommendations. It was not within the ERG's remit to change the recommendations that had been formulated by the GDG.

The SG identified the following topic areas where new recommendations needed to be developed for this guideline: self-administration of injectable contraception; over-the-counter (OTC) provision of oral contraceptive pills (OCPs); use of home-based ovulation predictor kits (OPKs) for fertility management; HPV self-sampling (HPVSS) for cervical cancer screening; and self-collection of samples (SCS) for sexually transmitted infection (STI) testing. In

addition, they identified the following areas where new good practice statements were needed: safe and sustainable management of health-care waste; environmentally preferable purchasing (EPP); economic considerations for access, uptake and equity; the life-course approach to SRHR; the use of digital health interventions to support the use of self-care interventions; and support for self-care interventions in humanitarian settings.

In accordance with the WHO guideline development process, when formulating the recommendations, the GDG members' deliberations were informed by the quality and certainty of the available evidence. WHO has adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to recommendation development.

For this guideline, specific attention was also focused on the need for an enabling environment for implementation of interventions (see Chapter 2), and the GDG was asked to consider the implications for human rights (both positive and negative) for each recommendation. A Global Values and Preferences Survey (GVPS) was also conducted on self-care interventions for SRHR (relevant GVPS findings are presented in Chapter 4). The values and preferences of the end-users and health-care providers, as well as consideration of the relevant feasibility, resource use and equity issues, all contribute to determining the strength of a recommendation.

This guideline presents new WHO recommendations that have been published for the first time in this guideline in 2019 (indicated by the label of "NEW"; see Table 1) and existing recommendations that have been previously published in other WHO guidelines that applied the GRADE approach, as well as new, adapted and existing good practice statements (again the former are labelled as "NEW"; see Table 2).

DEVELOPING THE RESEARCH AGENDA

Future research in self-care can be conceptualized under two broad areas: (i) *development* of self-care interventions and (ii) *delivery* of self-care interventions.

Underpinning the focus of research on efficacy, effectiveness, safety, implementation and delivery will be the perspectives of individuals, collectives, communities and providers, or systems perspectives. As such, attention needs to be given to matching the selection of outcomes to be measured with the relevant perspective. The same is true for studies of costs and cost-effectiveness.

The increasing adoption of digital health and digital therapeutics in the self-care space offers new opportunities to generate real-world evidence in real time. However, it demands that privacy, security and identity management are integral to the conduct of ethical self-care research. Transparency, a culture of trust, and mutual benefit between those who participate in research and those who conduct research are paramount to creating a sustainable research environment.

During the guideline development process and in-person GDG meeting, the GDG identified important knowledge gaps that need to be addressed through further primary research. Chapter 6 of the guideline discusses the limitations of the existing evidence base, presents illustrative research questions relevant to the enabling environment for self-care for SRHR, lists questions to address the identified research gaps related to the new recommendations in this guideline, as well as illustrative research questions on self-care interventions relevant to several outcome domains for measuring human rights and equity.

IMPLEMENTATION, APPLICABILITY, AND MONITORING AND EVALUATION OF THE GUIDELINE

Effective implementation of the recommendations and good practice statements in this guideline will likely require reorganization of care and redistribution of health-care resources, particularly in low- and middle-income countries. The potential barriers are reviewed in Chapter 7. Various strategies will be applied to ensure that the people-centred approach and key principles that underpin this guideline are operationalized, and to address these barriers and facilitate implementation.

The implementation and impact of these recommendations will be monitored at the health-service, regional and country levels, based on existing indicators. However, given the private space in which self-care is practised, alternative ways to assess the impact of the interventions need to be developed. Emphasis on use and uptake by vulnerable populations means that there will need to be meaningful engagement of affected communities.

UPDATING OF THE GUIDELINE

The concept for the format of this guideline is a “living guideline”. In a fast-moving field, this approach will allow for continual review of new evidence to inform further versions of the “living” document. The recommendations presented in this publication represent a subset of prioritized self-

care interventions for SRHR, and this guideline aims to gradually include a broader set of self-care interventions over subsequent versions, as well as updating the recommendations as new evidence becomes available.

This guideline will therefore be updated as new evidence becomes available. An update to this guideline will likely be required within 18–24 months of dissemination of the present version, to accommodate either new evidence on existing recommendations or to develop new recommendations based on emerging evidence, including on new SRHR self-care interventions that may not have been available or identified during the discussions for the current version.

WHO aims to develop further guidance for SRHR and other health areas that would be likely to promote equity, be feasible to implement, and contribute to improvements in self-care, so that the appropriate recommendations can be included in future versions of this guideline, and can be adopted and implemented by countries and programmes.

Table 1 presents the new and existing recommendations on self-care for SRHR covering the following topics: (1) Improving antenatal, delivery, postpartum and newborn care; (2) Providing high-quality services for family planning, including infertility services; (3) Eliminating unsafe abortion; and (4) Combating sexually transmitted infections, including HIV, reproductive tract infections, cervical cancer and other gynaecological morbidities. These topics represent four of the five priority areas of sexual and reproductive health that are targeted in the 2004 WHO Global Reproductive Health Strategy. There are no new or existing recommendations on self-care interventions for the fifth area – Promoting sexual health – but relevant existing WHO guidance is provided in this guideline.

Table 2 presents the new and existing good practice statements on self-care interventions, covering the topics of (1) Environmental considerations; (2) Financing and economic considerations; (3) Training needs of health-care providers; and (4) Implementation considerations for vulnerable populations.

TABLE 1: SUMMARY OF NEW AND EXISTING RECOMMENDATIONS (REC) ON SELF-CARE INTERVENTIONS FOR SEXUAL AND REPRODUCTIVE HEALTH (SRHR)^{2, 3}

RECOMMENDATION (REC) ^a	STRENGTH OF RECOMMENDATION, CERTAINTY OF EVIDENCE
1. Improving antenatal, delivery, postpartum and newborn care	
Existing recommendations on non-clinical interventions targeted at women to reduce unnecessary caesarean sections	
REC 1: Health education for women is an essential component of antenatal care. The following educational interventions and support programmes are recommended to reduce caesarean births only with targeted monitoring and evaluation.	Context-specific recommendation, low-certainty evidence
REC 1a: Childbirth training workshops (content includes sessions about childbirth fear and pain, pharmacological pain-relief techniques and their effects, non-pharmacological pain-relief methods, advantages and disadvantages of caesarean sections and vaginal delivery, indications and contraindications of caesarean sections, among others).	Low- to moderate-certainty evidence
REC 1b: Nurse-led applied relaxation training programme (content includes group discussion of anxiety and stress-related issues in pregnancy and purpose of applied relaxation, deep breathing techniques, among other relaxation techniques).	
REC 1c: Psychosocial couple-based prevention programme (content includes emotional self-management, conflict management, problem solving, communication and mutual support strategies that foster positive joint parenting of an infant). “Couple” in this recommendation includes couples, people in a primary relationship or other close people.	
REC 1d: Psychoeducation (for women with fear of pain; comprising information about fear and anxiety, fear of childbirth, normalization of individual reactions, stages of labour, hospital routines, birth process, and pain relief [led by a therapist and midwife], among other topics).	
Existing recommendations on antenatal care for a positive pregnancy experience – self-administered interventions for common physiological symptoms	
REC 2: When considering the educational interventions and support programmes, no specific format (e.g. pamphlet, videos, role play education) is recommended as more effective.	Not specified
Interventions for nausea and vomiting	
REC 3: Ginger, chamomile, vitamin B6 and/or acupuncture are recommended for the relief of nausea in early pregnancy, based on a woman’s preferences and available options.	Not specified
Interventions for heartburn	
REC 4: Advice on diet and lifestyle is recommended to prevent and relieve heartburn in pregnancy. Antacid preparations can be offered to women with troublesome symptoms that are not relieved by lifestyle modification.	Not specified

² Further details on assessment of the quality of the evidence and determination of the strength of recommendation can be found in Chapter 3, sections 3.5.2 and 3.5.3

³ See a list of existing recommendations for noncommunicable diseases (NCDs) in Annex 2.

TABLE 1 (continued)

RECOMMENDATION (REC) ^a	STRENGTH OF RECOMMENDATION, CERTAINTY OF EVIDENCE
Interventions for leg cramps	
REC 5: Magnesium, calcium or non-pharmacological treatment options can be used for the relief of leg cramps in pregnancy, based on a woman's preferences and available options.	Not specified
Interventions for low back and pelvic pain	
REC 6: Regular exercise throughout pregnancy is recommended to prevent low back and pelvic pain. There are a number of different treatment options that can be used, such as physiotherapy, support belts and acupuncture, based on a woman's preferences and available options.	Not specified
Interventions for constipation	
REC 7: Wheat bran or other fibre supplements can be used to relieve constipation in pregnancy if the condition fails to respond to dietary modification, based on a woman's preferences and available options.	Not specified
Interventions for varicose veins and oedema	
REC 8: Non-pharmacological options, such as compression stockings, leg elevation and water immersion, can be used for the management of varicose veins and oedema in pregnancy, based on a woman's preferences and available options.	Not specified
Existing recommendation on self-administered pain relief for prevention of delay in the first stage of labour	
REC 9: Pain relief for preventing delay and reducing the use of augmentation in labour is not recommended.	Weak recommendation, very low-quality evidence
2. Providing high-quality services for family planning, including infertility services	
New recommendation on self-administration of injectable contraception	
REC 10 (NEW): Self-administered injectable contraception should be made available as an additional approach to deliver injectable contraception for individuals of reproductive age.	Strong recommendation, moderate-certainty evidence
New recommendation on self-management of contraceptive use with over-the-counter oral contraceptive pills (OTC OCPs)	
REC 11 (NEW): Over-the-counter oral contraceptive pills (OCPs) should be made available without a prescription for individuals using OCPs.	Strong recommendation, very low-certainty evidence
New recommendation on self-screening with ovulation predictor kits (OPKs) for fertility regulation	
REC 12 (NEW): Home-based ovulation predictor kits (OPKs) should be made available as an additional approach to fertility management for individuals attempting to become pregnant.	Strong recommendation, low-certainty evidence

TABLE 1 (continued)

RECOMMENDATION (REC) ^a	STRENGTH OF RECOMMENDATION, CERTAINTY OF EVIDENCE
Existing recommendation on condoms	
REC 13: Consistent and correct use of male and female condoms is highly effective in preventing the sexual transmission of HIV; reducing the risk of HIV transmission both from men to women and women to men in serodiscordant couples; reducing the risk of acquiring other STIs and associated conditions, including genital warts and cervical cancer; and preventing unintended pregnancy.	Not specified
REC 14: The correct and consistent use of condoms with condom-compatible lubricants is recommended for all key populations to prevent sexual transmission of HIV and STIs.	Strong recommendation, moderate-quality evidence
Existing recommendations on the number of progestogen-only pill (POP) and combined oral contraceptive (COC) pill packs that should be provided at initial and return visits	
REC 15a: Provide up to one year's supply of pills, depending on the woman's preference and anticipated use.	Not specified
REC 15b: Programmes must balance the desirability of giving women maximum access to pills with concerns regarding contraceptive supply and logistics.	Not specified
REC 15c: The re-supply system should be flexible, so that the woman can obtain pills easily in the amount and at the time she requires them.	Not specified
3. Eliminating unsafe abortion	
Existing recommendations on self-management of the medical abortion process in the first trimester	
REC 16: Self-assessing eligibility [for medical abortion] is recommended in the context of rigorous research.	Not specified
REC 17: Managing the mifepristone and misoprostol medication without direct supervision of a health-care provider is recommended in specific circumstances. We recommend this option in circumstances where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.	Not specified
REC 18: Self-assessing completeness of the abortion process using pregnancy tests and checklists is recommended in specific circumstances. We recommend this option in circumstances where both mifepristone and misoprostol are being used and where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.	Not specified
Existing recommendations on post-abortion hormonal contraception initiation	
REC 19: Self-administering injectable contraceptives is recommended in specific circumstances. We recommend this option in contexts where mechanisms to provide the woman with appropriate information and training exist, referral linkages to a health-care provider are strong, and where monitoring and follow-up can be ensured.	Not specified

TABLE 1 (continued)

RECOMMENDATION (REC) ^a	STRENGTH OF RECOMMENDATION, CERTAINTY OF EVIDENCE
REC 20: For individuals undergoing medical abortion with the combination mifepristone and misoprostol regimen or the misoprostol-only regimen who desire hormonal contraception (oral contraceptive pills, contraceptive patch, contraceptive ring, contraceptive implant or contraceptive injections), we suggest that they be given the option of starting hormonal contraception immediately after the first pill of the medical abortion regimen.	Not specified
4. Combating sexually transmitted infections, including HIV, reproductive tract infections, cervical cancer and other gynaecological morbidities	
New recommendation on HPV self-sampling	
REC 21 (NEW): HPV self-sampling should be made available as an additional approach to sampling in cervical cancer screening services for individuals aged 30–60 years.	Strong recommendation, moderate-certainty evidence
New recommendation on self-collection of samples for STI testing	
REC 22a (NEW): Self-collection of samples for <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> should be made available as an additional approach to deliver STI testing services for individuals using STI testing services.	Strong recommendation, moderate-certainty evidence
REC 22b (NEW): Self-collection of samples for <i>Treponema pallidum</i> (syphilis) and <i>Trichomonas vaginalis</i> may be considered as an additional approach to deliver STI testing services for individuals using STI testing services.	Conditional recommendation, low-certainty evidence
Existing recommendation on HIV self-testing	
REC 23: HIV self-testing should be offered as an additional approach to HIV testing services.	Strong recommendation, moderate-quality evidence
Existing recommendation on self-efficacy and empowerment for women living with HIV	
REC 24: For women living with HIV, interventions on self-efficacy and empowerment around sexual and reproductive health and rights should be provided to maximize their health and fulfil their rights.	Strong recommendation, low-quality evidence
5. Promoting sexual health	
There are no new or existing recommendations on self-care interventions in this area, but relevant existing WHO guidance is provided in this guideline.	

^a The recommendations are grouped under the five priority aspects of sexual and reproductive health that are targeted in the 2004 WHO Global Reproductive Health Strategy (available at: https://www.who.int/reproductivehealth/publications/general/RHR_04_8/en/).

TABLE 2: SUMMARY OF NEW AND EXISTING GOOD PRACTICE STATEMENTS (GPS) ON SELF-CARE INTERVENTIONS FOR SRHR

GOOD PRACTICE STATEMENT (GPS)
1. Environmental considerations
Adapted good practice statement on safe and sustainable management of health-care waste
GPS 1 (ADAPTED): Safe and secure disposal of waste from self-care products should be promoted at all levels.
Adapted good practice statement on environmentally preferable purchasing (EPP)
GPS 2 (ADAPTED): Countries, donors and relevant stakeholders should work towards environmentally preferable purchasing (EPP) of self-care products by selecting supplies that are less wasteful, or can be recycled, or that produce less-hazardous waste products, or by using smaller quantities.
2. Financing and economic considerations
Adapted good practice statements on economic considerations for access, uptake and equity
GPS 3 (ADAPTED): Good-quality health services and self-care interventions should be made available, accessible, affordable and acceptable to vulnerable populations, based on: the principles of medical ethics; avoidance of stigma, coercion and violence; non-discrimination; and the right to health.
GPS 4 (ADAPTED): All individuals and communities should receive the health services and self-care interventions they need without suffering financial hardship.
3. Training needs of health-care providers
Existing good practice statement on values and competencies of the health workforce to promote self-care interventions
GPS 5: Health-care workers should receive appropriate recurrent training and sensitization to ensure that they have the skills, knowledge and understanding to provide services for adults and adolescents from key populations based on all persons' right to health, confidentiality and non-discrimination.
4. Implementation considerations for vulnerable populations
New good practice statement on the life-course approach to SRHR
GPS 6 (NEW): Sensitization about self-care interventions, including for SRHR, should be tailored to people's specific needs across the life course, and across different settings and circumstances, and should recognize their right to sexual and reproductive health across the life course.
New good practice statement on the use of digital health interventions to support the use of self-care interventions
GPS 7 (NEW): Digital health interventions offer opportunities to promote, offer information about and provide discussion forums for self-care interventions, including for SRHR.
New good practice statement on support for self-care interventions in humanitarian settings
GPS 8 (NEW): Provision of tailored and timely support for self-care interventions, including for SRHR, in humanitarian settings should be in accordance with international guidance, form part of emergency preparedness plans and be provided as part of ongoing responses.
Adapted and existing good practice statements relevant to implementation of self-care for vulnerable populations
GPS 9 (ADAPTED): People from vulnerable populations should be able to experience full, pleasurable sex lives and have access to a range and choice of reproductive health options.
GPS 10 (ADAPTED): Countries should work towards implementing and enforcing antidiscrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against vulnerable populations.
GPS 11: Countries should work towards decriminalization of behaviours such as drug use/injecting, sex work, same-sex activity and nonconforming gender identities, and towards elimination of the unjust application of civil law and regulations against people who use/inject drugs, sex workers, men who have sex with men and transgender people.
GPS 12: Countries are encouraged to examine their current consent policies and consider revising them to reduce age-related barriers to HIV services and to empower providers to act in the best interests of the adolescent.
GPS 13: It is recommended that sexual and reproductive health services, including contraceptive information and services, be provided for adolescents without mandatory parental and guardian authorization/notification.



1

INTRODUCTION



“Self-care interventions are among the most promising and exciting new approaches to improve health and well-being.”



CHAPTER AT A GLANCE

This chapter defines self-care and describes the context in which this guideline has emerged. It covers the purpose and specific objectives of the guideline, the different approaches and key principles of self-care, and an introduction to the conceptual framework for self-care interventions.

BACKGROUND AND OBJECTIVES

pp. 4–6

To our knowledge, there are no specific guidelines already in existence on self-care interventions for SRHR at national, regional or international levels. This consolidated guideline seeks to bring together both new and existing WHO recommendations and good practice statements, especially in relation to SRHR.

DEFINITION, APPROACH AND KEY PRINCIPLES OF SELF-CARE

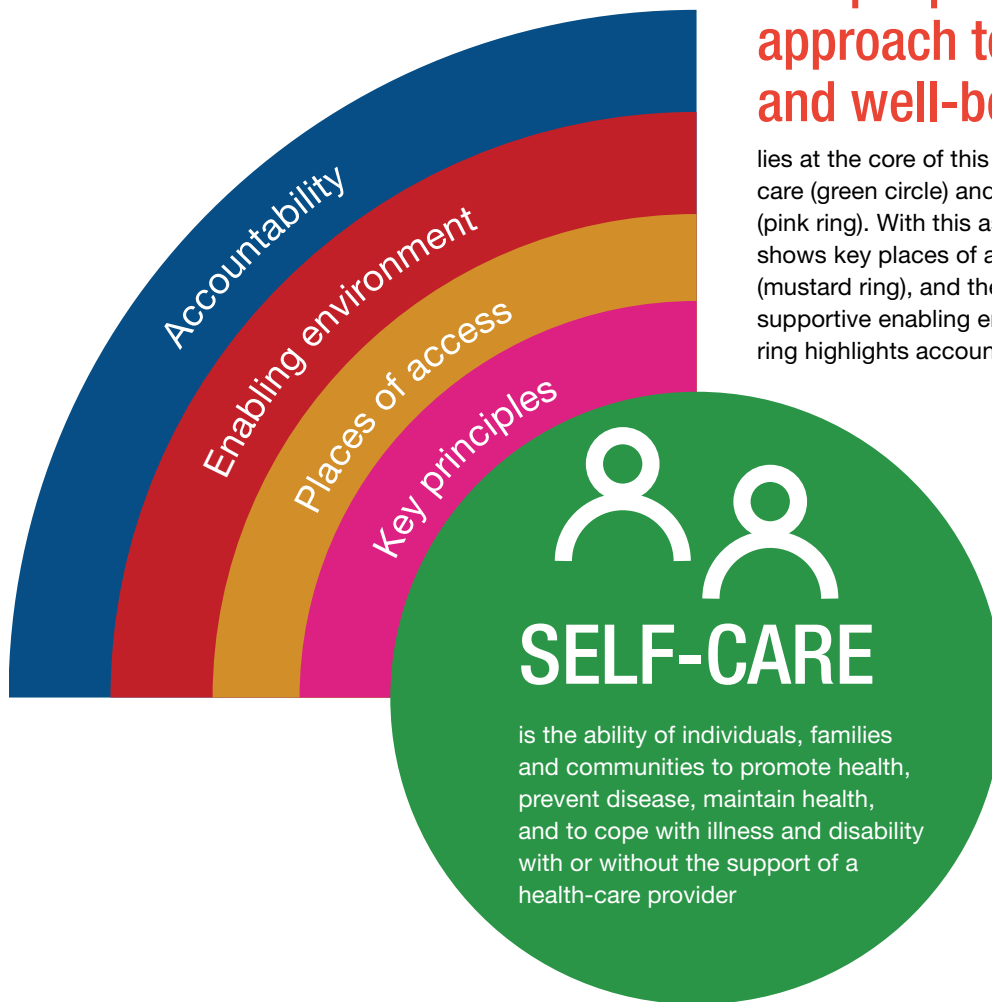
pp. 8–12

The conceptual framework for self-care is presented, including the working definition, approach and key principles.

ABOUT THIS GUIDELINE

pp. 12–15

These sections describe the scope, target audience, values and preferences taken into consideration with the development of this guideline



The people-centred approach to health and well-being

lies at the core of this conceptual framework for self-care (green circle) and is underpinned by “key principles” (pink ring). With this as a foundation, the framework then shows key places of access for self-care interventions (mustard ring), and then the key elements of a safe and supportive enabling environment (red ring). The outer blue ring highlights accountability at different levels.

OBJECTIVES OF THIS GUIDELINE ARE TO PROVIDE:

1 EVIDENCE-BASED RECOMMENDATIONS

on key public health self-care interventions, including for advancing SRHR, with a focus on vulnerable populations and settings with limited capacity and resources in the health system.

2 GOOD PRACTICE STATEMENTS

Key programmatic, operational and service-delivery issues that need to be addressed to promote and increase safe and equitable access, uptake and use of self-care interventions, including for advancing SRHR.

INTRODUCTION

1.1 BACKGROUND

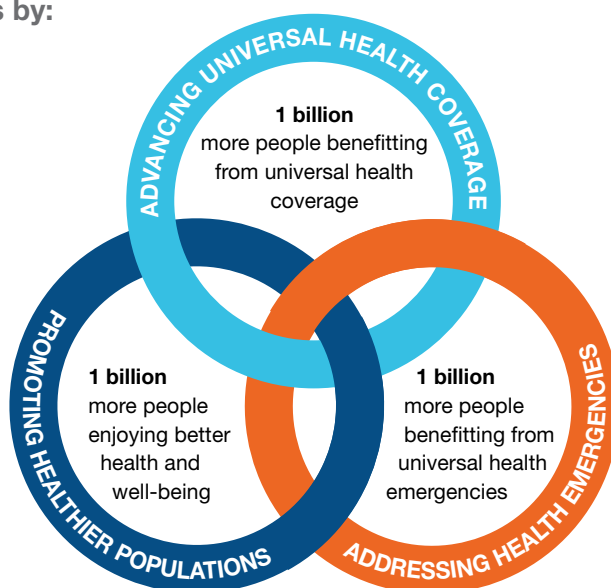
Very few countries have a health system that is staffed with sufficient numbers of trained and motivated health workers, supported by a well maintained infrastructure and a reliable supply of commodities, equipment and technologies, backed by adequate funding, and guided by strong health plans and evidence-based policies. Even in places with a well functioning health system, vulnerable and marginalized populations are often underserved and lack quality health care. Furthermore, worldwide, an estimated shortage of 18 million health workers is anticipated by 2030 (1), a record 130 million

people are currently in need of humanitarian assistance, and outbreaks of disease are a constant global threat. At least 400 million people worldwide lack access to the most essential health services, and every year 100 million people are plunged into poverty because they have to pay for health care out of their own pockets (2). There is, therefore, an urgent need to find innovative strategies that go beyond the conventional health sector response.

Innovative strategies are also needed to support the role of the World Health Organization (WHO) in moving forward with its 13th General Programme of Work (GPW13) and “triple billion” goals (see Figure 1.1).

FIGURE 1.1: WHO STRATEGIC PRIORITIES AND “TRIPLE BILLION” GOALS FROM THE 13TH GENERAL PROGRAMME OF WORK (GPW13)

Ensuring healthy lives and promoting well-being for all at all ages by:



Source: adapted from WHO, 2018 (3).

Self-care interventions are among the most promising and exciting new approaches to improve health and well-being, both from a health systems perspective and for people who might use these interventions. While “self-care” is not a new term or concept, self-care interventions have the potential to increase choice, when they are accessible and affordable, and they can also provide more opportunities for individuals to make informed decisions regarding their health and health care. In humanitarian settings, for example, due to a lack of or limited health infrastructure and medical services in

crisis-affected areas, self-care could play an important role to improve health-related outcomes.

Self-care builds upon existing movements, such as task sharing and task shifting, which are powerful strategies to support health systems.

A related practice is task sharing, whereby higher-level cadres continue to provide a service, but lower-level cadres can also provide the same service. Current WHO guidance reflects the



According to the WHO guidelines on task shifting (2008): Task shifting involves the rational redistribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health (4).

importance of both task shifting and task sharing, including entrusting certain aspects of health care to individuals to assess and manage their own care, including family planning (5), noting that “Women themselves have a role to play in managing their own health and this constitutes another important component of task sharing within health systems” (6).

In the area of sexual and reproductive health and rights (SRHR), this approach affirms and implements the WHO recommendations for self-care contained in this guidance, as well as the concept of building health assets, whereby

people can access usable, accurate information to inform their own decisions; make use of appropriate technologies; and seek health services and professional help when necessary (7). People practise many forms of self-care worldwide, often learning from health professionals and applying medical and/or traditional treatments themselves, especially when they are constrained by costs or have limited access to health-care facilities (8). For example, in rural northeast Thailand, 80% of self-reported mot luuk (uterus-related) complaints, such as vaginal discharge and pelvic pain, were self-treated, often with small doses of antibiotics bought from markets after seeing advertisements promoting branded tetracycline for these complaints (9). It is important, therefore, to have evidence-based normative guidance to ensure that quality interventions are available, accessible, acceptable and affordable.

Self-care interventions represent a significant push towards new and greater self-efficacy, autonomy and engagement in health for self-carers and caregivers. While risk and benefit calculations may be different in different settings and for different populations, with appropriate normative guidance and a safe and supportive enabling environment, self-care interventions offer strategies that promote active participation of individuals in their health and an exciting way forward to reach a range of improved outcomes, as listed in Figure 1.2.

FIGURE 1.2: IMPROVED OUTCOMES ASSOCIATED WITH SELF-CARE INTERVENTIONS



Self-care is increasingly being acknowledged in global initiatives, including for advancing primary health care (PHC) with the new Declaration of Astana (10) – coming 40 years after the 1978 Declaration of Alma-Ata (11) – to advance the health and well-being of people most effectively, equitably, efficiently and sustainably through PHC. The new Declaration calls for the mobilization of all stakeholders – health professionals, academia, patients, civil society, local and international partners, agencies and funds, the

private sector, faith-based organizations – to focus their efforts around the three main elements of PHC, which are as follows.

1. **Meeting people’s needs through comprehensive and integrated health services** (including promotive, protective, preventive, curative, rehabilitative and palliative) **throughout the entire life course**, prioritizing primary care and essential public health functions;

2. Systematically addressing the broader determinants of health (including social, economic and environmental factors, as well as individual characteristics and behaviours) through **evidence-informed policies and actions** across all sectors; and
3. **Empowering individuals, families and communities** to optimize their health as advocates for policies that promote and protect health and well-being, as co-developers of health and social services and **as self-carers and caregivers**.

In addition, the 2030 Agenda for Sustainable Development includes Sustainable Development Goals (SDGs) and targets for universal health coverage (UHC). Achieving UHC will require a paradigm shift in health service delivery and self-care interventions offer the possibility of making that paradigm shift while contributing to both UHC and PHC. Self-care within PHC represents a cornerstone of a sustainable health system for the achievement of UHC and to “ensure healthy lives and promote well-being for all at all ages” (SDG 3), as recognized by the Declaration of Astana (10).

The SDGs, particularly SDG 3 on health and well-being, SDG 4 on quality education and SDG 5 on gender equality, embrace a vision for leaving no one behind and, in doing so, call for us to reach out first to those who are furthest behind, including both in terms of coverage of essential services and related financial risk protection. In addition, SDG 9 on industry, innovation and infrastructure and SDG 12 on responsible consumption and production, encompass innovation and sustainability, and in the context of self-care interventions, this obliges us to anticipate an increase in the development, distribution and disposal of self-care products, reminding us that environmentally responsible management of health care production, consumption and waste will be required. SDG 10 on reduced inequalities is extremely relevant to the key principles of ethics and human rights which underpin this guideline and inform the recommendations. Finally, SDG 16 on peace, justice and strong institutions, emphasizes the importance of transparency, accountability and access to justice, which are all crucial aspects of an enabling environment for safe and effective health services, including self-care interventions.

1.2 OBJECTIVES

The purpose of this guidance is to develop a people-centred, evidence-based normative guideline that will support individuals, communities and countries with quality health services and self-care interventions, based on PHC

strategies, comprehensive essential service packages and people-centredness.

The specific objectives of this guideline are to provide:

- evidence-based **recommendations** on key public health self-care interventions, including for advancing SRHR, with a focus on vulnerable populations and settings with limited capacity and resources in the health system; and
- **good practice statements** on key programmatic, operational and service-delivery issues that need to be addressed to promote and increase safe and equitable access, uptake and use of self-care interventions, including for advancing SRHR.

1.3 LIVING GUIDELINE APPROACH

The concept for the format of this guideline is a “living guideline”. In a fast-moving field, this approach will allow for continual review of new evidence to inform further versions of the “living” document. The recommendations presented in this publication represent a subset of prioritized self-care interventions, in the area of SRHR, and this guideline aims to gradually include a broader set of self-care interventions over subsequent versions. The conceptual framework for self-care interventions (Figure 1.3 in section 1.4) provides a starting point for tackling the evolving field of self-care and for identifying self-care interventions for future updates. This first version of the guideline is intended to demonstrate the application of WHO Guidelines Review Committee (GRC) procedures to emerging self-care interventions, while also laying the groundwork for the inclusion of additional self-care interventions in future versions.

This “living guideline” approach also facilitates the updating of existing recommendations as new evidence becomes available, and the inclusion of additional health domains which may not be reflected in this initial release. In particular, the evidence and recommendations presented in this guideline are focused on some key aspects of SRHR, and a subsequent version of the guideline will expand the scope to other relevant SRHR topics as well as other relevant health areas. Future guidance on self-care in additional health areas will build upon existing tools and guidance. For instance, a WHO package of essential noncommunicable disease (NCD) interventions for PHC in low-resource settings includes far-reaching recommendations, including the use of self-testing and measurement, and self-adjustment of dosages. These recommendations also point to the importance of group education, and user-friendly, valid and

BOX 1.1: RELEVANT SUSTAINABLE DEVELOPMENT GOALS (SDGs) AND TARGETS

SDG 3: Ensure healthy lives and promote well-being for all at all ages

- **Target 3.7:** By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes
- **Target 3.8:** Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

SDG 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all

- **Target 4.5:** By 2030, eliminate gender disparities in education and ensure equal access to all levels of education and vocational training for the vulnerable, including persons with disabilities, indigenous peoples and children in vulnerable situations
- **Target 4.6:** By 2030, ensure that all youth and a substantial proportion of adults, both men and women, achieve literacy and numeracy

SDG 5: Achieve gender equality and empower all women and girls

- **Target 5.6:** Ensure universal access to sexual and reproductive health and reproductive rights as agreed in accordance with the Programme of Action of the International Conference on Population and Development and the Beijing Platform for Action and the outcome documents of their review conferences

SDG 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation

- **Target 9.5:** Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending

SDG 10: Reduce inequality within and among countries

- **Target 10.3:** Ensure equal opportunity and reduce inequalities of outcome, including by eliminating discriminatory laws, policies and practices and promoting appropriate legislation, policies and action in this regard
- **Target 10.4:** Adopt policies, especially fiscal, wage and social protection policies, and progressively achieve greater equality

SDG 12: Ensure sustainable consumption and production patterns

- **Target 12.7:** Promote public procurement practices that are sustainable, in accordance with national policies and priorities
- **Target 12.a:** Support developing countries to strengthen their scientific and technological capacity to move towards more sustainable patterns of consumption and production

SDG 16: Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels

- **Target 16.6:** Develop effective, accountable and transparent institutions at all levels

Source: United Nations Sustainable Development Goals Knowledge Platform (<https://sustainabledevelopment.un.org/sdgs>).

reliable online information (see existing recommendations on self-care for NCDs in Annex 2). Future versions of this living guideline on self-care interventions which discusses NCDs will build upon such existing guidance.

Chapter 7 describes how the living guideline approach is applied for updating and broadening the recommendations and good practice statements.

1.4 CONCEPTUAL FRAMEWORK FOR SELF-CARE INTERVENTIONS

The conceptual framework presented in Figure 1.3 is intended to support self-care interventions for health in general, including SRHR.

The framework illustrates core elements from both the “people-centred” and “health systems” approaches, which can support introduction, uptake and scale-up of self-care interventions (12). The people-centred approach to health and well-being (see section 1.6.1) lies at the core of this framework (green circle) and is underpinned by “key principles” (pink ring). With this as a foundation, the framework then shows key places of access for self-care interventions (mustard ring), and then the key elements of a safe and supportive enabling environment (red ring). The outer blue ring highlights accountability at different levels.



The framework illustrates core elements from both the “people-centred” and “health systems” approaches, which can support introduction, uptake and scale-up of selfcare interventions.

The 2018 Declaration of Astana underscores the importance of “[e]nabling and health-conducive environments in which individuals and communities are empowered and engaged in maintaining and enhancing their health and well-being” (10). Self-care interventions do not mean that there is any less government nor health system responsibility for health care. Noting that governments have the primary responsibility for promoting and protecting the right to health, this Declaration also highlights the need to “enable individuals and communities to identify their health needs, participate in the planning and delivery of services and play an active role in maintaining their own health and well-being” and to “support

people in acquiring the knowledge, skills and resources needed to maintain their health or the health of those for whom they care, guided by health professionals”. Self-care interventions, if situated in an environment that is safe and supportive, constitute an opportunity to help increase people’s active participation in their own health, including patient engagement.

1.5 DEFINITION OF SELF-CARE

The working definition of self-care for this consolidated guideline is:



Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health-care provider (13).

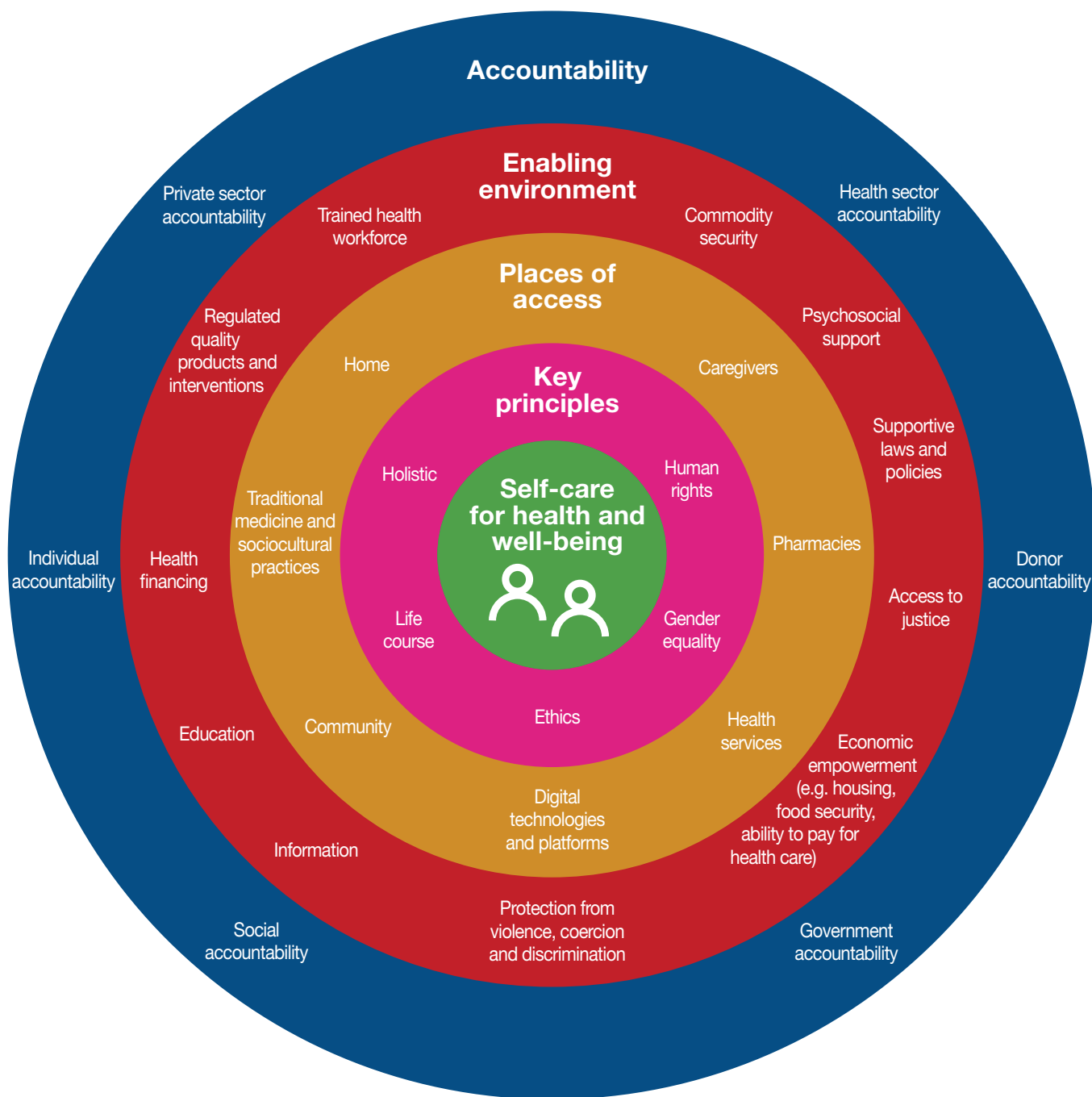
The scope of self-care as described in this definition includes health promotion; disease prevention and control; self-medication; providing care to dependent persons; seeking hospital/specialist/primary care if necessary; and rehabilitation including palliative care (14). It includes a range of self-care modes and approaches, as shown in Figure 1.4.

This definition of self-care is proposed based on a scoping review of WHO definitions of self-care. The scoping review and the definition are explained further in Annex 3.

1.6 APPROACH AND KEY PRINCIPLES

This guideline is grounded in and advocates for a strengthened, comprehensive, people-centred approach to health and well-being, including for SRHR. This approach is underpinned by the key principles of human rights, ethics and gender equality. People-centredness requires taking a holistic approach to the care of each person, taking account of their individual circumstances, needs and desires across their whole life course, as well as the environment within which they live.

FIGURE 1.3: CONCEPTUAL FRAMEWORK FOR SELF-CARE INTERVENTIONS



Source: adapted from Narasimhan et al., 2019 (12).

1.6.1 People-centred approach

People-centred health services are delivered using an approach to health care that consciously adopts the perspectives of individuals, families and communities.

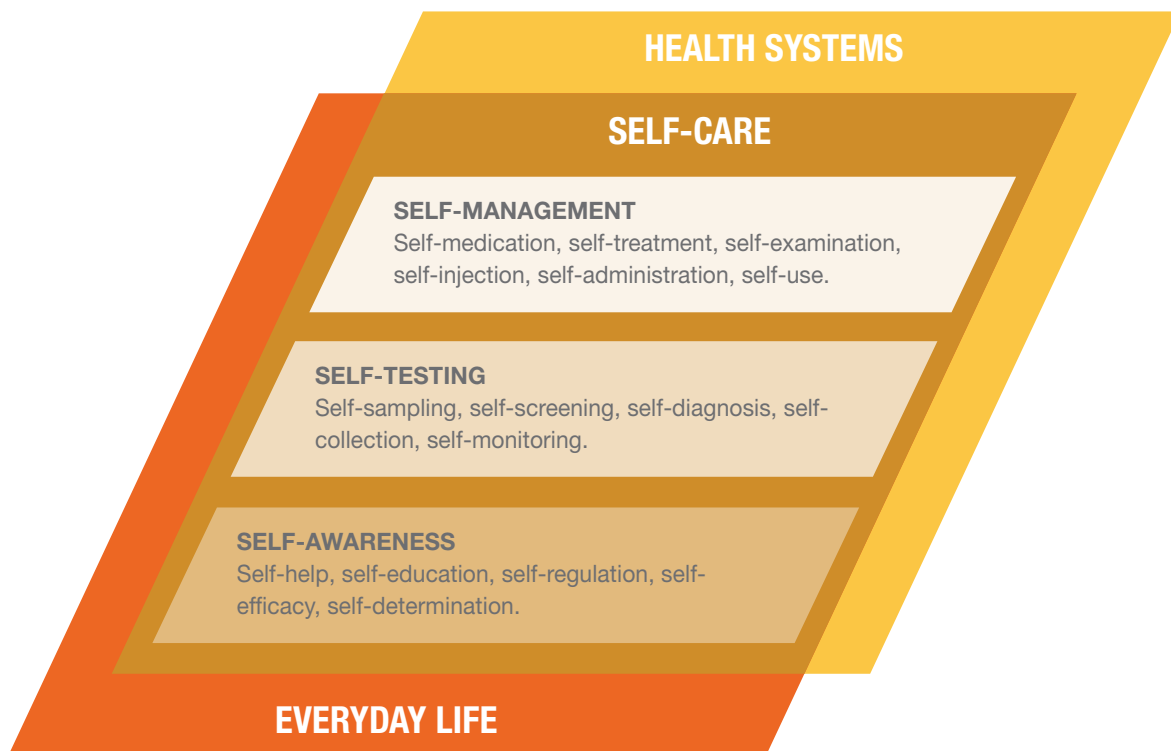
A people-centred approach (15, 16):

- sees individuals as active participants in, as well as beneficiaries of, trusted health systems that respond to their needs, rights and preferences in humane and holistic ways;
- emphasizes the promotion of gender equality as central to the achievement of health for all and promotes gender-transformative health services which examine harmful gender norms and support gender equality;
- requires that people are empowered – through education and support – to make and enact decisions in all aspects of their lives, including in relation to sexuality and reproduction;
- calls for strategies that promote people’s participation in their own health care;
- recognizes the strengths of individuals as active agents in relation to their health, and not merely passive recipients of health services; and
- is organized around the health needs and priorities of people themselves rather than disease management and control.

The Integrated People-Centred Health Services (IPCHS) framework calls for a fundamental shift in the way health services are funded, managed and delivered to respond to these challenges.

WHO recommends five interwoven strategies that need to be implemented in order to achieve IPCHS. Application of the approach can build robust and resilient health services, which are critical for progress towards UHC and fulfilling the SDGs (15).

FIGURE 1.4: SELF-CARE IN THE CONTEXT OF INTERVENTIONS LINKED TO HEALTH SYSTEMS



Source: adapted from Narasimhan et al., 2019 (12)

Self-care interventions should meet the health needs and aspirations of potential users at all stages of the life course. This helps ensure that the needs of different age groups are

considered and that people’s changing vulnerabilities over time are taken into account in terms of both access to and use of self-care interventions.



The IPCHS vision is that:

All people have equal access to quality health services that are co-produced⁴ in a way that meets their life course needs, are coordinated across the continuum of care and are comprehensive, safe, effective, timely, efficient and acceptable; and all carers are motivated, skilled and operate in a supportive environment (15).

1.6.2 Holistic approach

With people at the centre, their health has to be considered in a holistic manner, requiring attention to their overall health, not just one particular health issue. A holistic approach to health encompasses issues beyond access to or uptake of biomedical interventions (e.g. self-testing). In this context, the term self-care for health encompasses an overarching and innovative approach to health systems. And while SRHR is the focus of this present publication, self-care interventions are applicable in health care far beyond the field of SRHR; they can also be applied to a range of infectious diseases and noncommunicable diseases (NCDs), including mental health, among other areas.

Adopting a holistic approach requires working at multiple levels, from the individual, the family, and the community, to the broader health system and the overarching enabling environment. In this way, not only is every aspect of the individual's health considered but also the different pieces of the environment within which the individual lives, all of which influence individual health and care-seeking.

1.6.3 Human rights, ethics and gender equality approaches

An integrated approach, based on human rights, ethics and gender equality, lies at the heart of ensuring the dignity and

well-being of individuals. An ethical approach should inform all decisions about self-care interventions, underpinned by the principles of fairness and equity (17). This includes respect for medical ethics within health services, and it also goes beyond this to ensure an ethical approach anywhere that self-care interventions are accessed and used outside the health system.

Laws, policies and interventions should address gender inequalities, including harmful gender norms and stereotypes, unequal power in intimate relationships, and women's and sexual and gender minorities' relative lack of access to and control over resources. All of these inequalities exacerbate people's vulnerability, affect their access to and experience of health services, and create barriers that prevent them from fully exercising their health-related rights, including SRHR. The promotion of gender equality is central to facilitating access to self-care interventions for all those who might benefit from them.

The protection of human rights is fundamental to this guideline. Human rights relating to sexual and reproductive health (SRH) include: the rights of all people to have pleasurable and safe sexual experiences, free of coercion, discrimination and violence; the right to be informed of and have access to safe, effective, affordable and acceptable methods of fertility regulation of their choice; and the right of access to appropriate health services that will enable individuals to go safely through pregnancy and childbirth and provide individuals and couples with the best chance of having a healthy infant.⁵ Furthermore, article 27 of the Universal Declaration of Human Rights states that everyone has the right freely "to share in scientific advancement and its benefits" (19).

In its General Comment No. 22 (2016), the United Nations Committee on Economic, Social and Cultural Rights (CESCR) defined the right to SRH as an "integral part of the right to health enshrined in article 12 of the International Covenant on Economic, Social and Cultural Rights" (ICESCR) (20). According to this General Comment, the right to SRH entails a set of entitlements, including unhindered access to a whole range of health-care facilities, goods, services and information, which ensure – for all people – full enjoyment of the right to SRH under article 12 of the ICESCR (20). Showing respect for individual dignity and for the physical and mental integrity of

⁴ Definition: co-production of health:care that is delivered in an equal and reciprocal relationship between professionals, people using care services, their families and the communities to which they belong. It implies a long-term relationship between people, providers and health systems where information, decision-making and service delivery become shared (15).

⁵ For a more complete list of relevant rights, see the following pages on the WHO website: "Defining sexual health" (http://www.who.int/reproductivehealth/topics/sexual_health/sh_definitions/en/); "Reproductive health" (http://www.who.int/topics/reproductive_health/en/). See also the 2015 WHO publication, *Sexual health, human rights and the law* (18).

each person includes giving each one the opportunity to make autonomous reproductive choices (21, 22, 23). The principle of autonomy, expressed through free, full and informed decision-making, is a central theme in medical ethics, and is embodied in human rights law (24). This holds particular relevance in the context of self-care interventions, as people may rely on publicly available information rather than health-care professionals to make appropriate decisions when selecting and using them.

The Programme of Action of the 1994 International Conference on Population and Development (ICPD) highlighted SRH issues within a human rights framework (25). It defined reproductive rights as follows:



[R]eproductive rights embrace certain human rights that are already recognized in national laws, international human rights documents and other consensus documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health. It also includes their right to make decisions concerning reproduction free of discrimination, coercion and violence, as expressed in human rights documents (25: paragraph 7.3).

Since then, international and regional human rights standards and jurisprudence related to SRHR have evolved considerably. There is a growing consensus that sexual health cannot be achieved and maintained without respect for, and protection of, certain human rights. The application of existing human rights to sexuality and sexual health constitutes sexual rights. Sexual rights protect all people's rights to fulfil and express their sexuality and enjoy sexual health, with due regard for the rights of others and within a framework of protection against discrimination (26).

WHO has recognized certain human rights to be particularly and specifically integral to the promotion and protection of SRHR (24, 27). As such these human rights are equally applicable to self-care interventions for SRHR. Centred

around the user, Table 1.1 outlines the relevance of these human rights standards to the adoption and provision of self-care interventions.

In the course of developing this guideline, a literature review, focusing on a limited set of self-care interventions, was conducted to support a human-rights-based case for interventions that meet the needs and aspirations of even the most vulnerable populations (28). This analysis found that the above human rights standards and principles are critical to ensuring appropriate roll-out of self-care interventions. SRHR outcomes are not equal for people throughout the world, neither across nor within countries. Many of these disparities, which are rooted in underlying social determinants, are avoidable and unacceptable (29). In the provision of self-care interventions, systematic consideration of human rights, ethics and gender equality – in the context of a well functioning health system as well as a safe and supportive enabling environment – will help ensure better health for all.

1.7 SCOPE OF SELF-CARE INTERVENTIONS

1.7.1 Self-care for SRHR

Within the framework of WHO's definition of health, as "a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity" (30), SRH addresses sexuality and sexual relationships as well as the reproductive processes, functions and system at all stages of life. Ensuring the full implementation of human-rights-based laws and policies through SRH programmes is fundamental to health and human rights (see section 1.6.3 and Table 1.1).

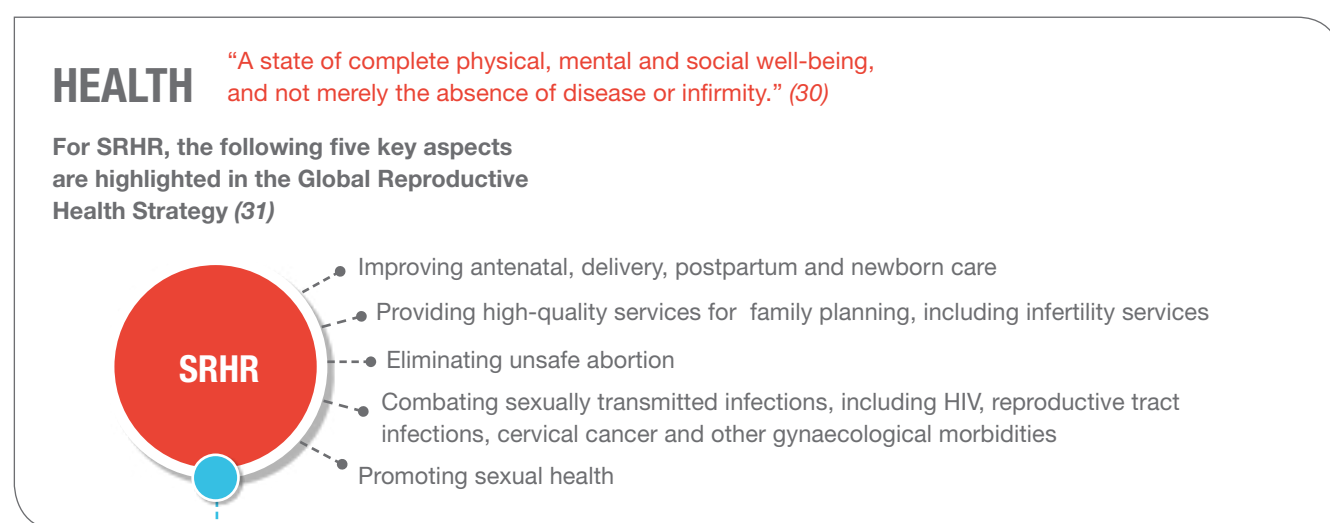
The comprehensive approach to SRHR endorsed by WHO Member States in the 2004 Global Reproductive Health Strategy covers five key areas (Figure 1.5) – maternal and perinatal health; family planning, including infertility services; abortion; sexually transmitted infections (STIs), including HIV, reproductive tract infections, cervical cancer and other gynaecological morbidities; and sexual health – as well as several cross-cutting areas such as gender-based violence (31).

While self-care is important in all aspects of health, it is particularly important – and particularly challenging to manage – for populations negatively affected by gender, political, cultural and power dynamics and for vulnerable persons (e.g. people with disabilities and mental impairment). This is true for self-care interventions for SRHR, since many people are unable to exercise autonomy over their bodies and are unable to make decisions around sexuality and reproduction.

TABLE 1.1: HUMAN RIGHTS APPROACH TO SELF-CARE INTERVENTIONS FOR SRHR

HUMAN RIGHTS STANDARD	RELEVANCE TO SELF-CARE INTERVENTIONS FOR SRHR
The right to health, including availability, accessibility, acceptability and quality of information, goods and services	The ability of the user to engage in the use of self-care interventions with information and products that are available, accessible, acceptable and of good quality is a core component of promoting and protecting their right to health.
The right to participation	Active, fully informed participation of individuals in decision-making processes that affect them extends to matters relating to health.
The right to equality and non-discrimination	This right highlights the particular challenges faced by people who may be marginalized or face discrimination and stigma, and it helps to ensure that relevant regulatory frameworks, laws, policies and practices conform to human rights principles.
The right to information	The right to information has implications for how the provision of information is regulated, including determinations about where liability falls for inaccurate or false information.
The right to informed decision-making	Availability of accurate, accessible, clear, user-friendly information framed in non-discriminatory terminology is central to informed decision-making around self-care interventions.
The right to privacy and confidentiality	Guarantees of privacy and confidentiality may require additional consideration where self-care interventions are accessed outside the health system.
The right to accountability	Accountability includes accountability of the health sector as a whole and regulation of the private sector, and encompasses the legal and policy environment more broadly. It also includes a system of redress that promotes access to justice in cases where rights related to self-care interventions may be neglected or violated.

FIGURE 1.5: SCOPE OF OF SELF-CARE INTERVENTIONS FOR SRHR



Self-care for vulnerable populations who may require additional information or support to make informed decisions about uptake and use of self-care interventions.

1.7.2 Self-care for vulnerable populations

Not all interventions are situated in the same space between users themselves and health-care providers. The use and uptake of self-care interventions is organic and the shift in responsibility, between full responsibility of the user and full responsibility of the health-care provider (or somewhere along that continuum), can also change over time for each intervention and for different population groups. There are interventions which users may have good knowledge of and feel comfortable with, while other interventions require further guidance before becoming better accepted and used by individuals autonomously. In addition, not all people require the same level of support, and vulnerable populations in particular may require additional information and/or support to make informed decisions about their uptake and use of self-care interventions. Safe and strong linkages between independent self-care and access to quality health care for vulnerable individuals is critically important to avoid harm. Where self-care is not a positive choice but is prompted by fear or lack of alternatives, it can increase vulnerabilities.

1.7.3 Scope of this guideline

To our knowledge, there are no specific guidelines already in existence on self-care interventions for SRHR at national, regional or international levels. This guideline will address this gap. WHO guidance already exists on several specific aspects of self-care. This consolidated guideline seeks to bring together both new and existing WHO recommendations and good practice statements, especially in relation to SRHR.

Where current WHO guidance exists, this document refers readers to those other publications for further information, as well as to other relevant WHO tools and documents on programme activities. The recommendations and good practice statements presented in this guideline relate either to specific health-related interventions aimed at advancing SRHR (see Chapter 4) or to creating and maintaining an enabling environment, particularly for vulnerable populations (see Chapter 5). All of the new WHO recommendations presented in this guideline have been developed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (32). The new recommendations focus on self-care interventions that are considered to be currently in transition from provision by facility-based health-care providers to delivery using a self-care approach. Section 3.4 in Chapter 3 describes how the issues to be addressed, and the specific recommendations and good practice statements to be included in this guideline, were determined. All of the new and existing recommendations presented in this guideline are summarized in Table 1 in the Executive summary and described in detail in Chapter 4.

WHO recommendations on self-care for NCDs are listed in Annex 2, as previously noted, and will inform the scope of future versions of this guideline.

Informal consultations are taking place at the regional level to examine the current situation of self-care interventions for SRHR at national levels and determine factors to facilitate the uptake of the guideline.

1.8 TARGET AUDIENCE

Primary target audience:

- national and international policy-makers, researchers, programme managers, health workers (including pharmacists), donors and civil society organizations responsible for making decisions or advising on delivery or promotion of self-care interventions.

Secondary target audience:

- product developers.

This new guideline is also expected to support:

- persons affected by the recommendations, i.e. persons taking care of themselves, and caregivers.

Health services and programmes in low-resource settings will benefit most from the guidance presented here, as they face the greatest challenges in providing services tailored to the needs and rights of vulnerable populations. However, this guideline is relevant for all settings and should, therefore, be considered as global guidance. In implementing these globally relevant recommendations and good practice statements, WHO regions and countries can adapt them to the local context, taking into account the economic conditions and the existing health services and health-care facilities.

1.9 VALUES AND PREFERENCES

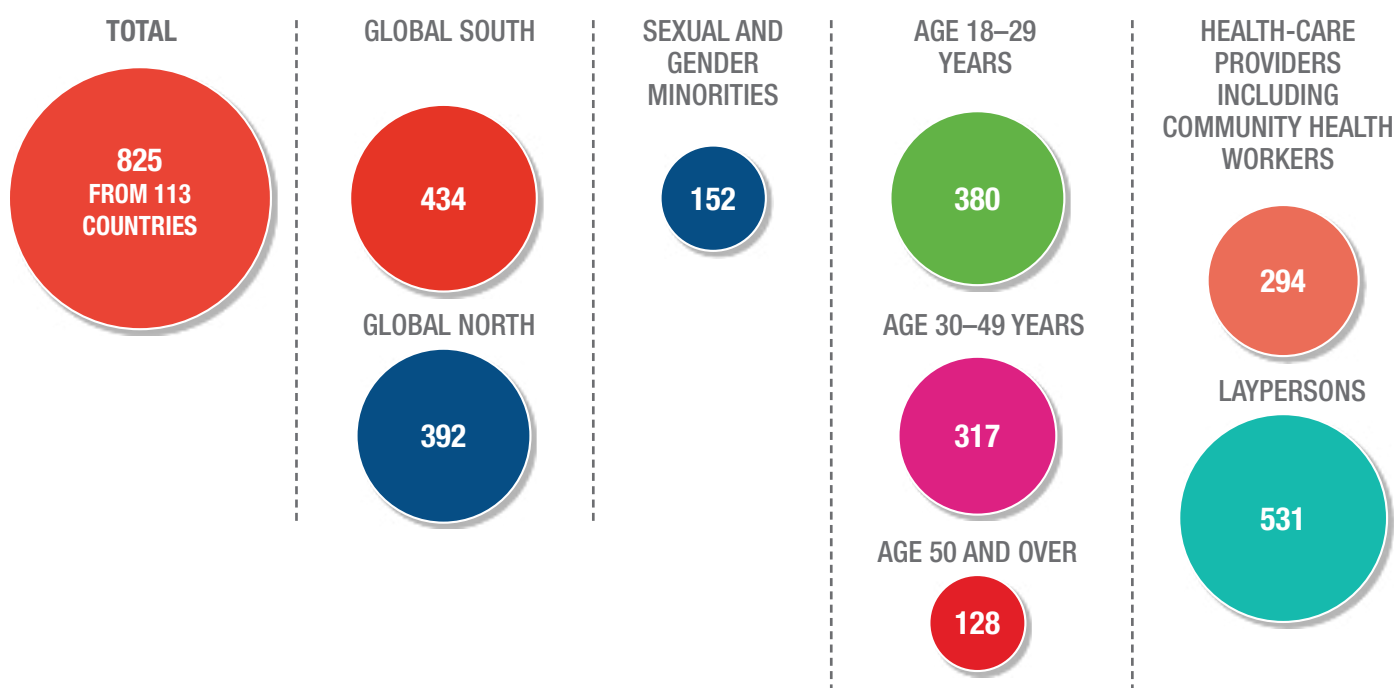
Building upon the best practice of assessing end-user values and preferences as used for the 2017 WHO *Consolidated guideline on sexual and reproductive health and rights of women living with HIV* (33), a global survey was conducted on self-care interventions for SRHR. The global survey, which was available online in English, French and Spanish, ran for seven weeks from mid-September to mid-November 2018. This survey, hereafter referred to as the Global Values and Preferences Survey (GVPS), is the largest survey to date on self-care interventions for SRHR.

A total of 825 people from 113 countries responded online to the web-based survey, including health-care providers (35.6% of respondents) (Figure 1.6). Approximately half of the participants were from the Global South (52.6%) and half from the Global North (47.4%). There was good regional representation with 26.1% of respondents from Africa, 17.6% from Asia, 27.2% from Europe, 15.0% from Latin America and the Caribbean, 13.3% from North America and 0.8% from Oceania. Respondents ranged in age from 18 to 70 years and came from a diverse range of backgrounds including: sexual and gender minorities (18.4%); young people between 18 and 29 years old (46.1%) and people aged 50 and older (15.5%). The limitations of the survey include: the survey was most likely to reach people who were able to locate and access an online survey using the Internet; and it was only available to persons who could read English, French or Spanish. The strengths of the survey include: the wide range of global

responses from every region, which provided a snapshot into differential access; and the inclusion of qualitative responses, highlighting a range of perspectives on self-care interventions for SRHR.

The GVPS results were presented at the Guideline Development Group (GDG) meeting, which was held 14–16 January 2019, in Montreux, Switzerland. The GDG took the findings of the GVPS into account in the process of developing the new recommendations for this guideline (just as they also took into account the findings of literature reviews on values and preferences related to each intervention addressed by the new recommendations). Relevant GVPS findings are included in Chapter 4 for three of the five new recommendations, and findings from the literature reviews on values and preferences are also summarized for each of the five recommendations (see sections 4.2.1 and 4.4.1).

FIGURE 1.6: NUMBER OF RESPONDENTS TO THE GLOBAL VALUES AND PREFERENCES SURVEY (GVPS) PER REGION



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2

ESSENTIAL STRATEGIES FOR CREATING AND MAINTAINING AN ENABLING ENVIRONMENT FOR SELF-CARE



“It is important to ensure that self-care interventions reach users with all the necessary checks and balances in place to support their rights and needs.”



CHAPTER AT A GLANCE

This chapter investigates essential strategies that help to create and maintain an enabling environment for self-care interventions. The main elements which need to be assessed and addressed are:

THE HEALTH SYSTEM AND ITS COMPONENTS

pp. 16–19

Health systems important in shaping a user's experiences of self-care interventions. This direct interaction between self-care and health systems, mean that it is essential that both elements adapt and respond to one another, to ensure effective and adequate care for the individual. This should be done at the level of each one of the six building blocks of the WHO health systems framework.

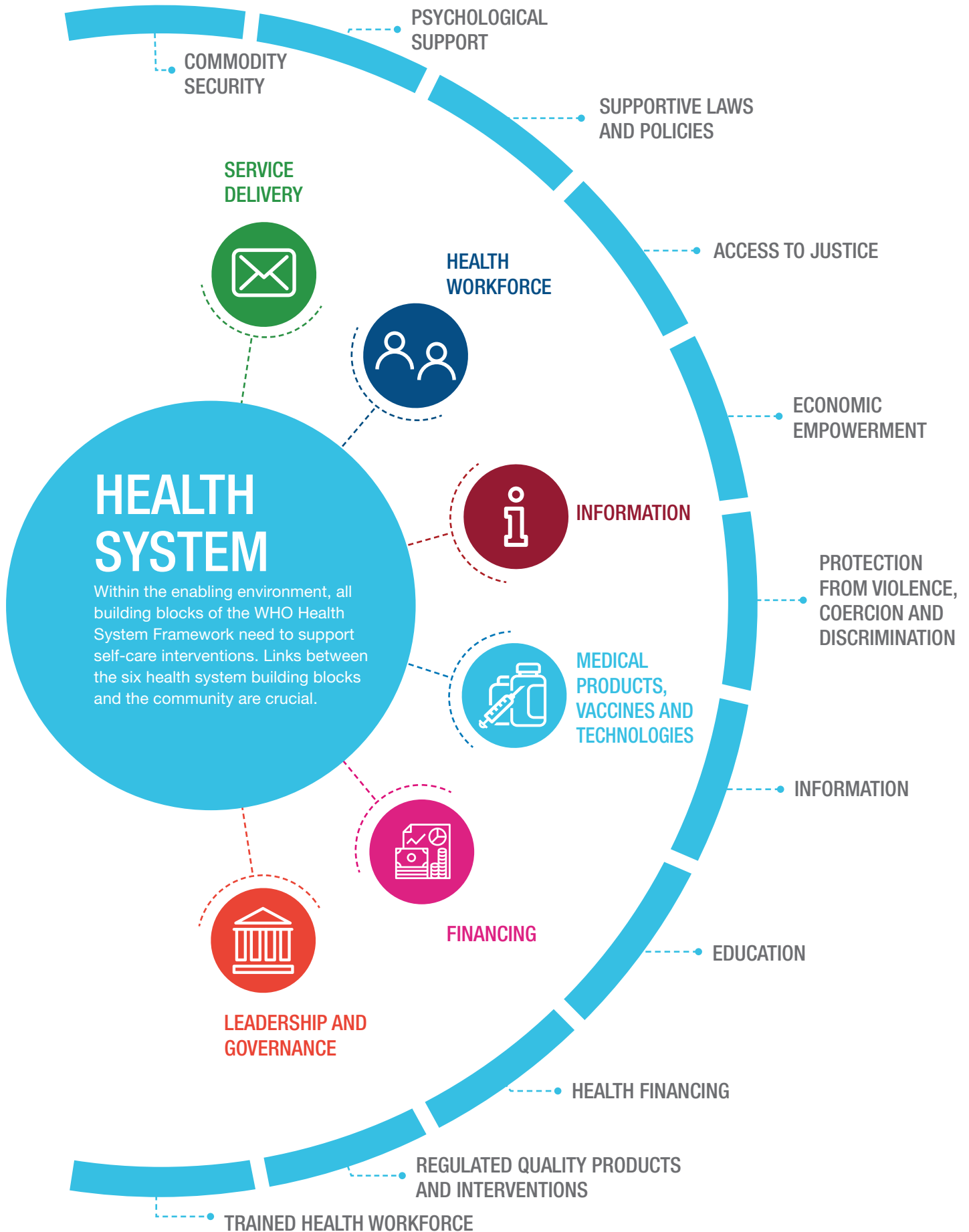
SOCIAL DETERMINANTS AND THE ENVIRONMENT ITSELF

pp. 20–22

Access to and use of health services are shaped by the environment in which both the individual and health system are situated. It is important that the environment is conducive to care providing access, coverage, quality and safety.

ENABLING ENVIRONMENT

These aspects of the environment play a crucial role in shaping individuals' access to and use of health services, as well as their health outcomes.



2.1 BACKGROUND

A safe and supportive enabling environment is essential to facilitate access to and uptake of products and interventions that can improve the health and well-being of vulnerable and marginalized populations. Achieving the SDG targets (see Box 1.1) therefore requires systematic attention to all aspects of the health system as well as the broader environment within which self-care interventions are delivered.

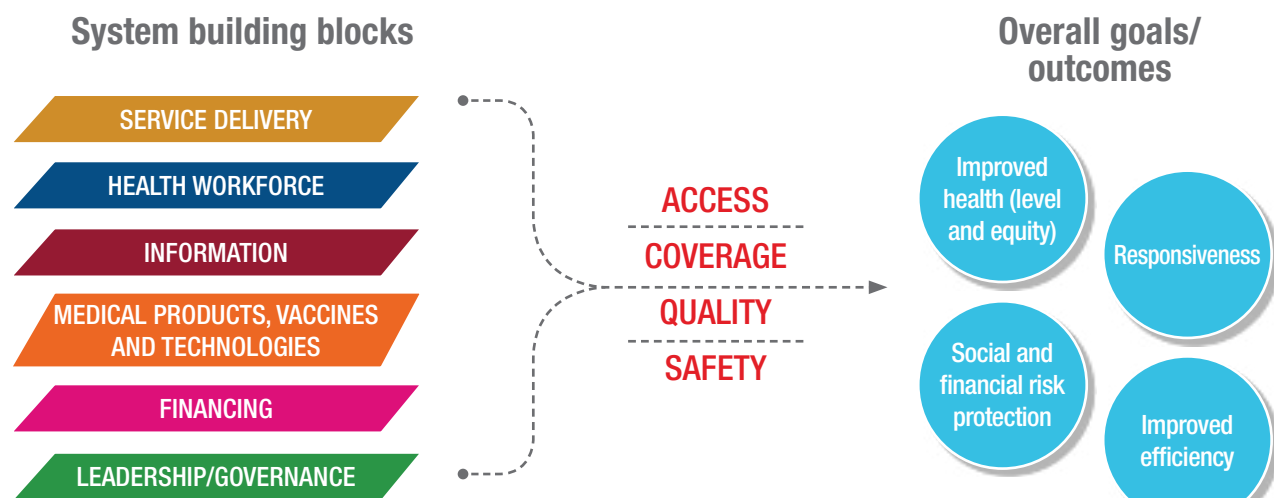
Creating and ensuring an enabling environment in which self-care interventions can be made available in safe and appropriate ways must be the key starting points of any strategy to introduce or scale-up these interventions. This should be informed by the profile of potential users, the services on offer to them, and the broader legal and policy environment and structural supports and barriers. It is important to ensure that self-care interventions reach users with all the necessary checks and balances in place to support their rights and needs. This guideline's key

principles are designed to draw systematic attention to key areas of potential concern in order to inform actions that might militate against these negative impacts and, instead, ensure a supportive and responsive health system and broader enabling environment.

2.2. THE HEALTH SYSTEM

Self-care interventions must be an adjunct to, rather than a replacement for, direct interaction with the health system, and this may require reconceptualizing the boundaries of the health system. Users' experiences of self-care interventions are shaped, in part, by the health system. To be safe and effective, and to reach individuals who may not be able to access health care, self-care interventions may need more – not less – support from the health system (1). Drawing on the WHO Health System Framework (2), every health system “building block” (see Figure 2.1) needs to be adapted to ensure its adequacy for effective self-care interventions.

FIGURE 2.1: THE WHO HEALTH SYSTEM FRAMEWORK



Source: WHO, 2007 (2).

In addition, there will be an increased need to reach out to communities to ensure that people have appropriate information about self-care interventions to make informed choices about using them, and that they seek support from health workers as needed. This is further explored in section 2.2.7, with the potential users of self-care interventions placed at the centre of all considerations relating to how the health system might have to respond.

2.2.1 Service delivery

Service provision or delivery is a direct function of the inputs into the health system, such as the health workforce, procurement/supplies, and financing: increased inputs should lead to improved service delivery and enhanced access to services. Ensuring availability of and access to health services that meet or exceed the minimum quality standards are key functions of a health system (3). Services are organized around the person's needs and preferences, not the disease

or the person's ability to pay. Users perceive health services as being responsive and acceptable to them (or not) and this promotes an approach where people are active partners in their own health care. Service delivery is organized to provide an individual with continuity of care across the network of services, health conditions, levels of care, and over the life course.

2.2.2 The health workforce

The forthcoming WHO global competency framework for universal health coverage (UHC) will cover health interventions across promotive, preventative, curative, rehabilitative and palliative health services, which can be provided by health professionals and community health workers at the primary health care level with a pre-service training pathway of 12–48 months (4). The framework will focus on the competencies (integrated knowledge, skills and behaviours) required to provide interventions, and will have relevance to both pre-service and in-service education and training. In order to maximize the opportunities to promote and facilitate self-care interventions for sexual and reproductive health and rights (SRHR), it is important that training for health workers incorporates: communication to enable informed decision-making; values clarification; interprofessional teamworking; and empathetic and compassionate approaches to care.

Delivery of care and treatment services should be accomplished in a people-centred and nonjudgemental way, allowing everyone to lead the decision-making about their own care in an informed and supported fashion. Self-care interventions, even if accessed and used outside health services, require some engagement with the health system and, as such, it is critical that the attitudes and behaviours of health workers be inclusive and non-stigmatizing, and that they promote safety, including patient safety and equality. Health-care providers and managers of health-care facilities – whether in the public or private sector – are responsible for delivering services appropriately and meeting standards based on professional ethics and internationally agreed human rights principles. Health workers also need to acknowledge that people have always and will continue to practise self-care that is not initiated by the health system.

2.2.3 Information

Health information and services must be available and accessible at the time and place they are needed, and they must also be acceptable and of high quality. With self-care interventions available outside the health system, potential users must have access to reliable, useful, quality information that is consistent with the needs of the individual

and the community. Additionally, pictures and visuals are useful in overcoming language barriers and literacy issues. Mobile phones, tablets and other information and communications technologies (ICTs) are providing new opportunities to deliver health information. There may be a need to devise different ways of providing information to populations with diverse needs and different levels of literacy that connects them back to the health system as appropriate.

Health information should be available to and used by health workers to address clinical and non-clinical aspects of self-care for SRHR. Information should be reliable and accurate, and it needs to be trusted by individuals, who rely on it to support their informed decision-making about their personal health and well-being and about their interactions with the health system. For example, patient information leaflets are a legal requirement in many countries, and they must be designed to ensure that patients who rely on the information provided can make informed decisions about the safe and effective use of the products and interventions described. Capturing information about self-care interventions may require the expansion of health management information systems (HMIS) beyond the traditional confines of the health system.

2.2.4 Medical products, vaccines and technologies

The sequence of processes to guarantee access to appropriate and safe medical products, vaccines and technologies includes health technology regulation, assessment and management (see Figure 2.2) (5). The national (i.e. government) regulatory authorities determine which medical products, vaccines and technologies can enter the local market. Necessary medical products and technologies must be made available to allow for the uninterrupted delivery of services and implementation of interventions; this includes supplies that might be accessed outside of traditional health services (e.g. through pharmacies or online). Even though most self-care interventions are likely to be used outside the health-care setting, the quality of the products and technologies must be appropriately regulated (see section 2.2.6).

Reproductive health commodity security (RHCS) exists when every person is able to choose, obtain and use quality contraceptives and other essential reproductive health products whenever they need them. As demand for reproductive health supplies increases, countries are under increasing pressure to establish and maintain secure systems for procuring reproductive health commodities

FIGURE 2.2: SEQUENCE OF PROCESSES TO GUARANTEE ACCESS TO APPROPRIATE AND SAFE MEDICAL DEVICES



Source: adapted from WHO, 2017 (6).

and managing their delivery. RHCS involves planning, implementation, and monitoring and evaluation of supply chain processes at the programme level, as well as broader policy advocacy, management of procurement issues, devising costing strategies, multi-sectoral coordination and addressing contextual considerations. Enabling and strengthening in-country capacity for RHCS is an essential step in guarding against shortfalls in much-needed reproductive health supplies (7).

2.2.5 Financing

Using self-care approaches and technologies to deliver certain health-care interventions could affect: (i) how much societies pay for delivering these interventions (and producing the associated health outcomes); (ii) who pays for these interventions; and (iii) who accesses them (8). A critical consideration for equity is that self-care should not be promoted as a means of saving costs for the health system by shifting costs to users. For example, if users have to obtain test kits or other devices or supplies to access an intervention which would otherwise be paid for by the health system if accessed within health services, then wherever possible these costs should remain with the health system and not be transferred to the user. Benefit packages and risk-pooling mechanisms may have to be designed to support those accessing self-care interventions in a range of settings and to ensure financial protection. Since UHC aims to ensure equitable and sustainable access to an essential package of quality care (see further information on UHC in Box 5.3 in section 5.3), there may be scope for differentiated financing models that include a combination of government subsidies, private financing, insurance coverage and partial out-of-pocket payments, based on the principle of progressive universalism. Budgetary allocations and

financing strategies need to be recognized for the critical role they play in creating the enabling environment for people to use self-care interventions to help achieve good health outcomes, contributing to UHC and promoting cost-effective service delivery. Health systems must also consider the potential savings that may result from earlier diagnosis and treatment due to self-care, and include these in the financial equation.

2.2.6 Leadership/governance – the regulatory environment

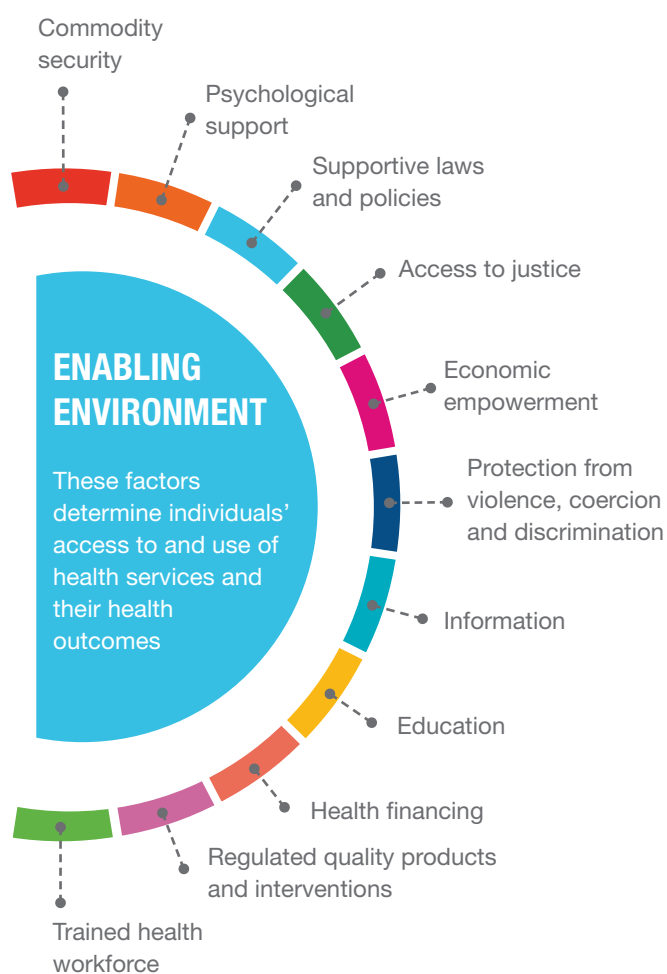
With self-care interventions encompassing many different products and places of access, regulation of a wide range of actors is necessary. Regulation of self-care interventions should be aligned with human rights laws and obligations and be sensitive to the relevant differences among interventions and among users, as well as across the diversity of locations where these interventions are purchased and used. It is likely that, as self-care interventions become increasingly available through the private sector and online, informal and/or unregulated vendors might supply products of unknown quality, safety and performance (9). Regulation is key in this context, and it is critical to balance ensuring quality and safety against restricting access. Detection and correction of any undesirable trends and distortions – i.e. any negative impacts or unintended uses of self-care interventions – is also important. The regulatory system also has a role to play to identify and prevent the spread of counterfeit products. Finally, transparent, accessible and effective accountability mechanisms must be put in place; these may operate alongside other social accountability mechanisms, but there must be avenues for remedy, redress and access to justice through the health system (10, 11).

2.2.7 Links between health systems and communities

In the context of self-care interventions, bridges between health systems and communities take on unprecedented importance for ensuring safe, informed and appropriate use of these interventions. This should include outreach to provide information on self-care interventions as well as the traditional/standard options available, and how and where to seek support from health services as and when required, including outreach to communities who may be unaware of new technological advances in self-care products.

Safe and effective provision of self-care interventions requires that mechanisms be put into place to overcome any barriers to service uptake, use and continued engagement with the health system. These barriers occur at the individual, interpersonal, community and societal levels. They may include challenges such as social exclusion

FIGURE 2.3: CHARACTERISTICS OF THE ENABLING ENVIRONMENT TO SHAPE ACCESS TO AND USE OF SELF-CARE INTERVENTIONS



and marginalization, criminalization, stigma, gender-based violence and gender inequality, among others. Strategies are needed across health system building blocks (see Figure 2.1) to improve the availability, accessibility, acceptability, affordability, uptake, equitable coverage, quality, effectiveness and efficiency of self-care interventions as well as links to services. Left unaddressed, such barriers could undermine health, even where self-care interventions are available; removing these barriers is a critical part of creating an enabling environment for self-care interventions.

2.3 ENABLING ENVIRONMENT

The environment within which the health system is situated and the individual resides plays a crucial role in shaping individuals' access to and use of health services, as well as their health outcomes (Figure 2.3). This is particularly true for self-care interventions, many of which are accessed and/or used outside health services (1). This environment must, therefore, be conducive to the realization of SRHR for all. The importance of the social determinants of SRHR, as manifested in laws, institutional arrangements and social practices that prevent individuals from effectively enjoying their SRHR, has been well documented (12).

2.3.1 Access to justice

Policies and procedures are needed to ensure that all people can safely report rights violations, such as discrimination, violations of medical confidentiality and denial of health services. Programmes should facilitate the same level of access to justice for individuals using self-care interventions. Primary considerations in facilitating access to justice must include safety, confidentiality, choice and autonomy in terms of whether or not an individual wants to report the violation experienced. A functional system of remedy and redress should be accessible to users; in the case of rights violations (e.g. discrimination), such a system provides a mechanism for seeking legal redress, through which users can hold duty-bearers, including health workers, accountable for their actions or inactions. Where appropriate, health-care providers should facilitate access to justice by offering to support clients who want to report violations to the police.

2.3.2 Economic empowerment

Livelihood insecurity, poverty and a lack of resources to meet key needs and expenses contribute to greater vulnerability and poor SRHR outcomes. Socioeconomic vulnerabilities can make it difficult for people to exercise their SRHR, such as in situations where individuals

are dependent on violent or abusive partners, or transactional sex, to ensure that their own and/or their children's basic needs are met. There is a risk that self-care interventions might shift the costs of care from the health system to the individual (see section 2.2.5). This could exacerbate inequities in terms of access to these interventions. Therefore, interventions focused on economic empowerment, poverty reduction and resource access, such as housing and food support, have the potential to improve access to health care and improve health outcomes for all.

2.3.3 Education

Education, particularly secondary education, is important for empowering people in relation to their SRHR, and has repeatedly been found to be associated with a wide range of better sexual and reproductive health (SRH) outcomes as well as improved knowledge of how to maintain good health (13, 14). The central role of comprehensive sexuality education (CSE) in empowering young people to take responsible and informed decisions about their sexuality and relationships is also well documented (15). Ensuring access to education, including CSE, for all will support informed decision-making with regard to self-care interventions and associated care seeking.

2.3.4 Protection from violence, coercion and discrimination

Violence can take various forms, including physical aggression, forced or coerced sexual contact, and psychological abuse, as well as controlling behaviours by an intimate partner (16). Multiple structural factors influence vulnerability to violence, including discriminatory or harsh laws and policing practices, and cultural and social norms that legitimize stigma and discrimination (16, 17). Violence may undermine people's ability to make and enact health-promoting decisions related to their sexual and reproductive life, or to access and utilize SRH services, including self-care interventions. Further, the negative psychological outcomes of violence may inhibit self-care (18). The potential risks of violence associated with the use of self-care interventions must be considered and mitigated.

Efforts to address violence in this context must involve other sectors along with the health sector. While appropriate action around violence could help improve SRHR for everyone, special attention should be paid to people who may be more vulnerable to stigma, exclusion and violence, including people living with HIV as well as sexual and gender minorities, people who use drugs and people engaged in sex work.

2.3.5 Psychosocial support

Psychosocial support (see definition in Annex 4: Glossary) helps individuals and communities to heal psychological wounds and rebuild social structures after an emergency or a critical event. It can help change people into active survivors rather than passive victims. Early and adequate psychosocial support can: (i) prevent distress and suffering developing into something more severe; (ii) help people cope better and become reconciled to everyday life; (iii) help beneficiaries to resume their normal lives; and (iv) meet community-identified needs (19).

2.3.6 Supportive laws and policies

The legal and policy environment shapes the availability of health services and programmes as well as the degree to which they are responsive to individuals' needs and aspirations. Laws and public policies are also key tools with which to influence social and economic context – they can reinforce positive social determinants and begin the process of addressing those social norms or conditions that exacerbate health inequity (20). The barriers created by, for example, criminalization of adult, consensual sexual conduct and other behaviours, as well as third-party authorization for accessing services, should be addressed. If these barriers persist, linkage to health services following the use of self-care interventions will continue to be impeded. In addition, the regulation required to promote access to self-care interventions without compromising quality or safety is a critical area for action to realize SRHR.

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3

METHODOLOGY AND PROCESS FOR DEVELOPMENT OF THE GUIDELINE

“Members of the working groups were selected so as to ensure a range of expertise and experience, including appropriate representation in terms of geography and gender.”



CHAPTER AT A GLANCE

This chapter outlines the rigorous approach taken in the development of this guideline. An overview of the key contributing working groups and subsequent methodology of reaching a set of recommendations are outlined in detail.

GUIDELINE DEVELOPMENT WORKING GROUPS

pp. 36–38

Three working groups were established and performed specific functions in the development of the guideline. These included the WHO Guideline Steering Group, the Guideline Development Group and the External Review Group. They were joined by the United Nations and external observers at the Guideline Development Group meeting in January 2019.

TOPIC AREAS FOR NEW RECOMMENDATIONS AND GOOD PRACTICE STATEMENTS

pp. 38–41

This guideline compiles new, adapted and existing recommendations and good practice statements on self-care. Five new recommendations and three new good practice statements are presented.

COMPILATION AND PRESENTATION OF THE GUIDELINE

pp. 41–43

The bulk of this chapter focuses on describing the knowledge gaps identified by the Guideline Development Group that need to be addressed through further primary research. Questions to address these gaps are presented by topic and by GRADE domain.

THE PROCESS OF FORMULATING RECOMMENDATIONS

Developing new recommendations required a systematic approach beginning with defining the scope and topic areas, followed by formulating the PICO questions (population, intervention, comparator, outcomes) and subsequently conducting relevant systematic reviews of the evidence.

IN THIS GUIDELINE:

- ✓ Five new recommendations
- ✓ Three new good practice statements

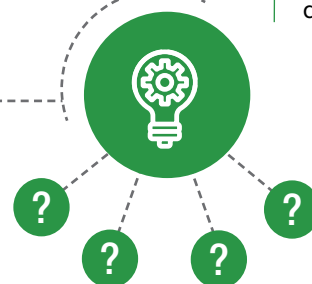


1 **MAP**
all existing SRHR guidance with relevance to self-care.



2 **REVIEW AND IDENTIFY**
gaps, overlaps and inconsistencies and determine the relevance of existing recommendations for inclusion in the guideline. In this step a list of topic areas where new recommendations need to be developed was compiled.

3 **DEVELOP**
the research questions.



4 **ASSESS**
the quality of evidence for recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. The certainty of available evidence was also taken into consideration.



5 **DETERMINE**
the strength of the recommendations – either “strong” or “conditional” – reflecting the degree of confidence the GDG has that the desirable effects of the recommendations outweigh the undesirable.

The WHO Department of Reproductive Health and Research led the development of this consolidated guideline, following WHO procedures and reporting standards laid out in the *WHO handbook for guideline development (1)*.

3.1 GUIDELINE DEVELOPMENT WORKING GROUPS

The Department set up three working groups to perform specific guideline development functions (Figure 3.1): the WHO Guideline Steering Group (SG), the Guideline Development Group (GDG) and the External Review Group (ERG). Members of the groups were selected so as to ensure a range of expertise and experience, including appropriate representation in terms of geography and gender. The three working groups are described in the following subsections and the names and institutional affiliations of the participants of each group are listed in Annex 1.

3.1.1 The WHO Guideline Steering Group (SG)

Due to the nature of the guideline, the SG included representation and expertise in sexual and reproductive health (SRHR), including the main fields of family

planning, sexually transmitted infections (STIs), maternal health, sexual health and abortion. In addition, gender, ethics, social accountability and human rights expertise ensured that key principles for building a strong enabling environment, particularly for vulnerable populations, were adequately reflected. Finally, regional and country WHO representation provided expert perspectives – from the very start of the normative guideline development process – on the practicalities of implementation and uptake of the recommendations and good practice statements in the various regions.

The SG, chaired by the Department of Reproductive Health and Research, led the guideline development process. The members drafted the initial scope of the guideline; identified and drafted the priority questions in PICO format (population, intervention, comparator, outcome); identified individuals to participate as guideline methodologist and as members of the systematic review teams, the GDG and the ERG (see below). The SG did not determine or agree on the final recommendations as this was the role of the GDG. The SG also finalized and published the guideline document and will oversee dissemination of the guideline and be involved in the development of implementation tools.

FIGURE 3.1: GUIDELINE DEVELOPMENT EXPERT WORKING GROUPS AND OBSERVERS



3.1.2 The Guideline Development Group (GDG)

The SG identified and invited external (non-WHO) experts to be part of the GDG, with expertise covering the same technical areas of work as the SG, including researchers, policy-makers and programme managers, and including young health professionals. All WHO regions were represented, with gender balance.

The GDG members were involved in reviewing and finalizing key PICO questions and reviewing evidence summaries from the commissioned systematic reviews. They were also responsible for formulating new WHO recommendations (REC) and good practice statements (GPS) at the GDG meeting (14–16 January 2019, in Montreux, Switzerland), as well as for achieving consensus on the final content of the guideline document.

3.1.3 The External Review Group (ERG)

The ERG members, who were identified and invited to participate by the SG, included peer reviewers with a broad range of expertise in issues related to SRHR. They included clinicians, researchers, policy-makers and programme managers, as well as representatives of civil society (including youth), and young health professionals. The ERG members were asked to review and comment on a version of the guideline that was shared with them after it had been reviewed and revised by the SG and the GDG. The purpose of this step was to provide technical feedback, identify factual errors, comment on the clarity of the language, and provide input on considerations related to implementation, adaptation and contextual issues. The group ensured that the guideline decision-making processes had considered and incorporated the contextual values and preferences of persons affected by the recommendations. It was not within the ERG's remit to change the recommendations that had been formulated by the GDG.

3.2 ADDITIONAL KEY CONTRIBUTORS

3.2.1 External partners

In accordance with guidance in the WHO handbook for guideline development (1), donors, partners and representatives of United Nations agencies were invited to attend the GDG meeting in January 2019 as observers with no role in determining the recommendations.

United Nations partners include:

- The Defeat-NCD Partnership
- International Agency for Research on Cancer (IARC)
- Joint United Nations Programme on HIV/AIDS (UNAIDS)
- Office of the United Nations High Commissioner for Human Rights (OHCHR)
- United Nations Children's Fund (UNICEF)
- United Nations Development Programme (UNDP)
- United Nations Population Fund (UNFPA)
- World Bank.

External partners represented the following agencies:

- Bill & Melinda Gates Foundation
- International Self-Care Foundation
- PATH
- Population Council
- Population Services International (PSI)
- White Ribbon Alliance.

3.3 DECLARATION OF INTERESTS BY EXTERNAL CONTRIBUTORS

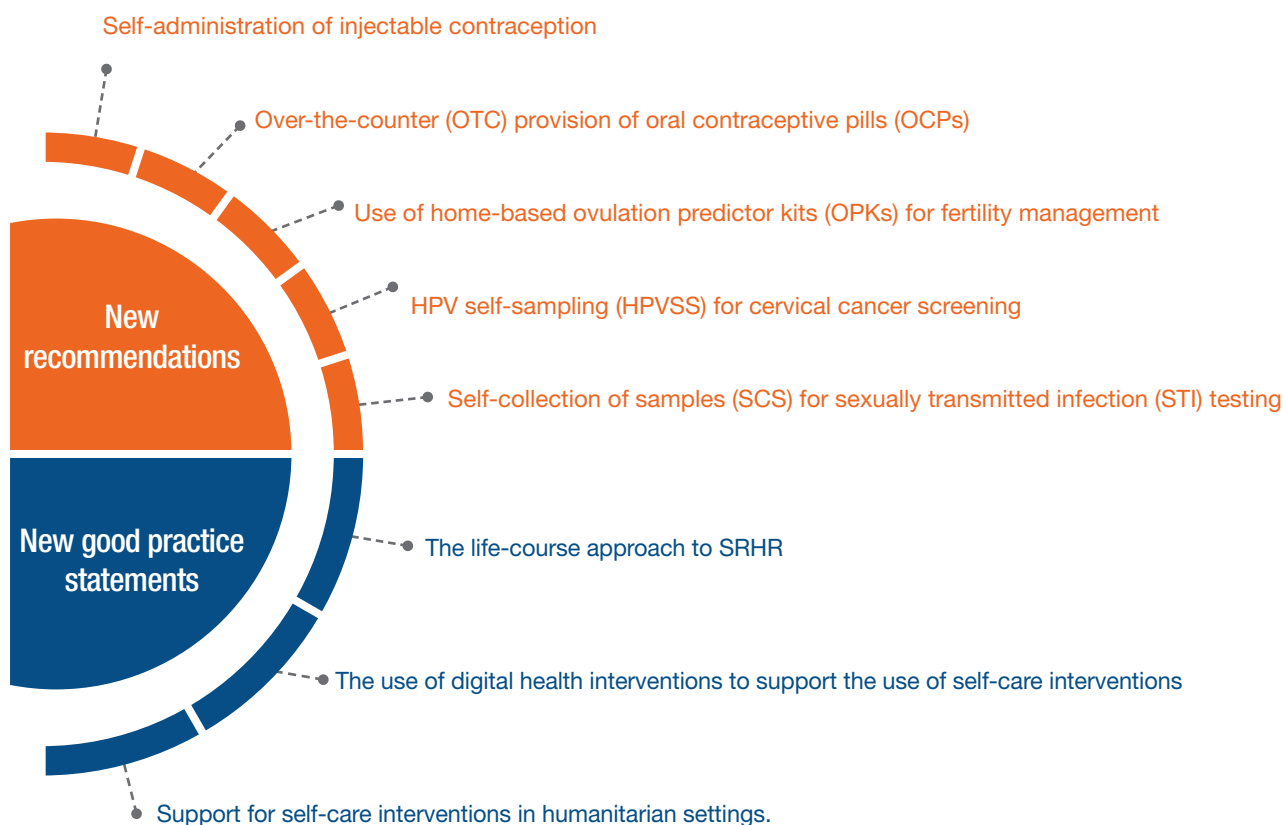
In accordance with the WHO handbook for guideline development (1), all proposed GDG and ERG members were requested to submit a one-page curriculum vitae and a signed WHO Declaration of Interest (DoI) form. Two members of the WHO Guideline Steering Group (SG) independently reviewed the DoI forms. The reviewers considered all possible conflicts of interest based on the latest guidance from the WHO Guidelines Review Committee (GRC), including placing a particular focus on possible financial or personal non-financial conflicts (e.g. academic contributions), as well as relationships with institutions producing self-care products.

Subsequently, biographical information for all GDG members deemed to not have significant conflicts of interest (i.e. conflicts which precluded their participation in the GDG) were posted on the WHO website for public comment 1–16 November 2018.⁶ GDG members were confirmed once this process was completed.

On confirmation of their eligibility to participate, all GDG and ERG experts were instructed to notify the responsible technical officer of any change in relevant interests during the guideline development process and to update and review any conflicts of interest accordingly. All GDG

⁶ Available at: <http://www.who.int/reproductivehealth/publications/dvlpt-guideline-self-care-interventions-srhr/en/>

FIGURE 3.2: AREAS WITH NEW RECOMMENDATIONS AND GOOD PRACTICE STATEMENTS DEVELOPED FOR THE GUIDELINE



members were required to verbally declare any conflict of interest at the start of the GDG meeting and subsequently before submitting comments on a draft version of the guideline. Interests were declared openly at the meeting so that all fellow GDG members were made aware of any interests that existed within the group. There were no cases of conflicts of interest that warranted management of DoI or assessment of potential conflicts of interest by the WHO Office of Compliance, Risk Management and Ethics.

No member had a financial conflict of interest. One GDG member had an intellectual conflict of interest, given their participation as a co-author on one of the systematic reviews, and recused themselves from the discussion and decision-making for the related PICO question. In addition, the GDG co-chairs did not present any conflicts of interest. A summary of the DoI statements and information on how conflicts of interest were managed are included in Annex 5.

The co-chairs had equal responsibilities and complementary expertise and perspectives, came from two different WHO regions, presented gender balance, and possessed areas of expertise relevant for this guideline. Both also had

experience in consensus-based processes. At the start of the GDG meeting, the choice of two co-chairs was presented to the GDG by the SG members, and agreement sought and obtained from the GDG members on the selection of the co-chairs.

3.4 DEFINING THE SCOPE AND TOPIC AREAS FOR NEW RECOMMENDATIONS AND GOOD PRACTICE STATEMENTS

Working within the general scope of the guideline as presented in Chapter 1, section 1.7, while also considering the intended users of the self-care interventions and the intention of addressing both an enabling environment and specific relevant health interventions, the SG first mapped all existing WHO SRHR guidance with relevance for self-care. The SG then reviewed these and other materials to identify gaps, overlaps and inconsistencies and to determine the relevance of existing recommendations for inclusion in this consolidated guideline. The SG identified the following topic areas where new recommendations needed to be developed for this guideline (Figure 3.2): self-administration of injectable

contraception; over-the-counter (OTC) provision of oral contraceptive pills (OCPs); use of home-based ovulation predictor kits (OPKs) for fertility management; HPV self-sampling (HPVSS) for cervical cancer screening; and self-collection of samples (SCS) for sexually transmitted infection (STI) testing. In addition, they identified the follow areas where new good practice statements were needed (Figure 3.2): the life-course approach to SRHR; the use of digital health interventions to support the use of self-care interventions; and support for self-care interventions in humanitarian settings.

3.5 REVIEW OF THE EVIDENCE AND FORMULATION OF RECOMMENDATIONS

3.5.1 Defining and reviewing priority questions

Development of the new recommendations on health interventions (RECs 10, 11, 12, 21 and 22; see Table 1 in the Executive summary, and Chapter 4) began with formulating the PICO questions and subsequently conducting relevant systematic reviews of the evidence. The five PICO questions for the new recommendations were as follows:

1. For individuals of reproductive age using injectable contraception, should self-administration be made available as an additional approach to deliver injectable contraception? (RECOMMENDATION 10)
2. For individuals using oral contraceptive pills (OCPs), should OCPs be made available over-the-counter (OTC), i.e. without a prescription? (RECOMMENDATION 11)
3. For individuals attempting to become pregnant, should home-based ovulation predictor kits (OPKs) be made available as an additional approach for fertility management? (RECOMMENDATION 12)
4. For individuals aged 30–60 years, should human papillomavirus (HPV) self-sampling be offered as an additional approach to sampling in cervical cancer screening services? (RECOMMENDATION 21)
5. For individuals using sexually transmitted infection (STI) testing services, should self-collection of samples (SCS) be offered as an additional approach to deliver STI testing services? (RECOMMENDATIONS 22a AND 22b)

The full details on the population, intervention, comparator and outcomes for each of the five PICO questions are presented in Annex 6.

A list of all reviews conducted for the development of this guideline – starting with the five systematic reviews on the PICO questions listed above – is presented in Annex 7. Please refer to the published systematic reviews for information about the methods used, including search strategies.

Among these reviews were literature reviews of the values and preferences of end-users/potential end-users and health-care providers relating to the self-care interventions addressed by each of the five PICO questions. The literature reviews on values and preferences for the OTC OCPs and for home-based OPKs were included within the same publications as the systematic reviews of the effectiveness of these self-care interventions (2, 3), and the methods for these reviews are therefore provided in those publications (see Annex 7). The literature reviews for the other three self-care interventions have not been published separately, but a summary of the findings of all five of these reviews for each of the self-care interventions is included at the end of each section where the five new recommendations are presented, in Chapter 4 (see sections 4.2.1 and 4.4.1). See also Chapter 1, section 1.9, about the Global Values and Preferences Survey (GVPS) on self-care interventions for SRHR.

3.5.2 Assessment of the quality of the evidence for recommendations

In accordance with the WHO guideline development process, when formulating the recommendations, the GDG members' deliberations were informed by the quality and certainty of the available evidence. WHO has adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to recommendation development (1). Regarding the application of GRADE, as explained by Balshem et al., "In the context of a systematic review, the ratings of the quality of evidence reflect the extent of our confidence that the estimates of the effect are correct. In the context of making recommendations, the quality ratings reflect the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation" (4). The GRADE approach specifies four levels of quality of evidence, which should be interpreted as detailed in Table 3.1.

The GRADE approach to appraising the quality of quantitative evidence was used for all the critical outcomes identified as part of the PICO questions (see Annex 6). Critical outcomes are those outcomes that are considered most important to individuals who are likely to be directly affected by the guidelines. The rating of the outcomes was identified a priori by the systematic review teams in consultation with the SG. Following completion of each

TABLE 3.1: DESCRIPTION OF THE FOUR GRADE LEVELS OF QUALITY OF EVIDENCE

QUALITY OF EVIDENCE	RATIONALE
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low	We have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.

Source: Balshem et al., 2011 (4).

systematic review, a GRADE Evidence to Decision (EtD) table was prepared for each quantitative critical outcome arising from each PICO. The GRADE tables are presented in the Web annex.⁷

3.5.3 Determining the strength of a recommendation

A recommendation for an intervention indicates that it should be implemented; a recommendation against an intervention indicates that it should not be implemented. The strength of a recommendation – assigned as either “strong” or “conditional” – reflects the degree of confidence the GDG has that the desirable effects of the recommendation outweigh the undesirable effects for a positive recommendation, or the reverse (that the undesirable effects outweigh the desirable effects) if the GDG is recommending against the intervention.

Desirable effects (i.e. benefits) may include beneficial health outcomes for individuals (e.g. reduced morbidity and mortality); reduced burden and/or costs for the individual, the family, the community, the programme and/or the health system; ease of implementation (feasibility); and improved equity. Undesirable effects (i.e. harms) may include adverse health outcomes for individuals (e.g. increased morbidity and mortality); and increased burden and/or costs for the individual, the family, the community, the programme and/or the health system. The burden and/or costs may include, for example, the resource use and cost implications of implementing the recommendations – which clients, health-care providers or programmes would have to bear – as well as potential legal ramifications where certain practices are criminalized.

A strong recommendation (for or against the intervention) is one for which there is confidence that the desirable effects of adherence to the recommendation clearly outweigh the undesirable effects. The higher the quality of the scientific evidence base, the more likely that a strong recommendation can be made. A conditional recommendation is one for which the quality of the scientific evidence base may be low or may apply only to specific groups or settings; or a conditional recommendation may be assigned in cases where the GDG concludes that the desirable effects of adherence to the recommendation probably outweigh the undesirable effects or are closely balanced, but the GDG is not confident about these trade-offs in all situations.

If implemented, an intervention that received a conditional recommendation (i.e. recommended in specific contexts, or recommended only in the context of rigorous research) should only be implemented in the appropriate context and should be monitored closely and evaluated rigorously. Further research will be required to address the uncertainties, and this may provide new evidence that may change the overall assessment of the quality of the evidence.

The values and preferences of the end-users (or potential end-users) in relation to the intervention and the acceptability to health-care providers of implementing the intervention, as well as consideration of the relevant resource use, feasibility and equity issues, all contribute to determining the strength of a recommendation (see Table 3.2). For this guideline, specific attention was also focused on the need for an enabling environment for implementation of interventions (see Chapter 2), and the

⁷ Available at: <https://www.who.int/reproductivehealth/self-care-interventions/en/>

GDG was asked to consider the human rights implications (both positive and negative) of each recommendation.

3.6 DECISION-MAKING BY THE GDG DURING GUIDELINE DEVELOPMENT

The GDG members were guided by the clear protocol in the WHO handbook for guideline development (1). Ideally all decisions would be made by consensus. However, at the beginning of the meeting the GDG members agreed that if any decisions required a vote, the vote would need to be carried by a 60% majority.

The GDG reviewed the evidence contained in the systematic reviews and in the GRADE EtD tables, and discussed the topics under consideration, facilitated by the guideline methodologist. The GDG meeting was designed to allow participants to consider and judge each of the GRADE

domains (see Table 3.2) and formulate the recommendations through a process of group discussion, engagement and revision. To gain an initial indication of GDG members' views on the direction of each recommendation (to recommend for or against an intervention), and on the strength of each recommendation (strong or conditional) as drafted, the methodologist sometimes asked participants to raise their hands in support of each separate option. This was not a formal vote, but a decision-making aid to allow the methodologist and co-chairs to gauge the distribution of opinion and subsequently work towards consensus through further discussion. The final wording of each recommendation, including an indication of its direction and strength, was confirmed by consensus among all GDG members. In one instance, a GDG member asked for their concerns regarding a specific decision to be noted in the guideline, but did not oppose the consensus agreement. The judgements made by the GDG related to each recommendation are noted in Annex 8.

TABLE 3.2: GRADE DOMAINS CONSIDERED WHEN ASSESSING THE STRENGTH OF RECOMMENDATIONS

DOMAIN	RATIONALE
Benefits and risks	When a new recommendation is developed, desirable effects (benefits) need to be weighed against undesirable effects (risks), considering any previous recommendation or another alternative. The larger the gap or gradient in favour of the benefits over the risks, the more likely that a strong recommendation will be made.
Values and preferences (acceptability)	If the recommendation is likely to be widely accepted or valued highly, it is likely that a strong recommendation will be made. If there is a great deal of variability or strong reasons that the recommended course of action is unlikely to be accepted, it is more likely that a conditional recommendation will be made.
Economic/financial implications (resource use)	Lower costs (monetary, infrastructure, equipment or human resources) or greater cost-effectiveness are more likely to support a strong recommendation.
Feasibility	The greater the feasibility of an intervention to all stakeholders, the greater the likelihood of a strong recommendation.
Equity	If an intervention will reduce inequities, improve equity or contribute to the realization of human rights, the greater the likelihood of a strong recommendation.

Source: Schünemann et al., 2013 (5).

3.7 COMPILATION AND PRESENTATION OF GUIDELINE CONTENT

Following the GDG meeting, members of the WHO Guideline Steering Group (SG) prepared a draft of the full guideline document, including revisions to the recommendations to accurately reflect the deliberations and decisions of the GDG members.

The draft guideline was then sent electronically to the GDG members for further comment, and their feedback was integrated into the document before it was sent to the External Review Group (ERG) members electronically for their input. The SG then carefully evaluated the input of the ERG members for inclusion in the guideline document and the revised version was again shared electronically with the GDG members for information. Any further modifications made to the guideline by the SG were limited to correction of factual errors and improvement in language to address any lack of clarity. The revised version was then submitted

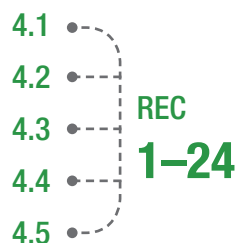
to the WHO Guidelines Review Committee (GRC) for approval and minor requested revisions were made before final copyediting and publication.

This guideline presents WHO recommendations that have been newly developed and published for the first time in this guideline in 2019 (indicated by the label of “NEW” after the recommendation number) as well as existing recommendations that have been previously published in other WHO guidelines that applied the GRADE approach (all the recommendations not labelled as “NEW”), as well as new, adapted and existing good practice statements (again the former are labelled as “NEW”).

The recommendations – numbered and labelled as “REC” in Table 1 in the Executive summary, and presented in detail in Chapter 4 – relate to health interventions, and are presented in five sections which reflect the priority areas of the 2004 WHO Global Reproductive Health Strategy (sections 4.1–4.5). In Chapter 4, new and existing recommendations are presented

FIGURE 3.3: PRESENTATION OF RECOMMENDATIONS AND GOOD PRACTICE STATEMENTS IN THE GUIDELINE

Chapter 4: Recommendations (REC)



Chapter 5: Good practice statements (GPS)



Inside each REC

- Strength
- Certainty
- Remarks
- Implementation
- Background
- Evidence and considerations, including rationale, effectiveness, resource use, feasibility, equity and acceptability' (for NEW recommendations)



Inside each NEW GPS

- Background
- Barriers to SRHR
- Components of an enabling environment
- Evidence and considerations

in boxes, including information about the strength of each recommendation and the certainty of the evidence on which it is based (assessed using the GRADE method, as described in section 3.5), followed by a list of remarks (if any), including key considerations for implementation highlighted by the GDG. For existing recommendations, the remarks are limited to the title, year of publication and the web link for the original source guideline, providing easy access to further information.

For each of the new recommendations, which address new topic areas or replace previous recommendations, additional information is presented in the following order after the box presenting the new recommendation(s):

- i. background information about the intervention;
- ii. a summary of evidence and considerations of the GDG, including results relating to the effectiveness of the intervention (benefits and risks), and explanations about the certainty of the evidence and the strength of the recommendation, in addition to information on resource use, feasibility and equity implications, and acceptability of the intervention to end-users and health-care providers (i.e. their values and preferences).

For existing recommendations, additional information after the box presenting the recommendations is limited to some background information about the intervention.

The good practice statements – numbered and labelled as “GPS” and presented in detail in Chapter 5 – apply to the implementation and programmatic considerations as well as the creation and maintenance of an enabling environment required for successful achievement of optimal SRHR. In Chapter 5, the new, adapted and existing good practice statements are presented in boxes. For existing and adapted good practice statements, the boxes include remarks (if any) on key implementation considerations; in most cases, the remarks are limited to the title, year of publication and the web link for the original source guideline, providing easy access to further information.

For each new good practice statement, additional information is presented in the following order after the box presenting the new good practice statement(s):

- i. background information;
- ii. barriers to SRHR;
- iii. components of an enabling environment that will address the barriers and support SRHR; and
- iv. a summary of evidence and considerations of the GDG, including any additional implementation considerations, to support optimal understanding, implementation and outcomes.

For adapted and existing good practice statements, additional information after the box presenting the statements is limited to some background information about the relevant practice.

In addition, in Chapter 5, for each topic section, one or more case study is included in a box at the end of the section. See Figure 3.3 for a summary of the information presented in Chapters 4 and 5.

Chapter 6 presents a list of research gaps and priorities, as identified by the GDG, which require further study.

Chapter 7 describes the plans for dissemination, application, monitoring and evaluation, and updating of the guideline and recommendations.

Evidence derived from the five systematic reviews in support of the five new recommendations (see Annex 7) was summarized in GRADE tables to provide the evidence base on effectiveness that informed the new recommendations in this guideline. These GRADE tables are presented separately in the Web annex.

REFERENCES FOR CHAPTER 3

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4

RECOMMENDATIONS



“In implementing these globally relevant recommendations, WHO regions and countries can adapt them to the local context, taking into account the economic conditions and the existing health services and health-care facilities.”



CHAPTER AT A GLANCE

This chapter summarizes the evidence and considerations for existing and new recommendations as identified throughout the development of this document.

RECOMMENDATIONS

pp. 50–78

The following steps were taken, and the subsequent findings were compiled and reported in further detail in this chapter:

- Evidence and considerations are summarized
- Certainty of the evidence is assessed
- Rationale for the strength and direction of the recommendation is given
- An estimate of the resource use required
- Feasibility is determined
- Impact on equity and human rights are analysed
- Acceptability of the intervention is assessed.



IMPROVING ANTENATAL, DELIVERY, POSTPARTUM AND NEWBORN CARE



Existing recommendations on self-care during antenatal care and delivery
(REC 1–9)

Additional existing guidance on self-care for prevention of postpartum haemorrhage (PPH)

PROVIDING HIGH QUALITY SERVICES FOR FAMILY PLANNING



New recommendations on self-care in family planning and fertility management
(REC 10–12)

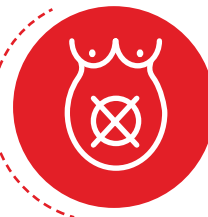
Existing recommendations on self-care with use of condoms and oral contraceptives
(REC 13–15)

Additional existing guidance on self-care in family planning

AREAS OF RECOMMENDATION

Both existing and new recommendations were assessed and reported.

ELIMINATING UNSAFE ABORTION



Existing recommendations on self-care in medical abortion and post-abortion contraception
(REC 16–20)

COMBATING SEXUALLY TRANSMITTED INFECTIONS (STIs)



New recommendations on self-sampling as part of cervical cancer screening and STI testing
(REC 21–22)

Existing recommendations on self-care and self-testing for HIV
(REC 23–24)

PROMOTING SEXUAL HEALTH

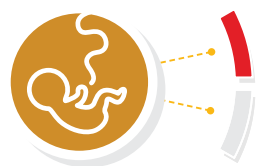


Existing guidance on self-care in relation to intimate partner violence and sexual violence

Existing guidance on sexuality education

Existing guidance on sexuality

4.1 IMPROVING ANTENATAL CARE, DELIVERY, POSTPARTUM AND NEWBORN CARE



4.1.1 Existing recommendations on self-care during antenatal care and delivery

Existing recommendations on non-clinical interventions to reduce unnecessary caesarean sections

REC 1: Health education for women is an essential component of antenatal care. The following educational interventions and support programmes are recommended to reduce caesarean births only with targeted monitoring and evaluation.

(context-specific recommendation, low-certainty evidence)

REC 1a: Childbirth training workshops (content includes sessions about childbirth fear and pain, pharmacological pain-relief techniques and their effects, non-pharmacological pain-relief methods, advantages and disadvantages of caesarean sections and vaginal delivery, indications and contraindications of caesarean sections, among others).

REC 1b: Nurse-led applied relaxation training programme (content includes group discussion of anxiety and stress-related issues in pregnancy and purpose of applied relaxation, deep breathing techniques, among other relaxation techniques).

REC 1c: Psychosocial couple-based prevention programme (content includes emotional self-management, conflict management, problem solving, communication and mutual support strategies that foster positive joint parenting of an infant). “Couple” in this recommendation includes couples, people in a primary relationship or other close people.

REC 1d: Psychoeducation (to address fear of pain; comprising information about fear and anxiety, fear of childbirth, normalization of individual reactions, stages of labour, hospital routines, birth process, and pain relief [led by a therapist and midwife], among other topics).

REC 2: When considering the educational interventions and support programmes, no specific format (e.g. pamphlet, videos, role play education) is recommended as more effective.

(low- to moderate-certainty evidence)

Remarks

- This existing recommendation was integrated into this guideline from the 2018 publication, *WHO recommendations: non-clinical interventions to reduce unnecessary caesarean sections (1)*.
- Further information can be found in the original publication, available at: <https://www.who.int/reproductivehealthpublications/non-clinical-interventions-to-reduce-cs/en/>

Existing recommendations on antenatal care for a positive pregnancy experience – self-administered interventions for common physiological symptoms

Interventions for nausea and vomiting:

REC 3: Ginger, chamomile, vitamin B6 and/or acupuncture are recommended for the relief of nausea in early pregnancy, based on a woman's preferences and available options.

Interventions for heartburn:

REC 4: Advice on diet and lifestyle is recommended to prevent and relieve heartburn in pregnancy. Antacid preparations can be offered to women with troublesome symptoms that are not relieved by lifestyle modification.

Interventions for leg cramps:

REC 5: Magnesium, calcium or non-pharmacological treatment options can be used for the relief of leg cramps in pregnancy, based on a woman's preferences and available options.

Interventions for low back and pelvic pain:

REC 6: Regular exercise throughout pregnancy is recommended to prevent low back and pelvic pain. There are a number of different treatment options that can be used, such as physiotherapy, support belts and acupuncture, based on a woman's preferences and available options.

Interventions for constipation:

REC 7: Wheat bran or other fibre supplements can be used to relieve constipation in pregnancy if the condition fails to respond to dietary modification, based on a woman's preferences and available options.

Interventions for varicose veins and oedema:

REC 8: Non-pharmacological options, such as compression stockings, leg elevation and water immersion, can be used for the management of varicose veins and oedema in pregnancy based on a woman's preferences and available options.

Remarks

- These existing recommendations were integrated into this guideline from the 2016 publication, *WHO recommendations on antenatal care for a positive pregnancy experience (2)*.
- Further information can be found in the original publication, available at: https://www.who.int/reproductivehealthpublications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/

Existing recommendation on self-administered pain relief for prevention of delay in the first stage of labour

REC 9: Pain relief for preventing delay and reducing the use of augmentation in labour is not recommended.

(weak recommendation, very low-quality evidence)

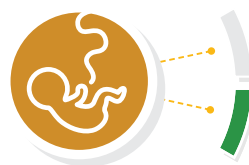
Remarks

- This existing recommendation was integrated into this guideline from the 2014 publication, *WHO recommendations for augmentation of labour* (3).
- This recommendation looked at evidence on: relaxation techniques in labour, yoga in labour, music in labour, acupuncture and acupressure in labour, hypnosis (including self-hypnosis), aromatherapy and biofeedback.
- Further information can be found in the original publication, available at: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/augmentation-labour/en/



i. Background

Focused or goal-oriented antenatal (ANC) services provide specific, evidence-based interventions to be carried out at certain critical times during all pregnancies. This includes a package of interventions including advice and support for clients and their family members for developing healthy home behaviours and a birth and emergency-preparedness plan to increase awareness of maternal and newborn health needs and self-care during pregnancy and the postnatal period, including the need for social support during and after pregnancy (4).



4.1.2 Additional existing guidance on self-care for prevention of postpartum haemorrhage (PPH)

Although self-care was reviewed by WHO in relation to uterotonics for the prevention of PPH for a guideline published in 2012, the GDG at that time concluded that there was insufficient evidence to recommend the antenatal distribution of misoprostol for self-administration during the third stage of labour for the prevention of PPH. Therefore, further research is needed on this topic.

Further information can be found in the original guideline, *WHO recommendations for the prevention and treatment of postpartum haemorrhage* (2012), available at: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/9789241548502/en/ (5).

4.2 PROVIDING HIGH-QUALITY SERVICES FOR FAMILY PLANNING, INCLUDING INFERTILITY SERVICES



4.2.1 New recommendations on self-care in family planning and fertility management

New recommendation on self-administration of injectable contraception

REC 10 (NEW): Self-administered injectable contraception should be made available as an additional approach to deliver injectable contraception for individuals of reproductive age.

(strong recommendation, moderate-certainty evidence)

Remarks

- Medical eligibility for the injectable contraceptive method should be verified according to the WHO *Medical eligibility criteria for contraceptive use* (MEC) (6), and providers should advise end-users of precautions and be available to discuss potential side-effects.
- This recommendation refers to depot medroxyprogesterone acetate in its subcutaneous form (DMPA-SC).
- Instructions on how to self-inject are available in the WHO global handbook for family planning providers (7).
- Note: For additional existing guidance on self-administration of injectable contraception, see the end of section 4.2.3.



i. Background

Injectable contraception is widely used globally. One form of injectable contraception, depot medroxyprogesterone acetate (DMPA), which contains only progestogen and no estrogen, is widely used in its intramuscular form (DMPA-IM). Recently, a subcutaneous form (DMPA-SC) has been developed which can be injected relatively easily and is safe and efficacious (8, 9). DMPA-SC is being produced and marketed as a prefilled needle and drug combination, which has regulatory approval in more than 40 countries (10, 11) and is currently available in at least 20 Family Planning 2020 (FP2020)⁸ countries. Providing the option to self-inject DMPA may improve DMPA continuation

by removing barriers, such as the need to return to a health-care facility every three months for a repeat injection. Self-administration of DMPA-SC, or other injectable contraceptives, could potentially expand access to contraception for those facing challenges in accessing health-care settings regularly, and in places where there are shortages of health-care providers.



ii. Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group (SG) determined to examine self-administration of injectable contraception as an additional approach to delivering injectable contraception. The PICO question was: **For individuals of reproductive age**

⁸ Further information available at: <http://www.familyplanning2020.org/>

using injectable contraception, should self-administration be made available as an additional approach to deliver injectable contraception? A systematic review was conducted of peer-reviewed journal publications in any location or language. The included studies on people using injectable contraception compared those who had the option of self-administration with those who did not have that option (i.e. the latter all received provider-administered injectable contraception). The studies measured one or more of the following outcomes: unintended pregnancy; side-effects or adverse events (e.g. bleeding, skin-site reactions, mental health); uptake of injectable contraception (initial use); continuation rate of injectable contraception (or, conversely, discontinuation); self-efficacy, knowledge and empowerment; and social harms (e.g. coercion, violence, psychosocial harm, self-harm), and whether these harms were corrected or had redress available (see Annex 6 for further details on the PICOs). More information on the review methods and findings can be found in the published review (12).

Results

The systematic review included six studies, published between 2012 and 2019, with a combined total of 3851 participants: three randomized controlled trials (RCTs) and three controlled cohort studies. Locations included Malawi, Scotland, Senegal, Uganda (one study each) and the United States of America (USA; two studies). Self-injection of DMPA-SC was compared to provider-administered DMPA-SC (three studies) or provider-administered DMPA-IM (three studies), with injections being every three months (12–13 weeks), with some leeway for early and late injections. All the studies followed the participants through 12 months of contraceptive coverage and measured continuation (or discontinuation) of injectable contraception.

Meta-analysis reported in the review found higher rates of continuation with self-administration of injectable contraception compared with provider administration both in the three RCTs (RR: 1.27, 95% CI: 1.16–1.39) and in the three controlled cohort studies (RR: 1.18, 95% CI: 1.10–1.26). Four studies reported pregnancies: meta-analysis showed no difference in this outcome across study arms. Four studies reported side-effects/adverse events: two controlled cohort studies showed increased injection-site reactions with self-administration, but no other side-effects increased with self-administration. One study reported no difference in social harms. No studies measured the outcomes of initial uptake or self-efficacy/empowerment.

Overall, moderate-certainty evidence from the three RCTs indicates that self-administration of injectable contraceptives probably increases continuation of injectable contraception,

but is probably equivalent with respect to rates of unintended pregnancy, side-effects/adverse events (except perhaps injection-site pain or irritation) and social harms. Evidence from the three observational studies was consistent with these findings. There were no clear differences in outcomes for different populations (12).

Certainty of the evidence for the recommendation

The available evidence was of moderate certainty overall.

Rationale for the strength and direction of the recommendation

A strong recommendation was made in favour of the intervention, with every GDG member who offered an opinion saying that benefits outweighed any potential harms. The GDG emphasized in the wording of this recommendation that the intervention should be made available as an *additional* approach, because nobody should have to self-inject due to having no access to provider-administered injections.

Resource use

There was evidence that longer-term contraceptive use is cost-effective for the end-user, but higher initial investment by the health system is required for the provision of training and support/supervision. A study in Uganda reported incremental costs at the start, leading to higher continuation rates and lower rates of unintended pregnancy, indicating that the intervention was quite cost-effective, and would also be cost-saving (13, 14).

Feasibility

All GDG members agreed that this recommendation is feasible.

Equity and human rights

The GDG agreed that, despite insufficient information, there is potential for this self-care intervention to improve equity if implemented in the context of an enabling environment. An enabling environment, however, may be lacking if literacy levels are low and there are barriers to education that may decrease access to the intervention. The GDG noted that the need for contact with a health-care provider before using this intervention means that there may still be a risk of discrimination. More information and evidence is needed on structural and regulatory issues, and on how best to implement this intervention without increasing inequity.

Acceptability of the intervention: values and preferences of end-users and health-care providers

A review was conducted to gather evidence on values and preferences related to this intervention as input for the development of a recommendation on this intervention for this guideline. The review included 14 studies: three used qualitative methods and 11 used quantitative or mixed methods. Two of the included studies were among adolescents and 12 were among the general female population; no studies were found on the values and preferences of providers or other stakeholders. Among the 14 studies, six took place in high-income countries (two in Scotland; four in the USA), one in an upper-middle-income country (Brazil), and seven in low-income countries (one in the Democratic Republic of the Congo; one in Ethiopia; two in Malawi; one in Senegal; two in Uganda). The evidence suggested that women generally like self-administration, find it easy to use, and often prefer it to provider administration. Benefits included saving time and money, ease of administration, and convenience. Barriers included fear of needles, fear of incorrect administration, or preference for seeing a health-care professional.

As described in Chapter 1, section 1.9, a Global Values and Preferences Survey (GVPS) was also conducted among health-care providers and potential end-users on their values and preferences in relation to this and other interventions covered by new recommendations in this guideline. The relevant findings from the GVPS are presented in the box below. Overall, more than 60% of potential users said they had heard of this

intervention, and many reported that convenience, access and privacy would be reasons for using it. Most said they would go to a doctor/clinic to obtain supplies for self-administration. The top two concerns reported by health-care providers were safety (e.g. side-effects) and incorrect use by patients.

The GDG reviewed the evidence on values and preferences of potential end-users, and noted that convenience of access was important to them, but there was insufficient evidence from potential users from a range of different subgroups (i.e. vulnerable individuals, different age groups). The GDG concluded that the values and preferences of the potential end-users were variable, and that the nature of the barriers may be easy to overcome.

The GDG noted that while there were limited data on health-care providers' perspectives, providers generally aim to offer the best possible care to their patients. Health-care providers in low-resource settings may find the option to task-shift the administration of injectable contraception to clients themselves acceptable, as long as effective training can be provided and the safety of users can be assured. Private-sector health-care practitioners, however, may be resistant to self-care interventions due in part to possible financial loss. Acceptability to health-care providers likely also differs by provider age, and level of confidence and/or training. In summary, the GDG concluded that acceptability to health-care providers was uncertain, noting reticence, but also noting that task shifting is achievable with training.

GLOBAL VALUES AND PREFERENCES SURVEY (GVPS) FINDINGS ON SELF-ADMINISTRATION OF INJECTABLE CONTRACEPTION

End-users and potential end-users

Respondents were asked about their knowledge and use of self-injectable long-acting contraceptives. While more than half of respondents (62.8%, n=486) reported knowing what self-injectable long-acting contraceptives were, less than 5% of respondents reported that they or their partner had ever used this intervention. Among participants who responded to a question on factors that would be important in choosing to use self-injectable long-acting contraceptives (n=420), respondents selected factors including: convenience (51.9%), accessibility (47.6%) and privacy and confidentiality (40.5%). Not feeling judged (23.6%) and feeling empowered (24.8%) were also identified as important factors in choosing to use self-injectable long acting contraceptives. There were no statistically

significant differences by residing in the Global North/Global South with regard to awareness of self-injectable long-acting contraceptives. However, participants in the Global North were significantly more likely to report accessing this intervention from a doctor or at a health clinic than those in the Global South. Participants below 50 years old were more likely to have heard of and used self-injectable long-acting contraceptives than those aged 50 and above. Furthermore, the qualitative findings from responses to the open-ended questions highlight acceptability of self-injectable long-acting contraceptives along with the need to provide users with information and guidance.

The largest proportion of respondents 47.7% (n=297 out of 622 responding about this intervention) indicated that they

GVPS FINDINGS (continued)

would go to the doctor or health clinic to access supplies for self-administration of injectable contraception. Other respondents reported that they would access it a pharmacy (17.7%; n=110), that they did not know where to get this (12.7%; n=79), that they would buy it online (1.6%; n=10), and that they did not need this intervention (30.2%; n=188). For those who responded about where they accessed information on self-injectable long-acting contraceptives (n=436), 64% (n=279) asked their doctor or health-care provider, 40.8% (n=178) went online, 15.4% (n=67) asked friends or community members, and 17.7% (n=77) reported not having received information on this intervention.

Health-care providers

When the health-care provider respondents of the GVPS were asked whether they had ever provided a referral for self-injectable contraceptives, of those who responded (n=325), more than one-third (41.2%, n=127) indicated they had, 28.2% (n=87) had not, 11% (n=34) responded that the intervention is not available where they live, and 20.8% (n=64) reported that it was not related to their job. When asked about their level of

confidence and knowledge on self-injectable long-acting contraceptives, of those who replied (n=296), more than half of respondents (52.4%; n=155) felt confident and informed. One-third (33.1%, n=98) needed more information and one-fifth (21.3%, n=63) needed training to provide this service.

Among participants who reported concerns regarding this intervention (n=229), 52% (n=119) indicated safety concerns, 47.2% (n=108) indicated concerns of misuse by patients, 40.2% (n=92) reported concerns that a patient would not access needed health care, and 21% (n=48) indicated concerns about the quality of products. Of those who responded about benefits of self-injectable contraceptives (n=224), 68.8% (n=154) indicated the benefit of convenience, 48.2% (n=108) indicated it is empowering, 44.6% (n=100) indicated reduction of health care workload, 35.3% (n=79) indicated removal of barriers, and 30.8% (n=69) indicated that it is cheaper for the client.

New recommendation on self-management of contraceptive use with over-the-counter oral contraceptive pills (OTC OCPs)

REC 11 (NEW): Over-the-counter oral contraceptive pills (OCPs) should be made available without a prescription for individuals using OCPs.

(strong recommendation, very low-certainty evidence)

Remarks

- Medical eligibility screening before initiation of OCPs is preferable.



i. Background

Oral contraceptive pills (OCPs), including both combined oral contraceptives (COCs) and progestogen-only pills (POPs), are widely used, safe and effective methods of birth control. Access to OCPs, however, varies around the world. In some countries, OCPs are available over the counter (OTC) – meaning without the need for a prescription; OTC includes (a) “off the shelf” availability with no screening and (b) “behind the counter” pharmacy access requiring eligibility screening by trained pharmacy staff before dispensation. In other countries, there is no OTC access to OCPs at all, such that a prescription from a health-care provider is required. A review of contraceptive access across 147 countries, published in 2015, found that 35 countries had OCPs legally available OTC, 56 countries had OCPs informally available OTC, 11 countries had OCPs available OTC but only after eligibility screening by trained pharmacy staff, and 45 countries required a prescription to obtain OCPs (no OTC access) (15). Given that, globally, an estimated 44% of pregnancies are unintended (16), making OCPs easier to access in more settings by making them available OTC (either “off the shelf” or “behind the counter”) could contribute to increasing OCP use and reducing unintended pregnancies.



ii. Summary of evidence and considerations for the new recommendation

The SG determined that OTC availability of OCPs should be reviewed as one of the topic areas for the development of new recommendations; therefore, a systematic review was conducted on the PICO question: **For individuals**

using oral contraceptive pills (OCPs), should OCPs be made available over-the-counter (OTC), i.e. without a prescription? Peer-reviewed articles published through 30 November 2018 were included if they compared either full OTC (“off the shelf”) or pharmacist dispensation (“behind the counter”) to prescription-only availability of OCPs and measured at least one of the selected outcomes of interest: uptake of OCPs (initial use); continuation of OCPs (or, conversely, discontinuation); adherence to OCPs (correct use); comprehension of instructions (product label); unintended pregnancy, side-effects, adverse events, or use of OCPs despite contraindications; social harms (e.g. coercion, violence, psychosocial harm, self-harm), and whether these harms were corrected or had redress available; and client satisfaction (see Annex 6 for further details on the PICOs). The focus was on daily OCP use for routine pregnancy prevention and so studies examining pills specifically for emergency contraception were not included. Meta-analysis was not conducted due to the small number of included studies (17).

Results

The effectiveness review included four observational studies with a total of 5197 participants, reported in six articles. Two of these studies were published in the 2000s, written up in four articles. One of these was the Border Contraceptive Access Study (a longitudinal cohort study from Texas, USA, which used convenience sampling and was reported in three articles), and the other was the 2000 Mexican National Health Survey (a cross-sectional comparison study, which was reported in one article). Both of these studies compared women who obtained OCPs OTC in Mexico to women who obtained OCPs from providers in either Mexico or the USA. The two other studies were from Bogota, Colombia

(1974 Fertility and Contraceptive Use Survey), and from Mexico (1979 Mexico National Fertility and Mortality Study), and were published in the 1970s, providing cross-sectional comparisons of women using OCPs obtained OTC or from a private-sector or national health-care provider. All studies included mainly women using COCs, rather than POPs (with differing pill formulations). The included studies reported on four of the seven outcomes of interest: continuation of OCPs, use of OCPs despite contraindications, side-effects and client satisfaction (17).

With a small evidence base, evidence from one observational study (the Border Contraceptive Access Study) indicated that women who get OCPs OTC may have higher OCP continuation rates over nine months of follow-up compared with women who get them from a clinic (adjusted hazard ratio: 1.58, 95% CI: 1.11–2.26). The two older studies also examined continuation. The Mexican study found no difference between the three groups (57–60% continuation after 12 months). The Colombian study found that after both 12 and 24 months, OCP continuation was approximately 5% higher for clinic users than OTC users.

Evidence from both of the more recent observational studies showed mixed evidence on whether women who get OCPs OTC are more likely to use OCPs despite contraindications. The Border Contraceptive Access Study found OTC users were more likely to report at least one WHO category 3 contraindication (13.4% versus 8.6%, $P = 0.006$), but not category 4 contraindications. Meanwhile, the analysis of the 2000 Mexican National Health Survey found no differences in contraindicated use. In the meta-analysis, the pooled effect size from these two studies showed higher odds of using OCPs despite at least one category 3 or 4 contraindication among OTC users (OR: 1.57, 95% CI: 1.18–2.09).

Two studies reported on side-effects of OCP use: the longitudinal Border Contraceptive Access Study reported fewer side-effects among OTC users and the Colombian study reported more side-effects among OTC users.

The longitudinal cohort study (Border Contraceptive Access Study) reported on client satisfaction, finding high patient satisfaction with both OTC and prescription access: “three quarters of clinic users and more than 70% of pharmacy users said they were very satisfied with their source ... Only about 4% of each group said they were either somewhat or very unsatisfied with their source” (18).

There were no data on initial uptake, correct use, comprehension of instructions, unintended pregnancy, adverse events, or social harms.

Certainty of the evidence for the recommendation

This recommendation was based on very low-certainty evidence. The GDG also noted the potential for bias with self-reporting of side-effects. Both of the more recent studies included in the systematic review found that women who obtained their OCPs OTC were different in at least some sociodemographic characteristics from those who obtained OCPs from clinics, but both studies used analysis methods to appropriately adjust for confounders to address this discrepancy, which the reviewers judged improved the validity of the effect estimates. Meanwhile, the two studies from the 1970s reported only minor sociodemographic differences between the groups, although neither presented supporting data nor adjusted for confounders. The Border Contraceptive Access Study relied on convenience sampling, but was strengthened by its longitudinal design. Conversely, the other three studies were cross-sectional, but were strengthened by their multi-stage sampling strategies (17).

Rationale for the strength and direction of the recommendation

Despite the very low-quality evidence, after extensive discussion, the GDG agreed that the benefits outweighed the harms and a strong recommendation was made in favour of the intervention. The GDG put the emphasis on equity, which is supported by the increased availability made possible by OTC access, and on high feasibility, given that the intervention is already available in many countries. While contraindications are an important concern, research has indicated that women can self-screen for contraindications fairly well using a simple checklist (19). In many parts of the world where OCPs are already available without a prescription, self-screening tools are provided with the OCP packaging. The GDG noted the preference for eligibility screening before initiation of OCPs.

The GDG also noted the need for regular linkages to the health system. In the 35 countries where OCPs are already legally available OTC, with neither prescription nor pharmacist screening required, locally adapted guidance (e.g. from WHO regional offices) could indicate that this approach should continue. The GDG agreed that since OTC availability is associated with higher continuation rates, this intervention should be available, even where health systems are not strong, but that more research is needed on managing contraindications.

In-country systems need to assess the way that OCPs are being made available without prescriptions; there need to be systems in place to ensure that end-users can be accurately screened for contraindications, whether that means (i) self-screening using a

checklist or other tool available at the point of sale, or (ii) being screened by a pharmacist or community health worker. The GDG also noted the need to be aware that many OTC drugs, potentially including OCPs, are counterfeit, off-label and/or contain toxic components. The quality of all drugs needs to be regulated to a high standard, but this issue is beyond the scope of these guidelines.

Resource use

The GDG agreed that this intervention is cheap in many places, noting that government subsidies should be retained if distribution is transferred to an OTC approach. The GDG expressed concerns that the burden of payment may fall to end-users themselves if insurance does not cover OTC availability, thus risking a decrease in accessibility. On the other hand, this intervention could be cost-saving for end-users as they will not have to pay to see a doctor, travel to a clinic or take time off work (and lose wages) for a clinic appointment. The resource implications for this intervention would be context specific, depending on current systems, costs and the burden of payment.

Feasibility

The GDG agreed that the intervention is feasible, given that it is already in use in several countries.

Equity and human rights

The GDG agreed that this intervention is likely to increase access and reduce discrimination (supporting human rights), especially among adolescent girls and young women and sexual and gender minorities, since it may remove the need to see a health-care provider and/or to get third-party authorization from a parent or spouse. Attention to context is important, however, as in some countries OCPs may not be sold to unmarried individuals. Furthermore, increased access could perhaps be accompanied by a decrease in quality of care.

Acceptability of the intervention: values and preferences of end-users and health-care providers

The systematic review for this PICO (17) included a review of 22 quantitative and qualitative studies (reported in 23 articles) on the values and preferences relating to OTC access to OCPs (including behind-the-counter pharmacy access) among current and potential users and women in general (13 articles); health-care providers and pharmacists (eight articles); the general public (one article); and a combination of women and health-care providers (one article). Nearly all the studies

were conducted in the USA, while one each was conducted in Canada, France and the Republic of Ireland. Regarding full OTC (off-the-shelf) access to OCPs, the evidence indicated that users/potential users generally favoured this, citing ease of access, convenience, privacy and time saved by avoiding clinic visits for prescriptions. Concerns of users included cost, continued use of preventive care/screening (e.g. Pap smears, breast exams, STI screening), and the safety of OTC access, especially for young people. Health-care providers were moderately supportive of full OTC access, expressing concerns including safety, efficacy, correct use and missed examinations for medical contraindications. Regarding OTC pharmacy (behind-the-counter) access, users also generally favoured and were satisfied with this, citing increased access and convenience. Pharmacists were generally very supportive of this approach while physicians were only moderately supportive. In general, providers were also more supportive of providing POPs OTC (behind the counter) compared with COCs. Potential barriers to this OTC pharmacy access included: safety, time constraints, lack of private space in the pharmacy, increased liability, and reimbursement. Overall, support was generally higher for OTC dispensation in pharmacies (behind the counter) compared with full OTC availability (off the shelf).

As described in Chapter 1, section 1.9, a Global Values and Preferences Survey (GVPS) was also conducted among health-care providers and potential end-users on their values and preferences in relation to this and other interventions covered by new recommendations in this guideline. The relevant findings from the GVPS are presented in the box below. Overall, almost all potential end-users who responded said they had heard of this intervention, and the most important factors affecting uptake were access, convenience, and privacy and confidentiality. Most said they would access the intervention through a doctor or health clinic. When responding health-care providers were asked about this intervention, the top two concerns reported were misuse by patients and safety (e.g. side-effects).

The GDG reviewed the evidence from the systematic review and the GVPS and concluded that overall there was minor variability in the values and preferences of potential end-users, and also minor variability in acceptability among health-care providers in relation to the intervention. The GDG noted that the data were from high-income countries where there may be resistance to this intervention due to health system issues surrounding insurance and reimbursement. This intervention is already in practice in many countries around the globe. More data are needed from drug stores and informal pharmacies, as well as from lower-cadre health workers and non-health professionals.

GLOBAL VALUES AND PREFERENCES SURVEY (GVPS) FINDINGS ON ACCESS TO OCPs

End-users and potential end-users

Of the GVPS respondents who reported whether or not they had heard of OCPs (n=783), 0.9% (n=7) reported not knowing what they are, 3.6% (n=28) reported that they knew what they were but they did not know how to access them, and 95.5% (748) reported that they both knew what they were and where to access them. When asked about their use of OCPs, approximately half of respondents (n=720) indicated that they or their partner had used oral contraceptives: 43.6% (n=314) had used them in the past, 6.8% (n=49) had used them within the past three months, 26.5% (n=191) had not used OCPs, and 23.1% (n=166) did not have a need for contraception. The most important factors related to OCP uptake, as reported by 513 respondents, were access (57.1%, n=293), convenience (56.3%, n=289) and privacy and confidentiality (46.4%, n=238). The possibility that OCPs can reduce the feeling of being judged (24.2%, n=124) and can foster a sense of empowerment (28.8%, n=148) were also listed as important factors associated with uptake.

There were no statistically significant differences in awareness of OCPs between respondents residing in the Global North versus the Global South. However, participants residing in the Global North were more likely to report using OCPs than those in the Global South. Those in the Global South were more likely to report accessing OCPs from a pharmacy, while those in the Global North reported being more likely to access OCPs from a doctor or a health clinic. Participants aged 50 and above were more likely to have heard of OCPs. There were no other differences in responses by place of residence, age or gender.

Participant responses related to OCPs in the open-ended (qualitative) survey responses revealed that OCPs were perceived as simple enough, compared to other interventions (e.g. abortion self-management), that using OCPs would not require the direct assistance of a health-care provider, and that OCPs should be made freely available. Concerns expressed regarding OCPs were focused more on the delivery and availability, as opposed to the intervention itself. Participants also discussed challenges with the care they received from health-care providers when accessing OCPs. Taken together, the qualitative responses reveal great promise for over-the-counter (OTC) access to OCPs in allowing individuals to

circumvent health-care providers who may stigmatize certain groups of OCP users. At the same time, providing instructions and contraindications for use of OCPs in an accessible language and format for people of various literacy levels is another implementation consideration.

Among respondents on this topic and for this intervention (n=658), 56.5% (n=372) would access OCPs through a doctor or health clinic and 45.4% (n=299) would access them through a pharmacy. Very few indicated online sources (2.7%; n=18) or not knowing where to get this intervention (0.5%; n=3). Nearly one fifth (18.8%; n=124) indicated not having a need for OCPs. Of the individuals who reported accessing information on OCPs (n=496), 76.2% (n=378) asked a doctor or health-care provider, 51.2% (n=254) went online, 24% (n=119) asked friends and community members, and 4.8% (n=24) have not received information on this.

Health-care providers

When asked about referrals for use of OCPs, of the health-care providers who responded (n=325), about three quarters (74.8%; n=243) reported having provided a referral, 6.8% (n=22) had not, nearly one fifth (18.5%; n=60) indicated it was not relevant to their job and one person (0.3%) indicated it is not available where they live. Out of respondents on this question (n=316), most said they feel confident and informed about OCPs (82.3%; n=260). There were 11.4% (n=36) of health-care providers who replied that they need more information and 9.2% (n=29) indicated that they need more training in order to provide a referral for OCPs. Of those who indicated their concerns regarding OCPs (n=263), most expressed concerns about misuse by patients (58.6%; n=154) and about safety (53.6%; n=141). Others indicated concerns that patients would not access health care when needed (31.6%; n=83) and concerns about the quality of products (27.8%; n=73). Of those respondents who answered regarding the benefits of OCPs (n=267), three quarters (75.7%; n=202) expressed that OCPs are convenient for the patient or client. Next, 49.8% (n=133) reported that OCPs are empowering, 44.2% (n=118) expressed that they will remove barriers like stigma, 40.4% (n=108) expressed that OCPs will reduce health care workload, and 40.1% (n=107) expressed the OCP use will be affordable.

New recommendation on self-screening with ovulation predictor kits (OPKs) for fertility management

REC 12 (NEW): Home-based ovulation predictor kits (OPKs) should be made available as an additional approach to fertility management for individuals attempting to become pregnant.

(strong recommendation, low-certainty evidence)



i. Background

For couples who are attempting pregnancy through coitus, or individuals who are attempting pregnancy through vaginal insemination, knowing when to do so can be difficult. There is a short window during the menstrual cycle when ovulation occurs and a mature egg or eggs have been released and are able to be fertilized by sperm, with subsequent embryo implantation. Reportedly, up to 85% of women will become pregnant on their own within 12 menstrual cycles (20, 21). However, global estimates indicate that 15–25% are unable to become pregnant despite attempting for at least five years (22, 23). Infertility is typically diagnosed if pregnancy has not been achieved after 12 months of regular intercourse without a condom (24), although this timeframe may vary by age and by presence of anatomical abnormalities or disease (25). Individuals who are diagnosed as infertile may turn to medically assisted reproduction (MAR) using various diagnostics and interventions for fertility care (26). However, some options are unaffordable or inaccessible, especially in resource-constrained settings.

Preventing fertile individuals and couples from assuming a status of infertility, when they may be able to help themselves to become pregnant with better knowledge of their reproductive cycles and fertile window, can be empowering and can avoid high costs, especially if there is an ability to prevent recourse to more expensive assisted reproductive technologies. Use of ovulation predictor kits (OPKs) can support better timing of condom-less intercourse or the self-intravaginal insemination during the fertile window. OPKs are readily available in many settings worldwide without the need for a prescription, including at pharmacies, supermarkets and other shops, as well as from websites found online, which can deliver goods anywhere in the world. OPKs do not actually predict ovulation, but rather they predict the surge of luteinizing hormone that precedes ovulation, while also tracking corresponding oestrogen levels (27). The

kits do not directly indicate a peak fertility day, and multiple pregnancy attempts may still be needed within the appropriate timeframe. OPKs increase fertility awareness and may alert individuals to potential menstrual cycle abnormalities. Individuals with HIV serodiscordant partners could use OPKs to time intercourse and limit exposure to condom-less sex in order to reduce the risk of transmission of HIV and other sexually transmitted infections (28, 29). Single individuals, those who wish to observe specific religious or cultural traditions, migrant/irregular workers, or couples in unconsummated marriages (e.g. due to male erectile dysfunction or physical disabilities) might benefit from using OPKs to appropriately time condom-less intercourse or attempt self-intravaginal insemination (30).



ii. Summary of evidence and considerations for the new recommendation

The SG determined that the use of home-based OPKs should be reviewed for the development of this guideline. Therefore, WHO commissioned a new systematic review of available evidence of effectiveness and values and preferences surrounding the use of home-based, self-initiated OPKs for fertility management (31). The PICO question was: **For individuals attempting to become pregnant, should home-based ovulation predictor kits (OPKs) be made available as an additional approach for fertility management?** To be included in the effectiveness review, studies had to compare individuals who managed their fertility using (commercially available) home-based OPKs with those who had clinician-led assessment only, or no ovulation prediction, and they had to be published in a peer-reviewed journal (through 21 November 2018). Included studies also had to report on at least one of the following outcomes of interest: time to pregnancy; pregnancy; live birth; stress/anxiety; social harms or adverse events (e.g. device-related issues, coercion, violence, psychosocial harm, self-harm, suicide, stigma, discrimination), and whether these harms were corrected or

had redress available (see Annex 6 for further details on the PICO). Inclusion was not restricted by location of the study or language of the publication.

OPKs used in the reviewed studies could include both urine- and serum-based kits and any modality (stick, monitor, digital, electronic slip that connects to a phone, etc.). To focus on OPKs as a specific biomedical and biochemical intervention, the review did not include behavioural and non-biochemical methods of ovulation prediction, such as calendar/standard days/fertility awareness methods, basal body temperature monitoring, Billings/cervical mucus monitoring methods, use of fertility beads, etc. (31).

Results

Four studies were included in the effectiveness (PICO) review: three RCTs and one prospective cohort (observational) study. The four studies included a total of 1487 women (or couples), with individual study sample sizes ranging from 117 to 1000, and with participants' ages ranging from 18 to 43. The articles were published between 1992 and 2013 and reported on studies taking place between 1991 and 2010. All studies were conducted in high-income countries: Australia, Scotland, the United Kingdom and the USA. Two studies recruited women from the general population nationwide, and the other two recruited women undergoing fertility treatment or investigation. All studies measured pregnancy as an outcome (with follow-up periods ranging from two to six menstrual cycles). Two studies measured time to pregnancy and one study reported on stress/anxiety. None of the studies presented comparative data on live births or social harms/adverse events.

All the included studies reported pregnancy rates. A single RCT from the 1990s among couples with unexplained or male-factor infertility provided uncertain results indicating no difference in clinical pregnancy rate (RR: 1.09, 95% CI: 0.51–2.32). Meta-analysis of two more recent RCTs (conducted in 2001–2002 and 2010) among the general population found higher self-reported pregnancy rates among OPK users (pooled RR: 1.40, 95% CI: 1.08–1.80). Meta-analysis of all three RCTs indicated that using a home-based OPK for timing intercourse was associated with higher rates of pregnancy compared with not using an OPK (pooled RR: 1.36, 95% CI: 1.07–1.73). A small observational study published in 1996 found higher rates of pregnancy with laboratory testing versus OPKs among women using donor insemination services (RR: 0.35, 95% CI: 0.15–0.86).

Two RCTs found that there may be no difference in time to pregnancy.

Results for measures of stress from a single RCT showed mixed results. When stress/anxiety was measured with the Perceived Stress Scale after two menstrual cycles using OPKs, results indicated that there may be no appreciable difference in stress/anxiety (mean difference [MD]: 1.98, 95% CI: –0.91 to 4.87). When stress was measured using the Positive and Negative Affect Schedule (PANAS positive affect scale), results showed there may have been an increase in stress in those using OPKs (MD: –4.51, 95% CI: –8.77 to –0.25).

Certainty of the evidence for the recommendation

This recommendation was based on low-certainty evidence, and a lack of data generated within low- and middle-income countries (LMICs). The risk of bias among the RCTs was generally high. Blinding was not possible for this intervention – all participants knew whether they were in the intervention or control group – increasing the risk of performance bias. The outcome “self-reported pregnancy” may have suffered from detection bias, as lack of blinding could lead to greater awareness of fertility, and increased frequency of pregnancy testing, and thus greater rates of positive pregnancy tests. Increased frequency of intercourse by couples using OPKs is also possible, which may have influenced the outcomes of pregnancy and time to pregnancy. There is also a high risk of publication bias, given the small number and small sample size of the included studies. In addition, two studies were funded by the OPK manufacturer and one study had its intervention delivered by the manufacturer; because of the commercial nature of OPKs, there may be some concern that data yielding negative results have not been published.

Rationale for the strength and direction of the recommendation

After extensive discussion, the GDG made a strong positive recommendation in favour of the intervention, despite the low certainty of the evidence and the fact that it was all from high-income countries. A strong recommendation was made because this intervention provides an additional choice and option for those who are concerned that they may not be attempting pregnancy during the appropriate time frame within the menstrual cycle. Another reason for making a strong recommendation, despite the limited evidence, is that this is a low-cost intervention that would be more likely to be needed in the context of LMICs where other fertility services are unaffordable or not available. But the intention of the recommendation is not to say that individuals or couples should use this intervention (e.g. if the cost is beyond their means). The GDG agreed that the benefits outweigh harms, noting that there are few to no harms if this intervention is provided with appropriate instructions. In addition, if an individual

or a couple are unable to become pregnant within six months to one year of attempting during the fertile window, it would be suggested that they seek advice from their health-care provider. They may be advised to either continue trying or be assessed for a potential infertility diagnosis. Since there are so many possible reasons for infertility, the GDG expressed concern about the use of OPKs beyond one year, without this additional suggestion. Although a strong recommendation has been made, it should be noted that there is a clear need for more research in LMICs on this topic, and for a larger review comparing this to other interventions for couples seeking to become pregnant. One GDG member wished their reservations to be noted – that a strong recommendation was not supported by the evidence – but agreed to support the consensus decision.

Resource use

The GDG agreed that the intervention may increase costs and that costs may be borne by the user. It was noted that the cost of OPKs differs widely – from one month's income on the minimum wage in Egypt to half a day's income on the minimum wage in the Philippines – and that this may not be affordable. The GDG noted that OPKs seem fairly expensive, even in high-income countries.

Feasibility

The GDG agreed that the intervention is feasible.

Equity and human rights

This intervention has the potential to improve equity, but the GDG noted that there is uncertainty surrounding this reproductive health issue. High cost could limit access (depending on who covers these costs), which may increase inequity. Not being able to build a family through pregnancy may be a challenge for individuals, couples and their families. OPKs have the potential to improve human rights, but also the potential to be harmful if appropriate information is not included with this intervention. As with all interventions related to the decision to, or not to, become pregnant, the gender dimension needs to be carefully assessed: Who is blamed for lack of pregnancy? Who can access the intervention? In poor families where individuals and couples are using

the intervention, if a pregnancy does not occur, there could be harm to the individuals (usually the woman) or in some societies even to the family. The GDG noted the potential for harm if there is coercion to use an OPK and that this might be minimized through education for individuals and couples on how the OPK could be used effectively with appropriate referral if pregnancy does not occur.

Acceptability of the intervention: values and preferences of end-users and health-care providers

The systematic review conducted for this topic also included a review of evidence on the values and preferences of end-users of OPKs. Seven articles reporting on six studies were included, all of which involved primary data collection, and the results were summarized qualitatively (31). Almost all end-users reported feeling satisfied with OPKs (i.e. they were viewed as easy to use and understand, convenient, accurate), as well as being comfortable and confident in their ability to use OPKs. They appreciated knowing more about their menstrual cycle and timing to attempt pregnancy, which decreased stress and enabled teamwork with their partner. However, those who do not become pregnant within a short time frame could become overdependent on any method of timing intercourse, including the use of OPKs, which could result in only planned coitus, and could foster obsession and doubt – especially if there is a lack of education or lack of referral to a health-care provider after six months or up to one year of trying. Most participants stated that they would use OPKs again in the future.

The GDG reviewed the evidence from the systematic review and concluded that there was minor variability in the available data on values and preferences among users. The GDG considered that from a consumer perspective, the intervention is viewed as empowering and useful.

Regarding acceptability among health-care providers, the GDG considered, based on their experience, that from a pharmacist perspective, a recommendation from WHO would give them more license to provide this intervention. The GDG concluded that there was minor variability in the acceptability of this intervention among health-care providers.



4.2.2 Existing recommendations on self-care with use of condoms and oral contraceptives

Existing recommendation on condoms

REC 13: Consistent and correct use of male and female condoms is highly effective in preventing the sexual transmission of HIV; reducing the risk of HIV transmission both from men to women and women to men in serodiscordant couples; reducing the risk of acquiring other STIs and associated conditions, including genital warts and cervical cancer; and preventing unintended pregnancy.

Remarks

- This existing recommendation was integrated into this guideline from the 2015 UNFPA, WHO and UNAIDS position statement on condoms and the prevention of HIV, other STIs and unintended pregnancy (32), available at: <https://www.who.int/hiv/mediacentre/news/condoms-joint-positionpaper/en/>

Existing recommendation on condoms for key populations⁹

REC 14: The correct and consistent use of condoms with condom-compatible lubricants is recommended for all key populations to prevent sexual transmission of HIV and STIs.

(strong recommendation, moderate quality of evidence)

Remarks

- This existing recommendation was integrated into this guideline from the 2014 WHO publication, *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (33).
- Other relevant recommendations (non-GRADE) and guidance mentioned in this guideline include:
 - Condoms and condom-compatible lubricants are recommended for anal sex.
 - Correct and consistent use of condoms and condom-compatible lubricants is recommended for sex workers and their clients.
 - It is important that contraceptive services are free, voluntary and non-coercive for all people from key populations.
- Further information can be found in the original publication, available at: <https://www.who.int/hiv/pub/guidelines/keypopulations/en/>

⁹ See definition in Annex 4: Glossary.

Existing recommendations on the number of POP pill packs and COC pill packs that should be provided at initial and return visits

- REC 15a:** Provide up to one year's supply of pills, depending on the woman's preference and anticipated use.
- REC 15b:** Programmes must balance the desirability of giving women maximum access to pills with concerns regarding contraceptive supply and logistics.
- REC 15c:** The re-supply system should be flexible, so that the woman can obtain pills easily in the amount and at the time she requires them.

Remarks

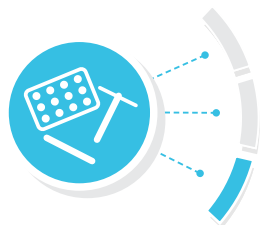
- The GDG concluded that restricting the number of cycles of pills can result in unwanted discontinuation of the method and increased risk of pregnancy.
- This existing recommendation and remark have been integrated into this guideline from the 2016 WHO publication, *Selected practice recommendations for contraceptive use, third edition (34)*, available at: <https://apps.who.int/iris/bitstream/handle/10665/252267/9789241565400-eng.pdf>



i. Background

Family planning is essential to promoting the well-being and autonomy of individuals, couples, their families and their communities. Quality of care in family planning is paramount for ensuring progress towards achieving high standards of health for all. As defined in the WHO publication, *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations*, five elements of quality of care in family planning include:

- choice among a wide range of contraceptive methods;
- evidence-based information on the effectiveness, risks and benefits of different methods;
- technically competent, trained health workers;
- provider–user relationships based on respect for informed choice, privacy and confidentiality; and
- the appropriate constellation of services that are available in the same locality (35).



4.2.3 Additional existing guidance on self-care in family planning

Existing guidance on self-administered contraception

The WHO guidance Medical eligibility for contraceptive use (MEC) includes a range of contraceptive methods that are self-administered by users, including the combined contraceptive patch, the combined contraceptive vaginal ring, the progesterone-releasing vaginal ring (PVR) and barrier methods, including condoms (male latex, male polyurethane and female condoms), the diaphragm (with spermicide) and the cervical cap.



Regarding barrier methods, the MEC says:

If there is a risk of sexually transmitted infections (STIs), including HIV, then the correct and consistent use of condoms is recommended. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms (6).

It is further noted that “Women with conditions that make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively higher typical-use failure rates.” The MEC provides further guidance on the use of barrier methods depending on the user’s personal characteristics and reproductive history, cardiovascular disease, rheumatic

diseases, neurologic conditions, depressive disorders, reproductive tract infections and disorders, HIV/AIDS, other infections, endocrine conditions, gastrointestinal conditions, anaemias and drug interactions, as well as additional comments.

The MEC includes recommendations on the safety of combined hormonal contraceptives (CHCs, which include combined oral contraceptives, the combined contraceptive patch and the combined contraceptive vaginal ring) for those with particular medical conditions or personal characteristics. The MEC also includes recommendations on the safety of hormonal contraception (including the combined contraceptive patch and the combined contraceptive vaginal ring among others) for women at high risk of HIV infection, women living with HIV, and women living with HIV using antiretroviral therapy (ART) (6).

For further information, see *Medical eligibility criteria for contraceptive use, fifth edition* (2015), available at: https://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/

In addition the *Selected practice recommendations for contraceptive use, third edition* (2016), which provides essential guidance on how to provide family planning/contraception – including how to address user errors and manage side-effects – is available at: https://www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/ (34).

Existing guidance on task sharing to improve access to family planning/contraception

To address the problem of poor access to family planning services due to inadequate numbers of health workers or their uneven distribution, “WHO recommends that family planning services and methods can be safely and effectively provided by different health worker cadres, under specified circumstances”, and this includes “user/self” (i.e. individual, client) among the cadres referred to in task shifting/sharing guidelines (36).

For further information, see *Task sharing to improve access to family planning/contraception* (2017), available at: <https://www.who.int/reproductivehealth/publications/task-sharing-access-fp-contraception/en/> (36).

4.3 ELIMINATING UNSAFE ABORTION¹⁰



4.3.1 Existing recommendations on self-care in medical abortion and post-abortion contraception

Existing recommendations on self-management of the medical abortion process in the first trimester

Individuals have a role to play in managing their own health and this constitutes another important component of task sharing within health systems. Therefore, the following recommendations for specific components were made related to self-assessment and self-management approaches in contexts where pregnant individuals have access to appropriate information and to health services should they need or want them at any stage of the process.

REC 16: Self-assessing eligibility [for medical abortion] is recommended in the context of rigorous research.

REC 17: Managing the mifepristone and misoprostol medication without direct supervision of a health-care provider is recommended in specific circumstances. We recommend this option in circumstances where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.^a

REC 18: Self-assessing completeness of the abortion process using pregnancy tests^b and checklists is recommended in specific circumstances. We recommend this option in circumstances where both mifepristone and misoprostol are being used and where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.

Remarks

- Self-management and self-assessment approaches can be empowering and also represent a way of optimizing available health workforce resources and sharing of tasks.
- These existing recommendations were integrated into this guideline from the 2015 WHO publication, *Health worker roles in providing safe abortion care and post-abortion contraception* (37).
- Further information can be found in the original publication, available at: https://www.who.int/reproductivehealth/publications/unsafe_abortion/abortion-task-shifting/en/

Notes from the 2018 *Medical management of abortion guideline*:

^a As a general implementation consideration with reference to REC 17: “When using the combination mifepristone and misoprostol regimen, the medical abortion process can be self-managed for pregnancies up to 12 weeks of gestation, including the ability to take the medications at home, without direct supervision of a health-care provider; it should be noted that there was limited evidence for pregnancies beyond 10 weeks” (38).

^b Regarding pregnancy tests mentioned in REC 18: “Pregnancy tests used to self-assess the success of the abortion process are low-sensitivity urine pregnancy tests, which are different from those tests commonly used to diagnose pregnancy” (38).

¹⁰ To the full extent of the law, safe abortion services should be readily available and affordable to all women. Self-management approaches reflect an active extension of health systems and health care. These recommendations are NOT an endorsement of clandestine self-use by women without access to information or a trained health-care provider/health-care facility as a backup. All women should have access to health services should they want or need it.



i. Background on medical abortion and self-management

Medical abortion care encompasses the management of various clinical conditions including spontaneous and induced abortion (both viable and non-viable pregnancies), incomplete abortion and intrauterine fetal demise, as well as post-abortion contraception. Medical management of abortion generally involves either a combination regimen of mifepristone and misoprostol, or a misoprostol-only regimen. Medical abortion care plays a crucial role in providing access to safe, effective and acceptable abortion care. In both high- and low-resource settings, the use of medical methods of abortion have contributed to task shifting and sharing and more efficient use of resources. Moreover, many interventions in medical abortion care, particularly those in early pregnancy, can now be provided at the primary-care level and on an outpatient basis, which further

increases access to care. Medical abortion care reduces the need for skilled surgical abortion providers and offers a non-invasive and highly acceptable option to pregnant individuals (38).

Furthermore, self-assessment and self-management approaches, as recommended in REC 16, 17 and 18 above, can be empowering for individuals and help to triage care, leading to a more optimal use of health-care resources.

Based on an updated review of the evidence, recommendations related to the timing, dosage, dosing intervals and routes of administration of medications to manage abortion, and also the timing of contraception initiation following a medical abortion, were published by WHO in 2018 in *Medical management of abortion* (38). However, the 2015 recommendations (see REC 16, 17 and 18) remain applicable, since the 2018 guideline focuses solely on the medication regimens.

Existing recommendations on post-abortion hormonal contraception initiation

REC 19: Self-administering injectable contraceptives is recommended in specific circumstances. We recommend this option in contexts where mechanisms to provide the woman with appropriate information and training exist, referral linkages to a health-care provider are strong, and where monitoring and follow-up can be ensured.

REC 20: For individuals undergoing medical abortion with the combination mifepristone and misoprostol regimen or the misoprostol-only regimen who desire hormonal contraception (oral contraceptive pills, contraceptive patch, contraceptive ring, contraceptive implant or contraceptive injections), we suggest that they be given the option of starting hormonal contraception immediately after the first pill of the medical abortion regimen.

Remarks

- REC 19 was integrated into this guideline from the 2015 publication, *Health worker roles in providing safe abortion care and post-abortion contraception* (37), available at: https://www.who.int/reproductivehealth/publications/unsafe_abortion/abortion-task-shifting/en/
- REC 20 was integrated into this guideline from the 2018 publication, *Medical management of abortion* (38), available at: <https://www.who.int/reproductivehealth/publications/medical-management-abortion/en/>



i. Background on post-abortion contraception and self-administration

Contraception can be initiated at the time of administration of the first pill of the medical abortion regimen or after

assessment of successful medical abortion. All contraceptive options may be used. Criteria laid out in the WHO publications *Medical eligibility criteria for contraceptive use* and *Ensuring human rights in the provision of contraceptive information and services* should be adhered to (6, 35).

4.4 COMBATING SEXUALLY TRANSMITTED INFECTIONS (INCLUDING HIV), REPRODUCTIVE TRACT INFECTIONS, CERVICAL CANCER AND OTHER GYNAECOLOGICAL MORBIDITIES



4.4.1 New recommendations on self-sampling as part of cervical cancer screening and STI testing

New recommendation on human papillomavirus (HPV) self-sampling as part of cervical cancer screening services

REC 21 (NEW): HPV self-sampling should be made available as an additional approach to sampling in cervical cancer screening services for individuals aged 30–60 years.

(strong recommendation, moderate-certainty evidence)



i. Background

Globally, cervical cancer is one of the most common types of cancer among women, and in LMICs, it is the leading cause of cancer deaths in women (39, 40). Cervical cancer develops from persistent infection with high-risk types of human papillomavirus (HPV) (41). Although there are vaccines that protect against infection and disease associated with specific types of HPV, many women do not have access to them and women still die of preventable cervical cancer (41). The two- to four-decade lag time between the peak of HPV infection and the peak of cervical cancer incidence provides an opportunity for cancer prevention (41). Secondary prevention measures include early detection and treatment of precancerous lesions. Population-based cervical cancer screening programmes have been successful in reducing cervical cancer incidence and mortality, especially in high-income settings with well organized programmes and good coverage and quality (42, 43). However, these programmes require an available and accessible screening test. Common tests include cervical cytology (Pap smear), visual inspection with acetic acid (VIA), and HPV testing.

Primary high-risk HPV testing is a relatively new method of secondary prevention for cervical cancer, with or without HPV immunization. A 2018 review found that self-collected HPV samples showed reasonably high diagnostic accuracy, compared with clinician samples (44). While HPVSS does not provide a diagnosis of cervical (pre-)cancer, it identifies women who are at higher risk. HPVSS has gained attention for its potential to increase

participation in screening, especially due to the privacy afforded by this approach. Self-sampling requires an individual to obtain a kit, collect one's own (cervico-)vaginal sample, and send the specimen to a laboratory where it is tested and then the results returned to the individual (45). Collection methods include lavage, brush, swab and vaginal patch. Using a kit, self-sampling can be conducted alone in private either at a health-care facility or elsewhere, and can be initiated either by health-care providers or by clients themselves.



ii. Summary of evidence and considerations for the new recommendation

The GDG determined to review the evidence on HPV self-sampling (HPVSS) for the development of this guideline. A systematic review and meta-analysis were conducted including studies that compared adult women using HPVSS with those receiving HPV testing through another modality, those receiving another cervical cancer screening test or those receiving no cervical cancer screening services (no intervention) (46). The PICO question was: **For individuals aged 30–60 years, should HPV self-sampling be offered as an additional approach to sampling in cervical cancer screening services?** Studies were included in the systematic review if they were published in a peer-reviewed journal (the search included publications in any language through October 2018) and reported on at least one of the following priority outcomes: uptake of cervical cancer screening services; frequency of cervical cancer screening; social harms or adverse events (e.g. device-related issues, coercion, violence, psychosocial harm, self-harm, suicide, stigma, discrimination), and whether

these harms were corrected or had redress available; linkage to clinical assessment or treatment of cervical lesions following a positive self-test result (e.g. the percentage of those with a positive result who reach the next stage of management, such as positive diagnosis for HPV by a health-care provider) (see Annex 6 for further details on the PICO). Inclusion was not restricted by location of the intervention.

Results

Thirty three studies (reported in 34 articles) with 369 017 total participants met the inclusion criteria for the systematic review: 29 RCTs and 4 observational studies (the latter comprised three prospective cohort studies and one cross-sectional study). Individual study sample sizes ranged from 63 to 36 390, with participants' ages ranging from 18 to 70, but most often in the 30–60 age range. The studies were published between 2007 and 2018. Studies were primarily conducted in high-income countries (one article each in Argentina, Australia, Belgium, Slovenia and Switzerland; two each in England, Finland and Italy; three each in Canada, Denmark, France and the Netherlands; and four each in Sweden and the USA) – accounting for 93% of participants. One study each took place in Mexico, Nigeria and Uganda.

All studies examined HPVSS and the comparison groups used standard care (e.g. clinician-collected HPV testing, Pap smear, VIA). Most studies (n=24) sent HPVSS kits directly to participants' home addresses, and six studies had health workers/research staff offer the kits door-to-door; with both of these approaches, recipients could simply opt out and not use the kits. Seven studies required participants to opt in to HPVSS by requesting a kit by phone, mail, text message or website, or by picking up a kit from a local pharmacy or health centre. In one study, participants self-collected samples for HPV testing at an HIV clinic. All 33 studies measured cervical cancer screening uptake, but follow-up periods ranged from immediately after being offered screening to 36 months, with half between 6 and 12 months. Five articles reported on linkage to clinical assessment or treatment of cervical lesions. None of the included articles reported comparative data on screening frequency or social harms/adverse events.

Evidence from 29 RCTs suggests HPVSS, especially if implemented using an opt-out strategy, is generally associated with increased uptake of cervical cancer screening services, regardless of country income classification, setting, supervision, socioeconomic status or age. Specifically, meta-analysis of the effect sizes from all 29 RCTs found that women were twice as likely to use cervical cancer screening services through HPVSS compared with standard care (RR: 2.13, 95% CI: 1.89–2.40).

Effect size varied by strategy used to disseminate the HPVSS kits, whether mailed directly to home addresses (RR: 2.27, 95% CI: 1.89–2.71), offered door-to-door (RR: 2.37, 95% CI: 1.12–5.03), or provided upon request (RR: 1.28, 95% CI: 0.90–1.82). Six RCTs using opt-out dissemination methods (mail or door-to-door) reported on linkage to clinical assessment or treatment following a positive test result. Meta-analysis showed that there was probably no difference in this outcome between the intervention and control group participants (RR: 1.12, 95% CI: 0.80–1.57) (46).

Certainty of the evidence for the recommendation

This recommendation is based on moderate-certainty evidence. The risk of bias in the 29 RCTs was generally low. It was not possible to blind participants and personnel to HPVSS versus standard care, but most outcomes were not likely to be influenced by lack of blinding.

Rationale for the strength and direction of the recommendation

The GDG agreed that the benefits of this intervention outweighed harms, and made a strong recommendation in favour of it, by consensus.

Resource use

Total programme costs increase as detection increases (since the intervention reaches a larger number of people), but per cervical lesion detected, it likely reduces hospital treatment costs and improves outcomes, and so the intervention may be cost-effective over time, considering both costs to the health system and to the patient. The kit itself is only part of the cost of the same service if provided at a health-care facility. This intervention significantly reduces the burden on health-care providers in overburdened settings. Cost-effectiveness must be contingent on effective linkage to care; data on this aspect are almost all from high-income countries.

Feasibility

The GDG agreed that the intervention is feasible. Previous research provides some information on this subject. Four systematic reviews of RCTs in the context of population-based screening programmes showed that offering high-risk HPVSS to never- and under-screened women increased participation compared with inviting women to have samples taken by health-care providers (44, 47, 48, 49). Unfortunately, in many countries, standard cervical cancer screening tests are not universally or even widely available: while almost

81% of countries have cervical cancer screening policies and strategies, only 48% have an operational plan with funding (50). The magnitude of this public health problem necessitates innovative approaches to support individuals, families and communities. Reaching more people at risk of cervical cancer with HPV testing, including women living with HIV who have higher risk of HPV infection and cervical cancer, is critical (51).

Equity and human rights

The GDG agreed that this intervention has the potential to improve equity all along the cascade, in particular through targeting and reaching those who are not currently accessing cervical cancer screening services, since access to care is a major factor in increasing equity. The GDG also noted that linkage to care is key – supportive services must be in place. A variety of interventions need to be available to achieve equity (e.g. a strategy of mailing kits to a home address will not work for homeless people; Internet-based strategies will not reach those without access to the Internet). In communities where sex outside of marriage is unacceptable, this intervention will provide a lot of unmarried individuals with a chance to get screened. Engagement in care is critical and more studies are needed on this aspect; clear research is needed on different ways to engage individuals in HPVSS for cervical cancer screening and to link them to appropriate services as required (e.g. door to door, mobile phones), keeping low-resource settings in mind. The GDG noted that the body of research has included women with vulnerabilities. The GDG expressed concerns about quality assurance and accountability, especially with regard to online access or researchers mailing test kits out to people. Also, this intervention could negatively affect equity if it is available online to people in high-income countries but not available to those in low-income countries who lack Internet access. An enabling environment for this intervention is needed to increase equity and to avoid potential unintended consequences.

Acceptability of the intervention: values and preferences of end-users and health-care providers

A review was conducted of the available evidence on values and preferences in relation to HPVSS as a method of cervical cancer screening among end-users and health-care providers, including 75 studies from a variety of countries from all WHO regions and all World Bank income classification categories. Almost all studies were cross-sectional surveys, but study designs also included in-depth interviews and focus groups. The findings indicate high acceptability for HPVSS among women in general, who tended to prefer HPVSS over HPV sampling by a health-care provider, citing privacy, convenience, time and effort saved, cost-effectiveness, ease, comfort (including decreased embarrassment, pain and anxiety), speed, safety and user-friendliness. Some concerns were expressed in relation to accuracy and reliability, but these concerns often diminished after repeated use. Respondents generally found kit directions easy to understand, and were comfortable with multiple devices used for HPVSS. Factors that increased the likelihood of HPVSS use among respondents included previous Pap testing, high perceived risk of cervical cancer, willingness to self-sample for HPV, high HPV knowledge, and giving high value or priority to cost-saving and/or time-saving. A small proportion of respondents preferred clinician-based cervical cancer screening regardless of the benefits of self-sampling, citing trust and confidence in provider services, and concerns about accuracy and reliability of HPVSS. Some generational differences were noted among end-users. Health-care providers saw HPVSS as a mechanism for encouraging more people to return to the health system.

The GDG considered the findings of the review and concluded that there was minor variability in values and preferences among end-users and potential end-users, and also concluded that there was minor variability in acceptability of the intervention among health-care providers.

New recommendation on self-collection of samples for STI testing

REC 22a (NEW): Self-collection of samples for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* should be made available as an additional approach to deliver STI testing services.

(strong recommendation, moderate-certainty evidence)

REC 22b (NEW): Self-collection of samples for *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* may be considered as an additional approach to deliver STI testing services.

(conditional recommendation, low-certainty evidence)

Remarks

- Please also refer to an existing recommendation below on HIV self-testing (REC 23).



i. Background

Globally, every year, there are an estimated 357 million new infections of four curable sexually transmitted infections (STIs): chlamydia, gonorrhoea, syphilis and trichomoniasis (52, 53). Etiological diagnosis via STI testing is the best way to determine infection status and appropriate treatment (54, 55). While STI diagnostic tests are in use in many high-income countries, they are largely unavailable in LMICs (54, 56, 57, 58), where syndromic management is the primary approach for STI treatment (56, 59). While practical, the syndromic approach has significant limitations (56, 60, 61). Social stigma and a lack of effective policies also affect the uptake of STI testing and treatment worldwide. Low coverage of STI testing and high transmission rates are common among at-risk vulnerable adolescents and key populations, including men who have sex with men (MSM), migrants, sex workers, indigenous and minority populations, and those affected by humanitarian emergencies (60).

Greater efforts are needed to expand STI testing services globally, and self-collection of samples (SCS) is one way to facilitate this. SCS means that individuals take a specimen themselves, either at a health-care facility or elsewhere, and send it to a laboratory for testing (45), and the laboratory returns the result to the individual. Follow-up in the case of positive test results requires linking the individual with the health system. In high-income countries, where laboratory facilities and health care are widely available, research shows that self-collected STI

samples are as accurate as clinician-collected samples (62), and that SCS is feasible and acceptable in a variety of populations (63). SCS approaches can also potentially address some barriers that often prevent people from seeking STI testing from a health-care provider or clinic, such as concerns about autonomy, inconvenience, stigma and lack of privacy (56, 64, 65).



ii. Summary of evidence and considerations for the new recommendation

For the development of this guideline, the GDG determined to investigate whether self-collection of samples (SCS) should be made available as an additional approach to deliver STI testing services. A systematic review was conducted, for which the PICO question was: **For individuals using STI testing services, should self-collection of samples (SCS) be offered as an additional approach to deliver STI testing services?** Studies were included if they compared people using SCS for STI testing with people using another mode of STI sample collection or no STI testing (no intervention), and if they were published in a peer-reviewed journal (in any language, through 18 July 2018), and reported on at least one of the following outcomes of interest: uptake of STI testing services; frequency of STI testing; social harms or adverse events (e.g. device-related issues, coercion, violence, psychosocial harm, self-harm, suicide, stigma, discrimination, frequency of HIV testing), and whether these harms were corrected or had redress available; case-finding (proportion of people who tested positive for an STI); linkage to clinical assessment or STI treatment following a positive test result; and reported sexual risk behaviour (see Annex 6 for

further details on the PICO). No restrictions were placed based on the location of the intervention, but studies were excluded if they compared STI SCS interventions delivered in one location versus another (e.g. SCS at home versus at a clinic) (63).

SCS for STI testing differs from self-testing, where individuals not only take the sample themselves but also perform the test and interpret the test results. Since self-testing is still under development for STIs other than HIV, the review focused on SCS for STIs, though self-testing was included if available. The review assessed SCS for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* (trichomoniasis or TV). This is in line with ongoing multicountry evaluations of promising point-of-care testing (POCT) interventions to detect these four STIs, as well as the goal of the WHO STI POCT initiative to achieve universal access to reliable and affordable STI testing (66). SCS methods included first-void urine, vaginal flush using saline, and pharyngeal, rectal, urethral and vaginal swabs.

Results

Eleven studies, published in 11 articles between 1998 and 2018, were included in the review (five RCTs and six observational studies, including four serial cross-sectional and two cross-sectional). Ten of the studies were included in the meta-analyses. All 11 studies (with 202 745 participants in total) were conducted in high-income countries: two in Australia, three in Denmark and six in the USA. Three studies focused on NG and CT; two studies on NG, CT and TV; five studies on CT alone; and one study did not specify which bacterial STIs were covered. No studies compared findings for syphilis. The studies varied in location of self-collection (i.e. three clinic-based studies and eight home-based studies) as well as target population (i.e. general population, MSM, people living with HIV, adolescents and young people, detainees, people who inject drugs, sex workers, and partners of CT-positive patients).

All five RCTs and three observational studies reported some measure of uptake of STI testing services. Regarding the secondary outcome, case finding, four RCTs and five observational studies reported comparisons of STI test positivity rate comparing participants who self-collected samples with those whose samples were collected by a clinician. No studies compared the impact of SCS to clinician-collection of samples on the following outcomes: frequency of STI testing, social harms or adverse events, linkage to clinical assessment or STI treatment following a positive test result, and reported sexual risk behaviour.

The meta-analysis of the five RCTs found that programmes offering SCS increased overall uptake of STI testing services

by almost three times, compared with clinician collection of samples (RR: 2.941, 95% CI: 1.188–7.281). The findings of the observational studies were similar. Meta-analysis of two observational studies testing for multiple STIs (CT and NG, and NG and TV) found a non-significant relative risk of 2.990. A third observational study, which could not be combined in meta-analysis, found that after implementing an “express clinic” with self-collection of genital and rectal samples at a large sexual health clinic, a total of 5335 patients were seen (at the express and main clinics) compared with 4804 patients seen through the prior routine STI testing services.

With regard to case finding, meta-analysis of four RCTs reporting on this (all of which measured CT only) found effects in opposite directions depending on the sensitivity analysis used. When all enrolled study participants were included in the calculation, meta-analysis found that the likelihood of receiving a positive test result doubled among those using SCS compared with the control group (RR: 2.166, 95% CI: 1.043–4.498). However, when the denominator was limited to only people who ultimately provided samples for STI testing, the association went in the opposite direction (RR: 0.718, 95% CI: 0.585–0.882). The observational studies generally showed no difference in case finding between SCS and clinician-collection groups, regardless of which group was used in the denominator for the meta-analyses, and regardless of which specific STI or combination of STIs were being tested for (63).

Certainty of the evidence for the recommendation

Recommendation 22a was based on moderate-certainty evidence while Recommendation 22b was based on low-certainty evidence. Risk of bias was deemed moderate in the RCTs. With regard to selection bias, one RCT used date of birth to randomize participants, while two did not specify the randomization method used. Given the nature of the intervention, blinding was impossible and may have biased performance. Four RCTs did not report on the blinding of the laboratory personnel conducting the STI testing. The observational studies were judged to have high risk of bias. None of the observational studies clearly controlled for confounders.

Rationale for the strength and direction of the recommendation

The GDG agreed that the benefits of this intervention outweigh the harms, and made a strong recommendation in favour of the intervention.

Resource use

The GDG concluded that this intervention may decrease future costs, but that costs may be borne by users.

Feasibility

The GDG concluded that this intervention is feasible.

Equity and human rights

The GDG agreed that this intervention has the potential to improve equity, but the group cautioned about the potential for coercion.

Acceptability of the intervention: values and preferences of end-users and health-care providers

A literature review on values and preferences related to SCS for STI testing was conducted, including 112 studies, presentations and conference abstracts. STIs assessed included CT, NG, syphilis and trichomoniasis. Study locations included countries in all WHO regions except the Eastern Mediterranean Region, but the location was not specified in 11 articles. The populations studied included females, males and key populations (including young people, MSM, female sex workers and people who inject drugs). Six articles included health-care providers as a study population. Seventy-nine articles used quantitative methods (including one RCT), 20 used qualitative methods and 8 used mixed methods. Findings suggest high acceptability of SCS for STI testing (high satisfaction, comfort, ease, privacy, convenience, and confidence – especially after the experience), though some participants mentioned pain, discomfort and concerns about safety. Pooled data from 36 articles indicated that 85% of patients found the method to be acceptable, and findings were similar in other studies

also. Pooled data from 28 articles indicated that 88% of participants found SCS to be “very easy”, “easy” or “not difficult” to perform, and findings were similar in other studies also. Pain and discomfort were each generally reported by approximately 13% of users, regardless of SCS method or gender of user. Privacy and safety were the most common concerns related to SCS. The most common reasons for refusing the intervention were lack of time or inconvenience, discomfort or dislike of the process or method, perception of not being at risk of an STI, having recently been tested, and current menstruation. Prohibitive costs, confidentiality, not wanting to know their STI diagnosis, and general lack of time were also mentioned, as well as a proportion who reported fears without specifying them.

As described in Chapter 1, section 1.9, a Global Values and Preferences Survey (GVPS) was also conducted among health-care providers and potential end-users on their values and preferences in relation to this and other interventions covered by new recommendations in this guideline. The relevant findings from the GVPS are presented in the box below. In summary, the findings were generally similar to the literature review with regard to users’ decision-making factors. However, although over 80% of end-users knew about STI self-sampling, and almost half knew where they could access it, only about 11% had ever used it. Many health-care providers wanted more training or information about this intervention, and their top two concerns about it were incorrect use by patients and worry that the patient will not access health care if/when needed.

The GDG considered the evidence from the literature review and the GVPS and concluded there was minor variability in the evidence on end-users’ values and preferences, as well as minor variability in acceptability among health-care providers.

GLOBAL VALUES AND PREFERENCES SURVEY (GVPS) FINDINGS ON SELF-COLLECTION OF SAMPLES (SCS) FOR STI TESTING

End-users and potential end-users

When asked whether they had heard of self-sampling or self-collection of samples (SCS) for STI testing, 46.5% (n=360 of 775 respondents) knew what this was and where to access it, 36.1% (n=280) knew what it was but did not know how to access it, and 17.4% (n=135) did not know what it was. For those who responded to questions regarding their use or their partner's use of SCS for STIs (n=708), approximately two thirds (66.7%; n=472) had never used SCS for STI testing, 8.2% (n=58) had previously used it, 3.0% (n=21) had used in the past three months, and 22.2% (n=157) reported not having a need for SCS for STI testing. Among those responding to this question (n=437), the option of privacy and confidentiality was the most important factor (62.9%, n=275), with convenience (45.3%, n=198) and access (45.3%, n=198) as the next most important factors. Not feeling judged (36.2%, n=158) and feeling empowered (27.7%, n=121) were also important factors in choosing to use SCS for STI testing.

Participants in the Global North were significantly more likely to have heard of SCS for STI testing than those in the Global South, and participants in the Global South were more likely to report that this intervention was not relevant for themselves/their partners. Participants who were younger than 50 years old were more likely to report having used the intervention than participants aged 50 and over. There were no gender differences in these responses.

In reviewing all responses to open-ended questions on the topic of SCS for STI testing, there was general support for this intervention, with reasons including convenience, cost-effectiveness and empowerment. The topic of linkage to care frequently came up in discussion of this intervention. As a 41-year-old woman from Kenya stated, "if it is a self-test that is positive, then it would be very important to have a health provider", with another woman (USA, 52 years old) going as far as to say "if positive, should be an automatic link to a local provider or some sort of affordable access to a provider with an ability to retest and provide treatments (antiretrovirals, abortion, fertility interventions)". However, there were those who felt that being given the tools to interpret the results for themselves because "having to seek a provider to

understand the results negates the advantage of self-testing" explains another 52-year-old woman from the USA. Lastly, concerns about SCS for STI testing arose with respect to existing barriers, with stigma being cited as a major concern about this intervention.

For respondents who indicated that they accessed SCS for STI testing (n=621), 46.5% (n=289) would go to the doctor or health clinic, 18.7% (n=116) would go to the pharmacy, and 6.3% (n=39) would buy it online. In addition, 20.3% of respondents (n=126) indicated not knowing where to get the intervention, and 20.6% (n=128) indicated not needing it. For SCS for STI testing (n=440), 59.8% (n=263) asked their doctor or health care provider, 44.1% (n=194) went online, 13% (n=57) asked friends and community, and 22% (n=97) have not received information on this.

Health-care providers

Of health-care providers who replied to questions regarding SCS for STI testing (n=307), one third (32.6%, n=100) had provided a referral, prescription or information on the intervention, while 35.8% (n=110) had not. For 15.6% (n=48) of respondents, SCS for STI testing is not available where they live, and for 19.5% (n=60), it is not relevant to their job. Regarding their information and confidence levels regarding SCS for STI testing, of those who replied (n=295), one third (34.2%, n=101) felt confident and informed. Nearly half of respondents (49.2%, n=145) reported needing more information and 21.7% (n=64) reported needing training to provide this service. For those who responded about SCS for STI testing (n=222), 57.2% (n=127) expressed concern about patients not seeking health care if needed, and 53.6% (n=119) expressed concern about misuse by patient. In addition, 25.7% (n=57) had concerns about safety and 24.3% (n=54) indicated concerns about the quality of product.

Among health-care providers responding to questions about the benefits of SCS for STI testing (n=231), more than two thirds (64.1%, n=148) reported convenience, 61.5% (n=142) reported it removed barriers, and 48.5% (n=112) reported it is empowering. Other benefits included reduction of health-care provider workload (44.6%, n=103) and affordability (30.3%, n=70).



4.4.2 Existing recommendations on self-care and self-testing for HIV

Existing recommendation on HIV self-testing

REC 23: HIV self-testing should be offered as an additional approach to HIV testing services.

(strong recommendation, moderate-quality evidence)

Remarks

- This existing recommendation was integrated into this guideline from the 2016 WHO publication, *Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services* (67).
- Further information can be found in the original publication, available at: <https://www.who.int/hiv/pub/self-testing/hiv-self-testing-guidelines/en/>

Existing recommendation on women living with HIV

REC 24: For women living with HIV, interventions on self-efficacy and empowerment around sexual and reproductive health and rights should be provided to maximize their health and fulfil their rights.

(strong recommendation, low quality evidence)

Remarks

- This existing recommendation was integrated into this guideline from the 2017 WHO publication, *Consolidated guideline on sexual and reproductive health and rights of women living with HIV* (68).
- Further information can be found in the original publication, available at: https://www.who.int/reproductivehealth/publications/gender_rights/srhr-women-hiv/en/



i. Background

HIV self-testing (HIVST) has been shown to be an empowering, discreet and highly acceptable option for many users, including key populations, men, young people, health workers, pregnant women and their male partners, couples and general

population groups. HIVST represents another forward step in line with efforts to increase patient autonomy, decentralize services and create demand for HIV testing among those not reached by existing services (69).

4.5 PROMOTING SEXUAL HEALTH

There are no new or existing recommendations in this area in relation to self-care for SRHR. Nevertheless, relevant existing WHO guidance is provided below.



4.5.1 Existing guidance on self-care in relation to intimate partner violence and sexual violence

Information in the *Consolidated guideline on sexual and reproductive health and rights of women living with HIV* (2017) highlights that self-care can be inhibited by the negative psychological outcomes of violence, and also states the following.



Social norms and taboos related to sexual orientation, sexual identity, gender, sexual health, sexuality and reproductive health create a culture of shame, blame and silence. Women living with HIV in such contexts can feel isolated and may internalize negative perceptions, leading to mental health problems such as depression and the neglect of self-care. In addition, the lack of confidential and non-judgemental health care services is a barrier for women living with HIV to obtain information and commodities, and to feel supported in expressing their SRH needs and concerns. Safe spaces (both within health-care facilities and social services) and confidential and stigma-free environments can encourage women living with HIV to access the services they need (68).

The 2014 WHO guidance, *Health care for women subjected to intimate partner violence or sexual violence: a clinical handbook*, includes a plan for self-care after sexual assault, including care of injuries and prevention of STIs (see Box 4.1), and guidance for strengthening positive coping methods after a violent event (see Box 4.2) (70).

BOX 4.1: PLAN FOR SELF-CARE AFTER SEXUAL ASSAULT

Explain your examination findings and treatment

Discuss the examination findings with the survivor of the assault, the health implications, and any treatments provided. Invite any questions and concerns. Respond in detail and check the survivor's understanding.

Care of injuries

- Teach the survivor how to care for any injuries.
- Describe the signs and symptoms of wound infection—warm, red, painful, or swollen wound; blood or pus; bad smell; fever. Recommend a follow-up visit to a health-care provider if these signs develop.
- Explain the importance of completing the course of any medications given, particularly antibiotics. Discuss any likely side-effects and what to do about them.

Prevention of STIs

- Discuss the signs and symptoms of STIs, including HIV. Recommend a follow-up visit for treatment if any signs or symptoms occur.
- Ask the survivor to refrain from sexual intercourse until all treatments or prophylaxis for STIs have finished. Encourage the use of condoms during sexual intercourse, at least until STI/HIV status has been determined at the 3- or 6-month visit.

Follow-up

- Plan follow-up visits at 2 weeks, 1 month, 3 months and 6 months after the assault.

Source: adapted from WHO, 2014 (70).

BOX 4.2: STRENGTHENING POSITIVE COPING METHODS AFTER A VIOLENT EVENT

After a violent event, the survivor may find it difficult to return to a normal routine. Encourage small and simple steps. Talk about her life and activities. Discuss and plan together, giving reassurance that things will likely get better over time.

Encourage survivors to:

- build on strengths and abilities, and coping methods used in difficult situations in the past
- continue normal activities, especially ones that used to be interesting or pleasurable
- engage in relaxing activities to reduce anxiety and tension

- keep a regular sleep schedule and avoid sleeping too much
- engage in regular physical activity
- avoid using self-prescribed medications, alcohol or illegal drugs to try to feel better
- recognize thoughts of self-harm or suicide and come back as soon as possible for help if they occur
- **return for a follow-up visit if these suggestions are not helping.**

Source: adapted from WHO, 2014 (70).

The publication also includes a relevant guiding principle: “**Self-determination** – being entitled to make their own decisions including sexual and reproductive decisions; entitled to refuse medical procedures and/or take legal action”.

Finally, the guidance provides advice for self-care for health-care providers, reminding them that their needs are as important as those of the people they care for, and that they themselves may have strong reactions or emotions when discussing violent incidents with clients, especially if the provider themselves has experienced violence or abuse: “Be aware of your emotions and take the opportunity to understand yourself better. Be sure to get the help and support you need for yourself” (70).



4.5.2 Existing guidance on sexuality education

The 2018 UNESCO publication, *International technical guidance on sexuality education: an evidence-informed approach*, provides a new definition (see Annex 4: Glossary) and description of comprehensive sexuality education (CSE), emphasizing that this is a process to empower children and young people. The guidance presents key considerations for understanding the evolving field of CSE. Taken as a whole, that publication constitutes the recommended set of CSE topics, as well as guidance on effective delivery (71).

The section on delivering effective CSE programmes includes 14 recommendations on effective curriculum development (see

summary table on p. 93 of the guidance), 10 recommendations on designing and implementing CSE programmes (see summary table on p. 97), 3 recommendations on monitoring and evaluation of CSE programmes, and 10 key principles for scaling up CSE (see p. 99) (71).



4.5.3 Existing guidance on sexuality

The 2018 WHO publication, *Brief sexuality-related communication: recommendations for a public health approach*, mentions, but does not provide a recommendation on, assessing self-efficacy/self-esteem.



The key study regarding adolescents that supports this recommendation is a study in Washington DC that used the Awareness, Skills, **Self-efficacy/Self-esteem**, and Social Support (ASSESS) Programme. It advocates “increasing adolescent awareness about sexual risks, skills to avoid risky sexual situations, **self-efficacy** (such as a feeling that peer pressure can be resisted), and social support (such that adolescents felt encouraged by the physician)” (72).

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5

IMPLEMENTATION CONSIDERATIONS AND GOOD PRACTICE STATEMENTS ON SELF-CARE

“Interventions that promote self-care and are promoted or used by the ‘professional’ sector must be implemented in a manner that respects people’s needs and rights.”



CHAPTER AT A GLANCE

This chapter acknowledges the impact that changes in self-care practices may have upon an individual and society. Good practice statements (GPS) are presented on four different topics which have implications for the implementation of self-care interventions for SRHR.

ENVIRONMENTAL CONSIDERATIONS

pp. 89–92

Roughly a quarter of all human disease and death in the world can be attributed to environmental factors.

FINANCING AND ECONOMIC CONSIDERATIONS

pp. 92–94

Self-care interventions present a critical opportunity for health systems to support the pillars of universal health coverage, namely equitable access, efficient delivery of quality health interventions, and financial protection.

TRAINING NEEDS OF HEALTH-CARE PROVIDERS

pp. 95–98

In order for self-care interventions to be successfully accessed and used, learning, communication and intersectoral collaboration are needed.

IMPLEMENTATION CONSIDERATIONS FOR VULNERABLE POPULATIONS

pp. 98–103

The needs and rights of vulnerable populations are highlighted in this guideline as certain situations or contexts, due to socioeconomic factors, disabilities, legal status and unequal power dynamics adversely affect health outcomes for populations who cannot access quality health care.

NEW, ADAPTED AND EXISTING GPSs

relevant to four different topics with implications for SRHR are presented. Implementing interventions in these areas has the potential to improve health and well-being by improving coverage of effective and safe health-care interventions.

ENVIRONMENTAL CONSIDERATIONS

FINANCING AND ECONOMIC CONSIDERATIONS

TRAINING NEEDS OF HEALTH-CARE PROVIDERS

IMPLEMENTATION CONSIDERATIONS FOR VULNERABLE POPULATIONS

INFORMATION PROVIDED FOR EACH TOPIC



BACKGROUND INFORMATION



BARRIERS TO SRHR



COMPONENTS OF AN ENABLING ENVIRONMENT



SUMMARY OF EVIDENCE AND CONSIDERATIONS

5.1 OVERVIEW

Many everyday health problems are treated at home and in communities, increasingly with modern pharmaceuticals obtained from pharmacies, stores and markets (1). Sometimes people combine remedies from traditional (folk) medicine and from modern medicine, learning from friends, family, the Internet, vendors and professionals, and applying the therapies themselves, especially if they are constrained by cost and/or distance (2). As Kleinman defined it, this is the “popular” health care sector. However, with the growth of virtual self-help communities and access to a vast range of information online, the division between lay and expert knowledge is becoming increasingly blurred (3).

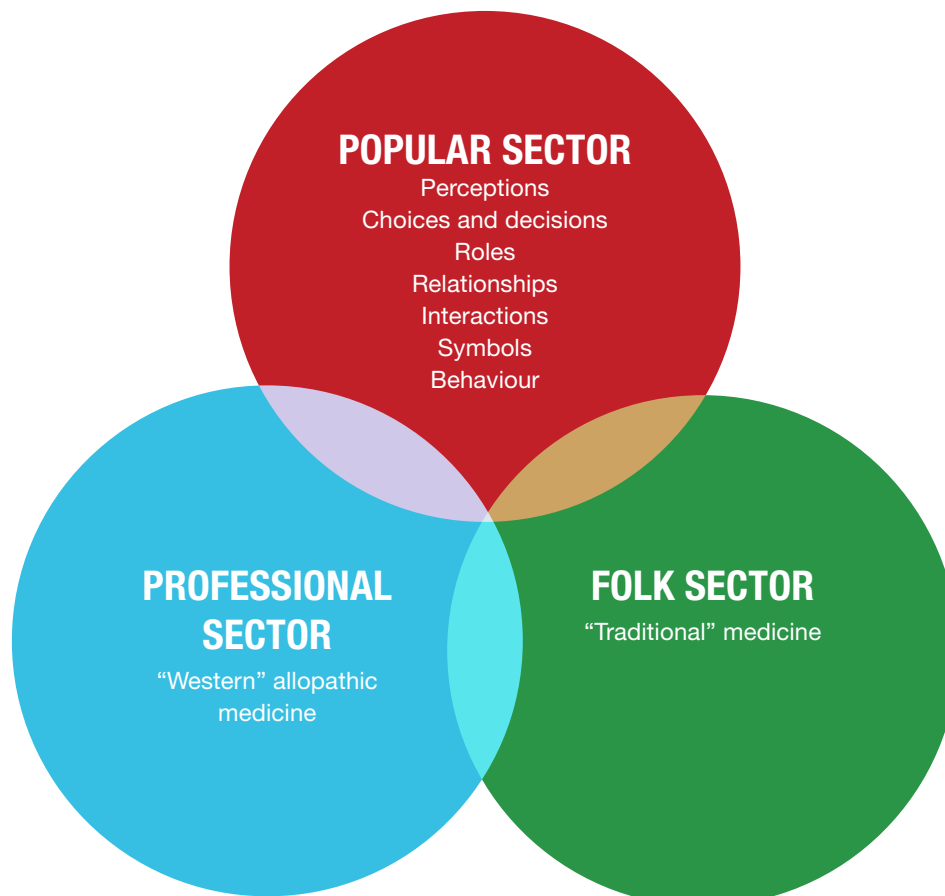
Given the popularity of self-care in the “popular” sector, interventions that promote self-care and are promoted or used by the “professional” sector must be implemented in a manner that respects people’s needs and rights (Figure 5.1).

Acknowledging and understanding how existing practices of self-care are embedded in people’s lives and in the

settings where they live is an important first step when developing, promoting or implementing self-care interventions. Furthermore, building partnerships between user-led and community-led platforms and health systems around self-care interventions is a promising approach to ensure correct and accelerated implementation of interventions that have the potential to improve health and well-being by improving coverage of effective and safe health-care interventions (5).

This chapter presents new and existing good practice statements (labelled as “GPS”) relevant to four different topics that have implications for the implementation of self-care interventions for SRHR: environmental considerations; financing and economic considerations; training of health-care providers; and implementation considerations for vulnerable populations. Background information relevant to each topic is provided, as well as a review of the evidence and the barriers and enabling factors relevant to each of the new good practice statements developed for this guideline. For each of the existing good practice statements adapted for this guideline from other WHO sources, a weblink is provided to the source document for further information.

FIGURE 5.1: KLEINMAN’S HEALTH CARE SECTORS



Source: adapted from Kleinman, 1978 (4).



5.2 ENVIRONMENTAL CONSIDERATIONS

5.2.1 Adapted good practice statements on management of waste from self-care products

Adapted good practice statement on safe and sustainable management of health-care waste

GPS 1 (ADAPTED): Safe and secure disposal of waste from self-care products should be promoted at all levels.

Remarks

- Promote adequate arrangements for storage, including for safe storage of sharps at home.
- Provide mechanisms for safe and secure disposal of equipment used for self-injection of contraceptives (especially in settings with high HIV prevalence), and provide training in the use of these mechanisms as needed.
- Provide accurate information and appropriate support to patients and their families to enable them to carry hazardous waste back to medical institutions or pharmacies; this includes providing training/promoting awareness about correct disposal of other (non-hazardous) waste materials from self-care products.
- In all self-care products, use appropriate labelling and package inserts that are aligned with the local or national recycling and disposal system for household waste.
- This good practice statement was adapted for this guideline from the 2014 WHO publication, *Safe management of wastes from health-care activities (6)*, available at: https://www.who.int/water_sanitation_health/publications/wastemanag/en/

Adapted good practice statement on environmentally preferable purchasing (EPP)

GPS 2 (ADAPTED): Countries, donors and relevant stakeholders should work towards environmentally preferable purchasing (EPP) of self-care products by selecting supplies that are less wasteful, or can be recycled, or that produce less hazardous waste products, or by using smaller quantities.

Remarks

- This good practice statement has been adapted for this guideline from the 2014 WHO publication, *Safe management of wastes from health-care activities (6)*; available at: https://www.who.int/water_sanitation_health/publications/wastemanag/en/



i. Background

Roughly a quarter of all human disease and death in the world can be attributed to environmental factors, including unsafe drinking water, poor sanitation and hygiene, indoor and outdoor air pollution, workplace hazards, industrial accidents, occupational injuries, automobile accidents, poor land-use practices and poor natural resource management (7). More than one quarter of the 6.6 million annual deaths to children under 5 years old are associated with environment-related causes and conditions (8). Compared with high-income countries, environmental health factors play a significantly larger role in low-income countries, where water and sanitation, along with indoor and outdoor air pollution, make major contributions to mortality (8).

As we reduce dependence on hospital-based systems and increase our reliance on people-centred/user-controlled interventions, an increase in waste disposal of self-care products by the general population is inevitable. For self-care interventions to be sustainable, a change in patterns of health-care consumption, more sustainable production methods of health-care commodities, and improved waste management techniques will be required. While data are scarce and research is limited – particularly in resource-constrained settings – the rising popularity and availability of self-care interventions offers a valuable opportunity to take steps to responsibly manage the environmental impacts.

Worldwide, an estimated 16 billion injections are administered every year. Not all needles and syringes are disposed of safely, creating a risk of injury and infection, and opportunities for reuse (9). In 2010, unsafe injections using contaminated supplies were still responsible for as many as 33 800 new HIV infections, 1.7 million hepatitis B virus (HBV) infections and 315 000 hepatitis C virus (HCV) infections. Additional hazards occur from scavenging at unsecured waste disposal sites and during the handling and manual sorting of hazardous waste from health-care facilities. These practices are common in many regions of the world, especially in low- and middle-income countries. The waste handlers are at immediate risk of needle-stick injuries and exposure to toxic or infectious materials. In 2015, a joint WHO–UNICEF assessment found that 58% of sampled facilities from 24 countries had adequate systems in place for the safe disposal of health-care waste (10).

In many parts of the world, the rising incidence of cardiovascular and respiratory diseases is the major driving factor for the growth of the market for self-care medical devices. Preference for home-based monitoring of these diseases has led to a reduction in the

frequency of visits to clinics and hospitals, and an increase in the uptake of self-care medical devices. Growing awareness about health and health care has also triggered the demand for self-care medical devices and this is expected to grow further.

To ensure that the rise of self-care products does not have unintended harmful effects on human health and the environment, the procurement of environmentally friendly (“green”) goods is important, while ensuring that clinical outcomes remain key. WHO subscribes to a “green” procurement policy, and seeks to procure goods and services that lessen the burden on the environment in their production, use and final disposal, whenever possible and economical (11).

To effect “green” procurement, WHO supports the “4R” strategy to:

- re-think the requirements to reduce environmental impact
- reduce material consumption
- recycle materials/waste and
- reduce energy consumption (11).

Before finalizing the procurement of goods and/or services, the environmental concerns must be considered, including energy consumption, toxicity, ozone depletion and radiation.

Environmentally preferable purchasing (EPP) refers to the purchase of the least damaging products and services, in terms of environmental impact. At its simplest, EPP may lead to the purchase of recycled paper, through to more sophisticated measures such as the selection of medical equipment based on an assessment of the environmental impact of the equipment from manufacture to final disposal – known as “life-cycle thinking” (12).

WHO supports the safe and sustainable management of wastes from health-care activities (12, 13).



To better understand the problem of health-care waste management, WHO guidance recommends that countries conduct assessments prior to any decision as to which health-care management methods be chosen. Tools are available to assist with the assessment and decision-making process so that appropriate policies lead to the choice of adapted technologies (13).

As stated in a subsequent key policy paper in 2007:



The WHO core principles require that all associated with financing and supporting health-care activities should provide for the costs of managing health-care waste. This is the duty of care. Manufacturers also share a responsibility to take waste management into account in the development and sale of their products and services (14).

In keeping with these core principles, that paper made a series of specific recommendations aimed at governments, donors/partners, nongovernmental organizations, the private sector and all concerned institutions and organizations: these are presented in Box 5.1 (14). The case study in Box 5.2 gives some information on progress that has already been achieved in this area.

BOX 5.1: WHO RECOMMENDATIONS ON SYSTEMS FOR HEALTH-CARE WASTE MANAGEMENT

Governments should:

- allocate a budget to cover the costs of establishment and maintenance of sound health-care waste management systems
- request donors, partners and other sources of external financing to include an adequate contribution towards the management of waste associated with their interventions
- implement and monitor sound health-care waste management systems, support capacity building, and ensure worker and community health.

Donors and partners should:

- include a provision in their health program assistance to cover the costs of sound health-care waste management systems.

Nongovernmental organizations should:

- include the promotion of sound health-care waste management in their advocacy
- undertake programs and activities that contribute to sound health-care waste management.

The private sector should:

- take responsibility for the sound management of health-care waste associated with the products and services they provide, including the design of products and packaging.

All concerned institutions and organizations should:

- promote sound health care waste management
- develop innovative solutions to reduce the volume and toxicity of the waste they produce and associated with their products
- ensure that global health strategies and programs take into account health-care waste management.

Source: WHO, 2007 (14).

BOX 5.2: CASE STUDY ON ENVIRONMENTAL CONSIDERATIONS RELATED TO SELF-CARE

Sustainable Health in Procurement Project (SHiPP), and the Sustainability Assessment of Antiretrovirals Long-Term Suppliers

The United Nations informal Interagency Task Team on Sustainable Procurement in the Health Sector (SPHS) is hosted at the United Nations Development Programme (UNDP) Istanbul Regional Hub. Its aim is to facilitate and coordinate the introduction of sustainable procurement in the health sector among its members and to leverage the normative mandate and joint procurement volumes of member agencies to influence the global health aid market and beyond, towards greener health systems and economies. The UNDP and Health Care Without Harm (HCWH) officially launched the new Sustainable Health in Procurement Project (SHiPP) inception workshop report in 2018. SHiPP aims to reduce the harm to people and the environment caused by the manufacture, use and disposal of medical products and by the implementation of health programmes (15).

Among many initiatives implemented under the UNDP's Procurement Strategy 2015–2017 was the sustainability assessment of antiretrovirals long-term suppliers. During 2015, the UNDP Global Fund Programme Procurement and Supply Management (PSM) team performed this assessment with the aim of enhancing the sustainability agenda together with the long-term agreement (LTA) holders, analysing their performance and establishing a sustainability baseline. The assessment was based on the responses and documentation provided by suppliers to a detailed questionnaire, which was developed taking into consideration international standards, recognized reporting systems and similar scorecards used by other international organizations and public procuring institutions. For the second year of the LTAs, it was recommended that a set of "call-off requirements" be established, to help to verify which suppliers are taking the necessary actions towards improving sustainability practices, without compromising their delivery of goods (16).



5.3 FINANCING AND ECONOMIC CONSIDERATIONS

5.3.1 Adapted good practice statements on economic considerations of self-care

Adapted good practice statements on economic considerations for access, uptake and equity

GPS 3 (ADAPTED): Good-quality health services and self-care interventions should be made available, accessible, affordable and acceptable to vulnerable populations, based on: the principles of medical ethics; avoidance of stigma, coercion and violence; non-discrimination; and the right to health.

GPS 4 (ADAPTED): All individuals and communities should receive the health services and self-care interventions they need without suffering financial hardship.

Remarks

- This good practice statement has been adapted for this guideline from the 2014 WHO publication, Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (17), available at: <https://www.who.int/hiv/pub/guidelines/keypopulations/en/>
- This good practice statement has been adapted for this guideline from the universal health coverage (UHC) principle (see Box 5.3).

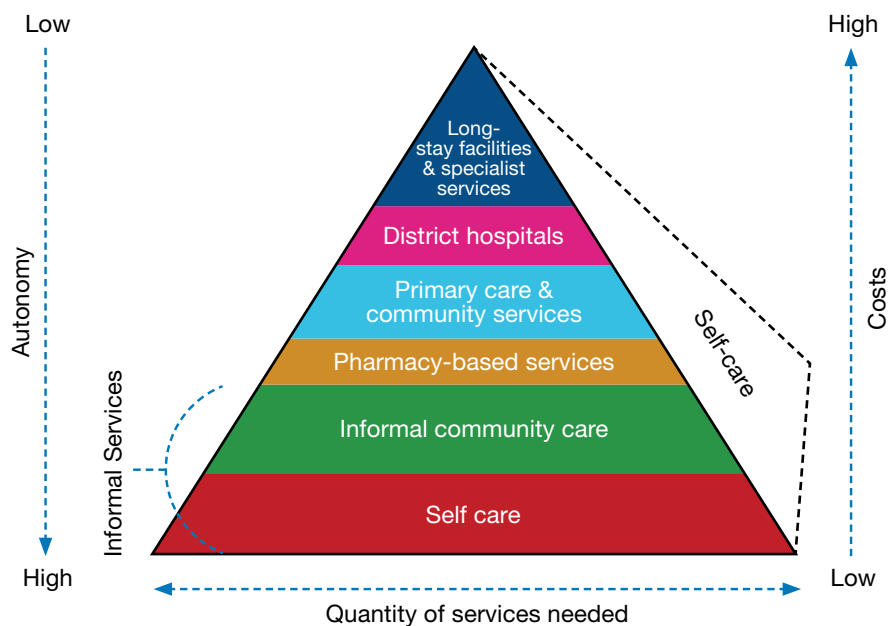


i. Background

In addition to increased user autonomy and engagement, self-care interventions present a critical opportunity for health systems to support the pillars of universal health coverage (UHC), namely equitable access, efficient delivery of quality health interventions, and financial protection (Figure 5.2) (18, 19). They could enhance the efficiency of health care delivery by co-opting users as lay health workers, thereby increasing access to essential services.

They could also increase the uptake of preventive services, and improve adherence to treatment, thereby reducing downstream complications and health care utilization (20). Vulnerable and marginalized populations could be given new routes of access to SRHR services that they would otherwise not access through health-care providers due to stigma, discrimination, distance and/or cost. However, there are also potential risks of introducing or further exacerbating vulnerabilities through the abrogation of government responsibility for quality health services. Moreover, shifting control to individuals may inadvertently shift the financial burden and increase out-of-pocket expenditures.

FIGURE 5.2: SELF-CARE WITHIN THE HEALTH-CARE PYRAMID



Source: adapted from WHO, 2003 (21).

BOX 5.3: UNIVERSAL HEALTH COVERAGE (UHC): WHAT IS IT?

- The United Nations resolution on UHC, adopted on 12 December 2012, acknowledges that UHC “implies that all people have access, without discrimination, to nationally determined sets of the promotive, preventive, curative and rehabilitative basic health services needed and essential, safe, affordable, effective and quality medicines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable and marginalized segments of the population” (22).
- “UHC embodies specific health and social goals: it is the aspiration that all people can obtain the quality health services they need (equity in service use) without fear of financial hardship (financial protection). This right is declared in the World Health Organization (WHO) Constitution and increasingly in many national constitutions or laws, thereby reflecting universal social values such as human security, social cohesion, and solidarity” (23).
- “Universal health coverage means that all people receive the health services they need, including public health services designed to promote better health (such as anti-tobacco information campaigns and taxes), prevent illness (such as vaccinations), and to provide treatment, rehabilitation and palliative care (such as end-of-life care) of sufficient quality to be effective, while at the same time ensuring that the use of these services does not expose the user to financial hardship” (24).

Access for all to essential health services of high quality is the cornerstone of UHC. However, since economic considerations are particularly important for vulnerable populations who do not frequently engage with the health system, it will be critical to assess the value for money of these interventions from a societal perspective that factors in the costs (and potential cost-savings) for individuals (25).

Self-care interventions can also help to contain some health system costs, by co-opting users as their own health-care providers and by taking care outside of health-care facilities, provided that the interventions largely maintain diagnostic accuracy, uptake and quality of care. Moreover, for most self-care interventions to remain safe and effective, the involvement of health-care providers is required along the continuum of care – from the provision of information about self-care interventions, to outreach to promote linkages to care where appropriate – which may constrain the cost-savings that can be generated for the health system, especially in the early stages of adoption of new technologies. Importantly, for these interventions to improve overall access for users, health systems will need

to be able to identify those users requiring different levels of support. The availability of self-care alongside facility-based health services may even contribute to more efficient health systems with better health outcomes, not least by including self-care as part of an integrated health system, allowing those who can manage their own health care to do so, while focusing health system resources on those who most need help.

When considering the financing of these interventions, a distinction should be made between entirely self-initiated/self-administered tools without health-care provider involvement, and those that are integrated within health-care provision. Self-care interventions must be promoted as part of a coherent health system, reinforced with health system support where required. The health system remains accountable for patient outcomes linked to the use of these interventions and should closely monitor their economic and financial implications for households and governments – otherwise, the wide use of self-care interventions may promote fragmented, consumerist approaches to health care and undermine integrated person-centred care.

BOX 5.4: CASE STUDY ON COSTS AND COST-EFFECTIVENESS OF SELF-INJECTING CONTRACEPTION

PATH conducted studies on the costs and cost-effectiveness of self-injecting contraception in Burkina Faso, Senegal and Uganda. The costs of delivering subcutaneous depot medroxyprogesterone acetate (DMPA-SC) were estimated under three strategies: (i) facility-based administration, (ii) community-based administration and (iii) self-injection. Both direct medical costs to health systems (e.g. commodity costs and provider time) and non-medical costs incurred by users (i.e. travel and time costs) were estimated. Depending on the distance from users' homes to the health-care facility, and after replacing a training booklet with a clinically effective one-page instruction sheet, the total costs were lowest for community-based administration of DMPA-SC in Uganda (US\$ 7.69), followed by self-injecting DMPA-SC in Uganda (US\$ 7.83) and Senegal (US\$ 8.38), and highest for facility-based administration (US\$ 10.12 Uganda and US\$ 9.46 Senegal). In all three countries, direct non-medical costs were lowest for users who were self-injecting contraceptives, compared with community-based and facility-based delivery (26).

In Uganda, the incremental cost-effectiveness of DMPA-SC was estimated per pregnancy averted and per disability-adjusted life year (DALY) averted. Self-injected DMPA-SC had greater health impacts, in terms of preventing unintended pregnancies and maternal DALYs per year, compared with provider-administered DMPA (DMPA-IM). From a societal perspective, due to savings in user time and travel costs, DMPA-SC could save US\$ 1.1 million or US\$ 84 000 per year. From a health system perspective, DMPA-SC could avert more pregnancies but cost more than provider-administered DMPA-IM, due to the training required during a client's first visit. Simplifying the training approach with feasible, clinically effective and less costly training aids would make DMPA-SC more cost-effective than DMPA-IM at US\$ 15 per unintended pregnancy averted and US\$ 98 per maternal DALY averted (27).



5.4 TRAINING NEEDS OF HEALTH-CARE PROVIDERS

5.4.1 Existing good practice statement on the promotion of self-care interventions by the health workforce

Existing good practice statement on values and competencies of the health workforce to promote self-care interventions

GPS 5: Health-care workers should receive appropriate recurrent training and sensitization to ensure that they have the skills, knowledge and understanding to provide services for adults and adolescents from key populations based on all persons' right to health, confidentiality and non-discrimination.

Remarks

- This good practice statement has been integrated into this guideline from the 2017 WHO publication, *Consolidated guideline on sexual and reproductive health and rights of women living with HIV (28)*, available at: https://www.who.int/reproductivehealth/publications/gender_rights/srhr-women-hiv/en/



i. Background

Workforce 2030 is WHO's global strategy on human resources for health (29) and, together with the report of the High-Level Commission on Health Employment and Economic Growth (30), both published in 2016, it describes an escalating mismatch between supply, demand and population need for health workers. The strategy proposes the reorientation of health systems towards population need (rather than around professional clinical specialties), and plans the scale-up of competency-based professional, technical and vocational education and training .

WHO is developing a global competency framework for UHC (31) which will focus on health-care interventions across promotive, preventative, curative, rehabilitative and palliative health services, which can be provided by health professionals and community health workers at the primary health care level with a pre-service training pathway of 12–48 months (31). The framework will focus on the competencies (integrated knowledge, skills and behaviours) required to provide interventions and will have relevance to both pre-service and in-service education and training. The term “health workforce”

here refers to those front-line health workers providing services targeted to patients and populations such as, but not limited to, physicians, doctors, nurses, midwives, pharmacists, lay health workers, managers and allied health professionals, including community health workers.

Members of the health workforce will need the ability to promote people's health-related human rights, and to enable individuals to become active participants of their own health care. The WHO European Region proposed the following core competencies for patient advocacy (32).

- Advocate for the role of individuals (and family members if appropriate) in making health-care decisions.
- Familiarize oneself with individual rights and professional obligations to provide safe, high-quality, affordable health and social care, by studying legal instruments: legal rights/civil law; quasi-legal rights, patient charters, patients' bill of rights and consumer protection policies.
- Educate people on their right to health care.

- Encourage and promote patients' broad social participation in governance of clinical settings by providing feedback on services received, building partnerships, engaging in political advocacy, promoting community leadership, collecting good data on social conditions and institutional factors, and enhancing communication for health equity.
- Advocate for the incorporation of patient outcomes into organizational strategies, with a special focus on vulnerable populations.
- Understand the effects of disparities in the quality of health care and in people's access to it.
- Balance the patient's care plan with an appropriate combination of medical and psychosocial interventions.
- Incorporate the patient's wishes, beliefs and life course into their care plan, while minimizing the extent to which provider preconceptions of illness and treatment obscure those expressed needs.
- Manage alternative and conflicting views (if appropriate) from family members, carers, friends and members of the multidisciplinary health-care team, to maintain focus on patient well-being.
- Use focused interventions to engage patients and increase their desire to improve their health and adhere to care plans (e.g. using motivational interviewing or motivational enhancement therapy).
- Assess all health behaviours, including treatment adherence, in a non-judgemental manner.

The reorientation of the health workforce will also require health workers to “approach patients, clients and communities differently, be more open to working in teams (particularly inter-professional teams), use data more effectively in their work and be willing to innovate in their practice” (33).

Furthermore, should the use of a self-care intervention lead to the need for further support or counselling within the health system (e.g. a positive test result), the ability to create conditions for providing coordinated and integrated services – centred on the needs, values and preferences of people – along a continuum of care and over the life course requires the following additional competencies.

- Comprehend that effective care planning requires creating a trusting relationship with the patient, by having several discussions with the patient and other parties, over time.
- Provide patient care that is timely, appropriate and effective for treating health problems and promoting health.
- Screen patients for multi-morbidity and assess cognitive impairment, mental health problems (including risky, harmful or dependent use of substances) and harm to self or others, as well as abuse, neglect and domestic violence.
- Assess the extent of the patient's personal and community support network and socioeconomic resources, which may impact the patient's health.
- Match and adjust the type and intensity of services to the needs of the patient over time, ensuring timely and unduplicated provision of care.

Health systems, and the training needs of health-care providers, have to be understood not only in relation to the communities and populations they are trying to serve but also in the wider sociocultural, economic, political and historical context in which they are situated and shaped. In order for self-care interventions to be successfully accessed and used, learning, communication and intersectoral collaboration are needed, to facilitate respectful engagement between community members, patients, health professionals and policy-makers. Respectful, non-judgemental, non-discriminatory attitudes of the health workforce will be essential for the effective introduction of self-care interventions. This includes, for instance, demonstrating active, empathic listening, and conveying information in a jargon-free and non-judgemental manner.

Adequate training and sensitization around a mode of service delivery that promotes user-led approaches and autonomy will require pre- and in-service training and on-the-job supervision. Furthermore, interdisciplinary approaches to promote inter-professional teamwork would enable optimization of the skills mix and delegation of roles through task sharing for delivery of services, with users themselves being recognized as “co-producers” of health. Furthermore, pre-service training through high-quality competency-based training curricula is more effective than one-off in-service interventions in terms of bringing about behaviour change for health.

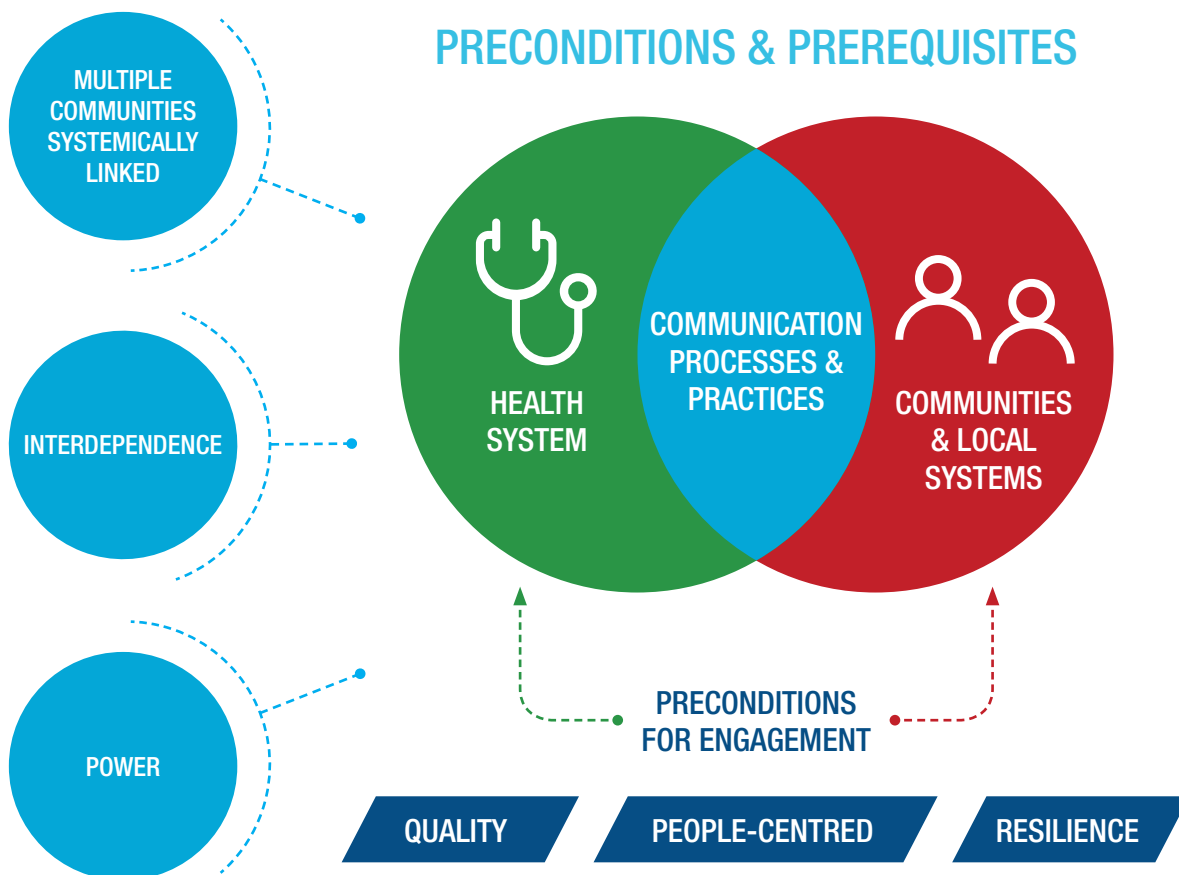
BOX 5.5: CASE STUDIES ON TRAINING NEEDS OF HEALTH-CARE PROVIDERS

1. Case study on self-care training needs of health-care providers

The WHO community engagement framework for quality, integrated, people-centred and resilient health services (WHO CEQ framework) aims to address existing mindsets and practices of health systems to:

- assess the strength of human interlinkages
- tailor a unique package of engagement interventions to support specific health cadres and functions
- embed feedback mechanisms at different levels and entry points of the health system
- build health service and health system responsiveness and resilience.

FIGURE 5.3: THE SCOPE OF THE WHO CEQ FRAMEWORK



Source: WHO, 2017, p.40 (34).

BOX 5.5 (continued)

2. Case study on sensitizing health-care workers in South Africa

South African National AIDS Council (<http://www.sanac.org.za>) and the South African Department of Health (<http://www.health.gov.za/>)

Discrimination by public health-care providers towards people from key populations¹¹ and “unfriendly” health facilities are barriers to access to services, contributing to poorer health outcomes. A multi-partner project in South Africa has developed an integrated approach to sensitizing health-care providers on issues affecting key populations and to empower public health staff members to interact appropriately (regarding both their attitude and their clinical expertise) with people from key populations. Trainings have been conducted in preparation for the implementation

of the National Operational Guidelines for HIV, STIs and TB Programmes for Key Populations in South Africa. The full training programme includes in-person training and mentoring. Thirty trainers participated in an initial training of trainers (TOT) workshop and were linked to local training centres and health facilities. In turn, they trained 420 health-care workers in six months. Where these trainings took place, people from key populations have reported improvements in health-care workers’ attitudes. Communities’ trust has increased, and so has use of health facilities, where the sensitization training has been linked with peer outreach and the prevention activities of civil society organizations. Further evaluation is planned to inform scale-up.

Source: WHO, 2014, p.93 (17).



5.5 IMPLEMENTATION CONSIDERATIONS FOR VULNERABLE POPULATIONS

5.5.1 New good practice statements on self-care for people of all ages, those in humanitarian settings, and by use of digital health interventions

New good practice statement on the life-course approach to SRHR

GPS 6 (NEW): Sensitization about self-care interventions, including for SRHR, should be tailored to people’s specific needs across the life course, and across different settings and circumstances, and should recognize their right to sexual and reproductive health across the life course.



i. Background

Under a life-course approach, health and the risk of disease are understood as the result of the life experiences, social and physical exposures throughout an individual’s life, from gestation to late adulthood (35). This approach promotes timely interventions to support the health of individuals at key

life stages, calling for actions targeting whole societies as well as the causes of disease and ill health, rather than just targeting the consequences in individuals. In sum, a life-course approach to health and well-being means recognizing the critical, interdependent roles of individual, inter-generational, social, environmental and temporal factors in the health and well-being of individuals and communities (36).

¹¹ See definition in Annex 4: Glossary.

The main outcome of the life-course approach is functional ability, which is determined by the individual's intrinsic capacity in their interactions with their physical and social environments and which is, thus, interdependent with the realization of human rights (37). Functional ability allows people to do what they value doing, which enables well-being at all ages, from gestation and birth, through infancy, early childhood, adolescence and adulthood, to older adulthood (38).



ii. Barriers to SRHR

A lack of systematic knowledge about the way health at different life stages interrelates and accumulates through a lifetime and generations is one of the main barriers to the implementation of the life-course approach to support health and well-being, including SRHR. There are few studies on this issue, most of them focusing on populations in the Global North. An obstacle to improving the understanding of health through time is the current focus on single diseases and specific age groups.

Age-based discrimination is another of the main barriers standing in the way of a better understanding of the SRHR needs of populations in particular age stages; for instance, notions about the sexual lives, needs and health of older populations and adolescents are often clouded by stereotypes. Discrimination against older populations has received increased attention since the 1980s, when the term “ageism” was coined to refer to this particular kind of age-based discrimination (39).

Better understanding of these barriers – and of why people will access self-care rather than facility-based health services – can allow for better use and uptake of self-care interventions. Reducing age-based discrimination and shifting the focus of research and action so that they take into account temporality and interconnectedness is critical to better tailor policy and actions.



iii. Components of an enabling environment that will address the barriers and support SRHR

Age-friendly environments will enable the SRHR needs of populations to be better addressed across the entire age spectrum. Fostering age-friendly environments, which entails reducing ageism, is part of WHO's Global Strategy on Ageing and Health (40). The United Nations and the Decade of Action on Healthy Ageing, to be launched in 2020 (41) recognize healthy ageing as a contributing factor to the attainment of the Sustainable Development Goals (SDGs) (42).

Based on case studies carried out by WHO on the implementation of the life-course approach to health in the small European countries of Iceland and Malta, three additional enabling factors were identified. The first entails strengthening collaboration across different government areas, sectors and society, as it was observed that planning and action benefitted from the perspectives and involvement of all actors involved. The second is about making health-care interventions sensitive and responsive to equity and gender, as these two factors are often at the root of disadvantages lasting an individual lifetime and persisting through generations. Finally, the third identified enabling factor was allocating time and resources to monitoring and knowledge exchange; these two activities are key to ensure the adoption and ongoing improvement and durability of the life-course approach and actions (43).



iv. Summary of the evidence and considerations of the GDG

The case of older populations illustrates well the potential benefits of the adoption of a life-course approach to health, particularly SRHR. “Older adults” remains too broad a category, as it is often shorthand for all adults in the second half of life (44). However, older adulthood comprises different stages of life that should be differentiated and better understood in order to meet the SRHR needs of specific stages. WHO currently identifies three age categories in older adulthood: middle adulthood (age 50–64 years) and two age groups in later adulthood (ages 65–79 and 80+) (45). Sexual health remains a key consideration among older adults (46). According to the few systematic reviews on the sexual health of older adults, there is also a lack of diversity in research, as most systematic studies on the matter are based on populations of older adults living in the Global North (47).

A life-course approach that is sensitive, respectful and knowledgeable about the particular challenges and opportunities at all ages would also help reduce age-based discrimination. Stereotypes regarding the sexualities and sexual lives of older adults persist despite various studies that have shown that sex and pleasure are integral to the lives and well-being of older adults. Although this issue remains understudied, the available evidence suggests that supporting older adults' intrinsic capacities for healthy living includes supporting them in their choice to enjoy safe and fulfilling sexual relationships and sexual pleasure as they age. In order to support informed choices, improving health literacy of older adults regarding accurate information, services and self-care for SRHR remains of the utmost importance.

New good practice statement on the use of digital health interventions to support the use of self-care interventions

GPS 7 (NEW): Digital health interventions offer opportunities to promote, offer information about and provide discussion forums for self-care interventions, including for SRHR.



i. Background

The provision of accurate and tailored information about specific health-care interventions and technologies, including through mobile devices, is important to promote safe and effective SRHR-related self-care. To this end information is needed to:

- facilitate access (e.g. with details of potential sources/ access points);
- promote appropriate use of an intervention/technology, through comprehensible (step-by-step) instructions;
- inform potential users about likely physical and emotional ramifications, plus potential side-effects and contraindications; and
- advise potential users about the circumstances under which they should seek care and how to do so.



ii. Barriers to SRHR

Self-care for SRHR has perhaps the greatest potential to address unmet needs or demands in marginalized populations or in contexts of limited access to health care, including, for instance, self-managed medical abortion in countries where abortion is illegal or restricted. In such contexts, a lack of access to specific interventions is often accompanied by a lack of appropriate information regarding the intervention (48) (e.g. when young people obtain emergency contraception from pharmacists but immediately discard the packaging and information sheet because of its potential to incriminate them) and reticence to discuss the intervention because of the associated stigma (49).

Many of the studies of digital health interventions, including use of eHealth and “mobile health” (mHealth, a component of

eHealth), which often facilitate targeted client communication or provider-client telemedicine, recognize issues around access (particularly in relation to the availability of mobile phones and connectivity) as well as potential issues of confidentiality. There are also limitations in terms of the research conducted on these interventions; data on health outcomes are limited and the studies rarely use a rigorous research design (50).



iii. Components of an enabling environment that will address the barriers and support SRHR

Digital health technologies offer potential conduits for information beyond more traditional information sources in the formal health system. Digital health technologies encompass a variety of approaches to information provision, including targeted provider-to-client communications; client-to-client communications; and on-demand information services for clients (51). In terms of on-demand SRHR information, the Internet is popular, particularly because the information online is available, affordable, anonymous and accessed in private (52, 53). Online discussion forums – using social media or a range of applications (apps) – can be sources of peer-to-peer information around SRHR self-care technologies. With regard to information provision via mobile phones (text message/SMS or apps on smart phones), recent reviews have demonstrated high feasibility and acceptability of the provision of SRHR-related information, with studies also demonstrating knowledge and behaviour change (54).



iv. Summary of the evidence and considerations of the GDG

A recent systematic review of studies of adolescents accessing SRHR information online highlighted a demand for information and education about sexual experiences (not just technical information) and reviewed the impact of accessing information in this way in terms of behaviour change. The review also highlighted how

demand for information varied across the adolescent age groups and showed that adolescents were generally good at evaluating information. However, there is a lack of research on the role of social media in providing SRHR-related information. The relatively few studies undertaken highlight issues with measuring impact, limitations of study designs and a lack of standard reporting (55).

Recent reviews highlight how the effectiveness of digital health interventions to provide appropriate information for safe and effective self-care for SRHR is predicated on consideration for: (i) potential users' access to technology/digital devices, including limited connectivity; (ii) diversity and changes in the types of delivery channels (e.g. text, voice, apps, etc);

(iii) age- and population-specific (e.g. gender, sexuality, disability) information priorities and needs; (iv) the need to tailor content and maintain fidelity of messages; (v) concerns about confidentiality; and (vi) current levels of literacy, as well as digital and health literacy.

Additionally, the *WHO guideline: recommendations on digital health interventions for health system strengthening* presents 10 recommendations on digital health interventions, based on an assessment of their effectiveness (benefits and harms), as well as considerations of resource use, feasibility, equity and acceptability (values and preference) (56).

New good practice statement on support for self-care interventions in humanitarian settings

GPS 8 (NEW): Provision of tailored and timely support for self-care interventions, including for SRHR, in humanitarian settings should be in accordance with international guidance, form part of emergency preparedness plans and be provided as part of ongoing responses.



i. Background

In 2015, UNHCR – the United Nations Refugee Agency – estimated that the global population of forcibly displaced people exceeded 65 million for the first time in history. Of those needing humanitarian assistance, it is estimated that approximately 1 in 4 are women and girls of reproductive age. The diversity in populations (refugees, asylum seekers, internally displaced persons), settings (from refugee camps to urban areas), circumstances (conflict, post-conflict, natural disasters) and their varying access to rights (e.g. citizens versus non-citizens) all add to the complexity of providing quality care in challenging circumstances (57). With approximately 40% of refugees experiencing displacement for over five years, and many for over 20 years, this underscores the need for a life-course approach to health care for refugees (58).



ii. Barriers to SRHR

The ability to realize SRHR in the context of humanitarian crises is constrained by a complex interplay of factors, including increased poverty; gender-based violence; trauma and mental

health challenges; limited access to and quality of health care; breakdown of familial, social and community networks; and problematic living conditions (59). Language also often presents a barrier to health-care access and may result in avoidance of care, misdiagnosis and decreased medical compliance. Thus, there is a need to adapt innovative SRHR service-delivery models for humanitarian contexts (60).



iii. Components of an enabling environment that will address the barriers and support SRHR

Health system strengthening during emergencies remains essential to support and facilitate access to self-care interventions for SRHR. Communities also respond on their own to crises, developing informal yet strong social support systems and an enabling environment. All these are entry points to supporting individuals to improve health outcomes (57). The growing evidence base on implementing comprehensive approaches to delivery of the Minimum Initial Service Package (MISP) will support improved health outcomes, but there is still much work to be done in this field (61).



iv. Summary of the evidence and considerations of the GDG

Given the lack of longitudinal data or studies with an adequate control comparison group, innovative ways of collecting data should be tested, such as using information and communications technologies (ICTs) that are widely used by many conflict-affected populations (e.g. WhatsApp). These data-collection methods may prove beneficial for

researchers, health-care providers and organizations seeking to collect health outcome data at the individual-level, including from populations on the move who have traditionally been challenging to follow up (60). There is also a need for innovation in establishing stronger referral and follow-up systems in humanitarian settings to ensure that health outcome indicators used to assess effectiveness are truly the most appropriate for this purpose. Researchers should also consider use of alternative study designs where standard randomized controlled trials are not operationally or ethically possible (60).

5.5.2 Adapted and existing good practice statements on self-care for vulnerable populations

Existing good practice statement on values and competencies of the health workforce to promote self-care interventions

GPS 9 (ADAPTED): People from vulnerable populations should be able to experience full, pleasurable sex lives and have access to a range and choice of reproductive health options.

GPS 10 (ADAPTED): Countries should work towards implementing and enforcing antidiscrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against vulnerable populations.

GPS 11: Countries should work towards decriminalization of behaviours such as drug use/injecting, sex work, same-sex activity and nonconforming gender identities, and towards elimination of the unjust application of civil law and regulations against people who use/inject drugs, sex workers, men who have sex with men and transgender people.

GPS 12: Countries are encouraged to examine their current consent policies and consider revising them to reduce age-related barriers to HIV services and to empower providers to act in the best interests of the adolescent.

GPS 13: It is recommended that sexual and reproductive health services, including contraceptive information and services, be provided for adolescents without mandatory parental and guardian authorization/notification.

Remarks

- These good practice statements have been integrated into this guideline (with slight wording adaptations in some cases) from the 2014 WHO *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (17), available at: <https://www.who.int/hiv/pub/guidelines/keypopulations/en/>
- For GPS 11, this can be read as also applying to sexual and gender minorities (rather than just applying to people who use/inject drugs, sex workers, men who have sex with men and transgender people as stated in the original wording).



i. Background

People from vulnerable populations¹² should enjoy the same reproductive health and rights as all other individuals; it is important that they have access to family planning and other reproductive health services, including reproductive tract cancer prevention, screening and treatment.

As described in WHO's *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*, efforts to reduce stigma and discrimination at the national level, such as promoting antidiscrimination and protective policies for all key populations, can foster a supportive environment, particularly within the health-care and justice systems – and the same applies to other vulnerable populations. Policies are most effective when they simultaneously address individual, organizational and public policy factors that enable or drive stigma and discrimination. Programmes, both within and outside the health sector, need to institute anti-stigma and

antidiscrimination policies and codes of conduct. Monitoring and oversight are important to ensure that standards are implemented and maintained. Additionally, mechanisms for anonymous reporting should be made available to anyone who may experience stigma and/or discrimination when they try to obtain health services (17).

Laws and policies can help to protect the human rights of vulnerable populations. Legal reforms, such as decriminalizing sexual behaviours and legal recognition of transgender status are critical enablers that can change a hostile environment to a safe and supportive, enabling environment. Specific consideration should be given to such legal reforms as part of any revision of policies and programmes for vulnerable populations. Supporting the health and well-being of vulnerable populations may require changing legislation and adopting new policies and protective laws in accordance with international human rights standards. Without protective policies, barriers to access, uptake and use of essential health services – including self-care interventions – will remain (17).

BOX 5.6: CASE STUDIES RELEVANT TO SELF-CARE FOR VULNERABLE POPULATIONS

1. Case study: Building health literacy among young injecting drug users in Mexico

Programa de Política de Drogas (Espolea, A.C), Mexico (www.espolea.org)

Espolea, a youth-led organization in Mexico City, opened its Drug Policy and Harm Reduction Programme in 2008 and has since developed online and face-to-face channels to provide objective information about drugs and risk reduction to young people ages 15–29 years. The organization has found that information is most effective when disseminated at places where young people use drugs, particularly electronic dance music festivals, rock concerts and cultural gatherings. At these events,

Espolea sets up a stand as a safe space for young people to obtain information about drugs that may be being consumed. The organization also facilitates workshops in schools and in communities with concentrations of most-at-risk young people. Espolea has an active outreach strategy, using social media, including Facebook and Twitter as well as Internet blogs. One blog – www.universodelasdrogas.org – serves as a databank on drugs and has become the axis of the programme's harm reduction campaign. Staff members, collaborators and young people produce the information. Printed materials offer facts and recommendations about nightlife, alcohol consumption, risky sexual behaviours, HIV and other STIs.

Source: WHO, 2014 (17).

¹² See definition in Annex 4: Glossary.

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6

DEVELOPING THE RESEARCH AGENDA ON SELF-CARE INTERVENTIONS FOR SRHR

“Human rights and issues of equity were emphasized as an integral component of both the development and the delivery of self-care interventions.”



CHAPTER AT A GLANCE

This chapter establishes good research practices and considerations to support future research into optimal development and delivery of self-care interventions.

RESEARCH ON SELF-CARE CONTRIBUTING TO WHO'S "TRIPLE BILLION" GOALS

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There are particular considerations for the self-care research and implementation agenda in the context of WHO's "triple billion" goals.

TOWARD AN APPROPRIATE APPROACH TO RESEARCH ON SELF-CARE FOR SRHR

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The field of self-care is dynamic and fast-moving, requiring a multi-sectoral approach driven by a collaborative ethos.

SPECIFIC RESEARCH QUESTIONS TO STRENGTHEN THE EVIDENCE BASE

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The bulk of this chapter focuses on describing the knowledge gaps identified by the Guideline Development Group (GDG) that need to be addressed through further primary research. Questions to address these gaps are presented by topic and by GRADE domain.

FUTURE RESEARCH IN SELF-CARE FOR SRHR



FUTURE RESEARCH ON SELF-CARE

can be conceptualized under two broad areas of self-care interventions:



WORKING GROUPS

developed a list of questions to address the research gaps identified throughout the process of developing these guidelines.



DEVELOPMENT



DELIVERY

Researchers investigating the effectiveness of self-care interventions are advised to consistently consider how human rights and equity can inform the appropriate implementation of self-care interventions.

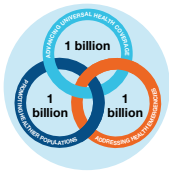
The GDG noted that outcomes specific to human rights and equity were consistently absent from the studies included in the systematic reviews and noted this as a key research gap.



HUMAN RIGHTS



EQUITY



6.1 RESEARCH ON SELF-CARE CONTRIBUTING TO WHO'S "TRIPLE BILLION" GOALS

In the context of WHO's goal for strategies that will allow 1 billion more people to benefit from universal health coverage (UHC), improving access to essential self-care interventions for primary health care will require a strong evidence base and specific efforts to reach populations who are currently not being reached. The research and development agenda will be defined and coordinated in line with national and regional public health priorities.

In the context of WHO's goal to better protect 1 billion more people from health emergencies, the research agenda should also focus on innovative self-care tools, products and interventions that can be delivered for populations affected by high-threat health hazards and humanitarian emergencies.

In the context of WHO's goal for 1 billion more people to enjoy better health and well-being, research will be required into the optimal delivery of self-care interventions to reduce health risk factors and promote optimal health outcomes. This can be achieved through multisectoral action, which must include meaningful engagement of all stakeholders, especially civil society, and both the public and private sectors.



6.2 TOWARDS AN APPROPRIATE APPROACH TO RESEARCH ON SELF-CARE FOR SRHR

The field of self-care interventions is fast-moving, multisectoral and multidisciplinary. As such, it is important that research environments are dynamic and flexible and driven by a collaborative ethos. Principal to successful collaboration will be the inclusion and contribution of end-users to shaping the research agenda and promoting meaningful user engagement, including patient engagement.

Future research on self-care can be conceptualized under two broad areas: (i) *development* of self-care interventions; and (ii) *delivery* of self-care interventions.

- An example of a *development* research question is: What are the optimal design features of a culturally appropriate self-care intervention for displaced populations?

- An example of a *delivery* question is: Will a specific self-care intervention improve coverage, protect and promote equity and human rights, reduce out-of-pocket expenditure, and be responsive to current and emerging population needs?

Underpinning the focus of research on efficacy, effectiveness, safety, implementation and delivery will be the perspectives of individuals, collectives, communities and providers, or systems perspectives. As such, attention needs to be given to matching the selection of outcomes to be measured with the relevant perspective. The same is true for studies of costs and cost-effectiveness.

The increasing adoption of digital health and digital therapeutics in the self-care space offers new opportunities to generate real-world evidence in real time. However, it demands that privacy, security and identity management are integral to the conduct of ethical self-care research. Transparency, a culture of trust, and mutual benefit for those who participate in research and those who conduct research are paramount to creating a sustainable research environment.

The research endeavour specific to self-care interventions can be conceptualized as combining conventional health-care epidemiological principles with human rights, gender equality, ethics and the law. Studies on self-care interventions for SRHR should clearly identify the contribution of the study to advancing knowledge with respect to a holistic approach to health and well-being, reducing disparities, vulnerabilities and power differentials, and advancing UHC.



6.3 SPECIFIC RESEARCH CONSIDERATIONS TO STRENGTHEN THE EVIDENCE BASE

During the guideline development process and in-person Guideline Development Group (GDG) meeting, the GDG identified important knowledge gaps that need to be addressed through further primary research.

For several of the questions addressed by new recommendations in this guideline, the evidence base was limited. The reasons for this include: (i) few rigorous studies related to the topics of interest have been published in peer-reviewed journals; (ii) there was little representation of research from low- and middle-income countries; and (iii) few outcomes of interest (especially

harms) were included in the studies. In addition, most results were not disaggregated to support understanding of potential differences in outcomes among different groups of (potential) users of self-care interventions.

The certainty of evidence was rated as “low” or “very low” for several of the interventions evaluated. According to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology,¹³ where the certainty of evidence is “low” or “very low” for critical outcomes, this implies that further research on these interventions is likely to have an impact on future certainty and subsequent recommendations related to these interventions. These issues were noted by the GDG and informed the identification of research gaps.

Measurement of social harms as an outcome was consistently absent from the studies included in the reviews that were prepared for this guideline (see Annex 7). The GDG noted that in the self-care field, social harms are especially important to measure as the use of the intervention is intended to take place outside the health system. Both the social benefits

and the social harms need to be delineated and included as research outcomes when designing studies. Linkage to care within the health system may be a desirable outcome of a self-care intervention, especially if further health-care assistance is required, for example, following the use of a self-care intervention for screening or sampling. Researchers need to recognize the complexity of evaluating a self-care intervention that may reduce the burden on some aspects of the health system while simultaneously increasing the burden in other areas through the need for provision of information for informed decision-making and appropriate linkage to care.

Illustrative research questions are provided in Box 6.1 in relation to the enabling environment for self-care interventions for SRHR, and then some intervention-specific questions are presented – following the structure of the GRADE framework – in Tables 6.1 and 6.2. Each research question should take into account the range of self-care interventions, the diversity of potential users and the different locations in which self-care interventions are purchased and used.

BOX 6.1: ILLUSTRATIVE RESEARCH QUESTIONS RELATED TO THE ENABLING ENVIRONMENT FOR SELF-CARE FOR SRHR

- How best can linkage to the health system be supported for people using self-care interventions for SRHR?
- What laws might create barriers to the use of self-care interventions for certain populations and how might these be changed?
- What is the impact of removing legal barriers to accessing services or barriers to the uptake of self-care interventions?
- What regulation of self-care interventions for SRHR exists that complies with human rights law and obligations?
- What are the potential risks of violence and coercion associated with self-care interventions and how can these be minimized?
- What types of accountability mechanisms (including legal, social and others) are most effective in the context of self-care interventions?
- While the monitoring of progress in health and climate change is improving, there are weaknesses in coverage and in stakeholder engagement (1). What research will ensure a stronger evidence base for the argument that health indicators should be included among the indicators for the Sustainable Development Goal (SDG) targets on climate change?
- How does using sustainable materials for self-care technologies influence price and therefore access?
- How can single-use products be designed to be environmentally friendly?
- What are common characteristics of environments that support successful implementation of self-care interventions (i.e. where these interventions achieve goals of expanded coverage, reduced cost, improved equity, etc.)?

¹³ For further information, see: <http://www.gradeworkinggroup.org/>

Table 6.1 lists questions to address the research gaps identified by the GDG, organized by topic (for the self-care interventions addressed by new recommendations in this guideline) and by GRADE domain. This list is not intended

to be comprehensive and many other topics may also merit further research. In addition, the list has not undergone a formal priority-setting exercise and no hierarchy of importance is implied by the order.

TABLE 6.1: QUESTIONS TO GUIDE FUTURE RESEARCH ON THE SELF-CARE INTERVENTIONS FOR SRHR ADDRESSED BY THE NEW RECOMMENDATIONS IN THIS GUIDELINE

GRADE DOMAIN	RESEARCH QUESTIONS TO ADDRESS GAPS
Self-administration of injectable contraception (REC 10)	
Values and preferences	<ul style="list-style-type: none"> • Are there differences between groups of end-users (e.g. age, socioeconomic indicators, occupation and/or education level) in terms of their values and preferences? • What happens after discontinuation of self-administered injectable contraception – do people use other methods? • What is the relationship between stigma and the choice of self-injectable contraception? • What are the optimal models of information provision for raising awareness and increasing knowledge?
Acceptability	<ul style="list-style-type: none"> • Do characteristics of health-care providers (e.g. age, income status of country, private/public sector) have an impact on whether they view self-injection of contraception by users as acceptable? • What is the scale and consequence of incorrect use of self-injection?
Resource use	<ul style="list-style-type: none"> • What are the associated costs – for the health system and the user – of self-administration of injectable contraception? • What are the costs and benefits of self-injection of contraception, and is it cost-effective? • What is the environmental impact of disposal of self-injectable contraception supplies?
Equity and human rights	<ul style="list-style-type: none"> • What implementation measures can ensure that inequity in access is reduced or minimized when self-injection is introduced? • Is there evidence of social harms (e.g. violence) arising from self-administration of injectable contraception?
Self-management of contraceptive use with over-the-counter oral contraceptive pills (OTC OCPs) (REC 11)	
Benefits versus harms	<ul style="list-style-type: none"> • What adverse events arise from the use of OTC OCPs? • Are there differences in the quality of OCPs that are available OTC and those that are available on prescription? • What are the optimal ways to provide advice on switching oral contraceptives or using other contraceptive options (e.g. via text messaging)? • What are the benefits and harms of providing the progestogen-only pill OTC? (Note: The evidence only included data from the combined oral contraceptive pill.)
Values and preferences	<ul style="list-style-type: none"> • What are the values and preferences of end-users living in low- and middle-income countries related to OTC OCPs? • Do adults and adolescents have different values and preferences with regard to OTC OCPs? • How does willingness to pay affect uptake of OTC OCPs?
Acceptability	<ul style="list-style-type: none"> • What do health-care providers know, think and feel about provision of OTC OCPs, especially in low- and middle-income settings? • What are optimal approaches to the promotion of the availability of OTC OCPs? • Does the implementation of OTC OCPs change the extent to which stigma and discrimination act as barriers to OCP use?
Resource use	<ul style="list-style-type: none"> • Who bears the cost of OTC OCPs – is the cost shifted from the health system to the user?
Equity and human rights	<ul style="list-style-type: none"> • Will potential end-users of all ages be able to access OTC OCPs? What barriers will remain? • How can information best be provided to ensure informed decision-making around OTC OCPs, including uptake, continuation and care-seeking in the case of side-effects?

TABLE 6.1 (continued)

GRADE DOMAIN	RESEARCH QUESTIONS TO ADDRESS GAPS
Self-screening with ovulation predictor kits (OPKs) for fertility regulation (REC 12)	
Benefits versus harms	<ul style="list-style-type: none"> • Does fertility management with OPKs lead to better outcomes than fertility management without OPKs in low- and middle-income settings?
Resource use	<ul style="list-style-type: none"> • What are the costs and benefits of home-based OPKs and are they cost-effective compared with other fertility management options?
Values and preferences	<ul style="list-style-type: none"> • What are people’s values and preferences regarding the need to become pregnant and have a child, rather than experience childlessness in high-, low- and middle-income countries? • How does willingness to pay affect uptake of OPKs? • What is the impact of using a home-based OPK on communication between partners?
Equity and human rights	<ul style="list-style-type: none"> • How does uptake of home-based OPKs affect intra-household gender dynamics?
HPV self-sampling (HPVSS) for cervical cancer screening (REC 21)	
Values and preferences	<ul style="list-style-type: none"> • What is (are) the optimal way(s) to engage potential users (e.g. via text or via community-based means)? • Is HPVSS an acceptable strategy for increasing access to screening and treatment for transgender men?
Resource use	<ul style="list-style-type: none"> • What are the costs and benefits of HPVSS and is it cost-effective when linkage to care is included as an outcome? • What are the differences in costs between high-income and low-income regions?
Equity and human rights	<ul style="list-style-type: none"> • How can linkage to care (for different groups of end-users) be ensured following self-sampling? • What are the optimal methods for accessing specific populations (e.g. homeless people, adolescents, people in humanitarian settings)?
Self-collection of samples (SCS) for STI testing (RECs 22a and 22b)	
Benefits versus harms	<ul style="list-style-type: none"> • What is the impact of SCS for STI testing on partner screening? • What proportion of people who receive a positive result after SCS for STI testing seek appropriate STI care and treatment services? • What is the impact of SCS for STI testing on linkage to care and case-finding? • Does SCS for STI testing offer a benefit in low-income settings? • What are the benefits and harms of SCS for STI testing of viral aetiology? • Does SCS for STI testing increase self-treatment for STIs (both appropriate and inappropriate)?
Values and preferences	<ul style="list-style-type: none"> • What are the values and preferences of marginalized populations (e.g. sexual and gender minorities, sex workers) regarding SCS for STI testing?
Resource use	<ul style="list-style-type: none"> • What are the costs and benefits of SCS for STI testing for the health system and the user, and is it cost-effective?
Equity and human rights	<ul style="list-style-type: none"> • Is there potential for coercion in SCS for STI testing? If so, how can this be avoided?



6.4 ADOPTING A HUMAN RIGHTS AND EQUITY LENS FOR SELF-CARE FOR SRHR

Throughout the development process for this guideline and during the in-person GDG meeting, human rights and issues of equity were emphasized as an integral component of both the development and the delivery of self-care interventions. During the GRADE decision-making process, each intervention was interrogated for its potential impact on human rights and equity. The GDG noted that outcomes specific to human

rights and equity were consistently absent from the studies included in the systematic reviews and noted this as a key research gap. Researchers investigating the effectiveness of self-care interventions are therefore advised to consistently consider how human rights and ethics can inform appropriate implementation of self-care interventions, as well as the impact of the intervention under study on human rights and equity. In order to achieve this, the GDG endorsed the inclusion of specific outcome domains to measure human rights and equity in self-care research; these are presented in Table 6.2, along with illustrative research questions for each.

TABLE 6.2: OUTCOME DOMAINS FOR MEASURING HUMAN RIGHTS AND EQUITY IN SELF-CARE RESEARCH, AND ILLUSTRATIVE RESEARCH QUESTIONS

HUMAN RIGHTS STANDARD	ILLUSTRATIVE RESEARCH QUESTIONS RELATING TO SELF-CARE INTERVENTIONS
The right to health, including availability, accessibility, acceptability and quality of information, goods and services	<ul style="list-style-type: none"> • How might self-care interventions promote access, autonomy and empowerment without compromising safety and quality? • What financial risk protection mechanisms can help promote access to self-care interventions for all populations? • What are users' preferred venues for accessing and using different self-care interventions? • What barriers to accessing health services might have to be addressed in order to ensure linkage to care following use of self-care interventions? • Is the quality of self-care interventions/technologies accessed outside the health system the same as interventions accessed within the health system? • To what extent does the promotion of self-care technologies have a (negative) impact on service provision in primary care, particularly on investment in human resources?
Participation	<ul style="list-style-type: none"> • How can users be involved in the design of different self-care interventions, including products, as well as how these are made available?
Equality and non-discrimination	<ul style="list-style-type: none"> • How will vulnerable populations be identified and regulations be tailored in ways that take their needs into account to ensure access in different locations and in relation to different self-care interventions? • How might gender dynamics influence uptake of self-care interventions as well as potential negative impacts of their use? • Do self-care interventions improve health equity along dimensions of gender, socio-economic status or race/ethnicity where there are existing inequalities in coverage and need?
Right to information	<ul style="list-style-type: none"> • What are the different ways in which people access information for self-care technologies, both online and offline? • How can the quality of information about self-care interventions best be monitored and regulated?
Informed decision-making	<ul style="list-style-type: none"> • What interventions improve self-efficacy, empowerment and informed decision-making for self-care interventions? • What types of psychosocial support/interventions might be needed for different self-care interventions?
Privacy and confidentiality	<ul style="list-style-type: none"> • How can single-use products be designed to maintain confidentiality? • How might health management information systems have to evolve to ensure confidentiality relating to self-care interventions that may be used outside the health-care setting?
Accountability	<ul style="list-style-type: none"> • What mechanisms for accountability and redress are effective in the context of self-care interventions?

Further work is required to explore and identify the specific outcomes related to these domains and the optimal instruments to accurately measure such domains. The experience and guidance of the COMET (Core Outcome Measures in Effectiveness Trials) initiative are instructive in this regard. COMET aims to bring together people interested in the development and application of agreed, standardized sets of outcomes, known as “core outcome sets”.¹⁴ These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, and are also suitable for use in clinical auditing or research other than randomized trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported – making it easier for the results of trials to be compared, contrasted and combined as appropriate – while researchers continue to explore other outcomes as well.

WHO has previously noted the need to strengthen research on, and evaluation of, human-rights-based approaches to women’s and children’s health, and highlighted the value

of a multidisciplinary research and evaluation network of policy-makers, practitioners and scholars with this focus (2). This could include research around all of the human-rights-related questions on self-care interventions, both with regard to service-delivery processes and the intended and unintended outcomes of the use of self-care interventions.

The process for the development of WHO’s consolidated guideline on SRHR of women living with HIV (3) enabled extensive, meaningful participation of rights holders, including from marginalized groups, and this has been highlighted as an example of best practice. The balanced group of health-care providers, researchers and communities (in that case, women living with HIV) and other experts in the guideline development process allowed for the meaningful involvement of communities in the development of the research agenda from the start of the process, including using the GRADE methodology (4). A similar process of meaningful community engagement will be included in planned research activities for self-care interventions.

REFERENCES FOR CHAPTER 6

1. COP24 special report: health & climate change. Geneva: World Health Organization; 2018 (<https://www.who.int/globalchange/publications/COP24-report-health-climate-change/en/>, accessed 20 February 2019).
2. Bustreo F, Hunt P, Gruskin S, Eide A, McGoey L, Rao S, et al. Women’s and children’s health: evidence of impact of human rights. Geneva: World Health Organization; 2013 (https://apps.who.int/iris/bitstream/handle/10665/84203/9789241505420_eng.pdf, accessed 16 May 2019).
3. Consolidated guideline on sexual and reproductive health and rights of women living with HIV. Geneva: World Health Organization; 2017 (https://www.who.int/reproductivehealth/publications/gender_rights/srhr-women-hiv/en/, accessed 3 May 2019).
4. Seigfried N, Narasimhan M, Welbourn A, Yuvraj A. Using GRADE as a framework to guide research on the sexual and reproductive health and rights (SRHR) of women living with HIV: methodological opportunities and challenges. *AIDS Care*. 2017;29(9):1088-93. doi:10.1080/09540121.2017.1317711.

¹⁴ Further information is available at: www.comet-initiative.org

7

DISSEMINATION, APPLICABILITY AND UPDATING OF THE GUIDELINE AND RECOMMENDATIONS

“Effective implementation of the recommendations and good practice statements in this guideline will likely require reorganization of care and redistribution of health-care resources, particularly in low- and middle-income countries.”



CHAPTER AT A GLANCE

This chapter identifies the many channels via which the guideline will be disseminated, and analyses the anticipated impacts of the guideline.

DISSEMINATION OF THE GUIDELINE

pp. 122

This guideline will be available for download and also as a printed publication. Dissemination plans also include technical meetings, the development of evidence briefs, and workshops and briefings with global and regional stakeholder groups.

APPLICABILITY OF THE GUIDELINE

pp. 122

This section describes the potential barriers to implementation as well as plans for monitoring and evaluation of the guideline impacts.

UPDATING THE GUIDELINE

pp. 123

The rapidly evolving nature of self-care interventions calls for a continuous review of the literature. An update to this guideline will likely be required within 18–24 months of dissemination of this edition.

DISTRIBUTION OF THE GUIDELINE



FOR
DOWNLOAD

AVAILABLE VIA:

- The website of the WHO Department of Reproductive Health and Research
- Reproductive Health Library (RHL)



PRINTED
PUBLICATION

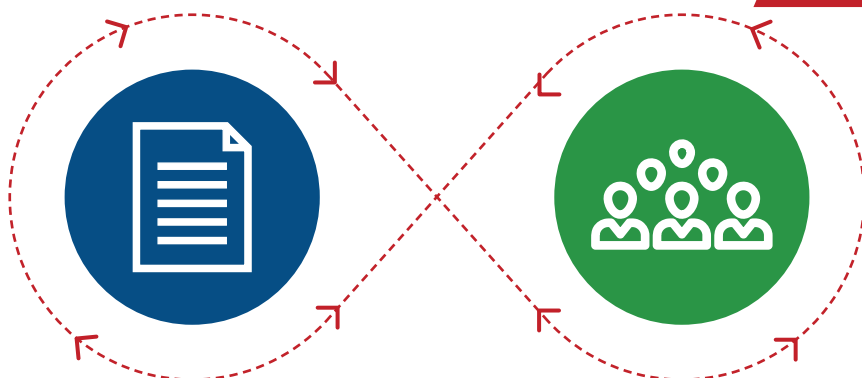
DISTRIBUTED TO:

- WHO regional and country offices
- Ministries of health
- WHO collaborating centres
- Nongovernmental organization partners
- Professional associations

LIVING GUIDELINE CONCEPT

This publication will follow a “living guideline” concept, which means it will undergo continuous updating as many more interventions become available. The updates will also accommodate either new evidence on existing recommendations or the development of new recommendations based on emerging evidence, including on new SRHR self-care interventions that may not have been available or identified during the discussions for the current version.

Future updates will include topics, recommendations and good practice statements relevant to SRHR and noncommunicable diseases, and other areas of health





7.1 DISSEMINATION

This guideline will be available online for download and also as a printed publication. Online versions will be available via the website of the WHO Department of Reproductive Health and Research, and through the WHO Reproductive Health Library (RHL).¹⁵ Print versions will be distributed to WHO regional and country offices, ministries of health, WHO collaborating centres, nongovernmental organization partners and professional associations. Technical meetings will be held jointly with the Department and the regional offices to share the recommendations and derivative products, which will include implementation tools for the new recommendations and good practice statements. Two sets of evidence briefs will also be developed – one set for policy-makers and programme managers and the other for health-care professionals – highlighting the recommendations and implementation-related contextual issues.

The dissemination plans also include workshops and briefings with different stakeholders at the global and regional levels. It is expected that detailed plans for development of the evidence briefs and implementation tools, as well as for dissemination and implementation of the guideline, will be formulated in collaboration with implementing partners, national stakeholders and civil society, and will allow for derivative products to be tailored to the needs in different national contexts.

The executive summary and recommendations from this publication will be translated into the six United Nations languages for dissemination through the WHO regional offices and during meetings organized or attended by staff of relevant WHO departments.

The guideline will be launched on the website of the WHO Department of Reproductive Health and Research and in “HRP News”, the monthly electronic newsletter.¹⁶ HRP News currently has over 3000 subscribers including clinicians, programme managers, policy-makers and health-service users worldwide. This guideline will also be shared through several knowledge-sharing platforms, including the Implementing Best Practices (IBP) initiative,¹⁷ and on the website of the Interagency Working Group on SRH & HIV Linkages;¹⁸ both

of these groups reach key partners working in the field of sexual and reproductive health and rights (SRHR). In addition, the systematic and literature reviews that were conducted for the development of this guideline have been published (see Annex 7), in compliance with WHO’s open access and copyright policies.

To increase the dissemination of WHO guidelines on SRHR, a search function with the ability to search the database of WHO guidelines and recommendations has been created and recently launched by the Department. The recommendations of this guideline will be made available via this new search function.¹⁹



7.2 APPLICABILITY

7.2.1 Anticipated impact of the guideline

Effective implementation of the recommendations and good practice statements in this guideline will likely require reorganization of care and redistribution of health-care resources, particularly in low- and middle-income countries (LMICs). The potential barriers to implementation include:

- lack of human resources with the necessary expertise and skills to implement, supervise and support recommended practices, including client counselling;
- lack of infrastructure to support the intervention;
- lack of physical space to conduct individual or group counselling;
- lack of quality physical resources, such as equipment, test kits, supplies, medicines and nutritional supplements;
- lack of effective referral mechanisms, integrated services and care pathways for people who may require additional care;
- lack of understanding of the value of newly recommended interventions among health-care providers and health system managers;

¹⁵ Available at: <http://apps.who.int/rhl/en/>

¹⁶ Please see the “What’s new?” page of the RHR/HRP website, which includes a link to subscribe to HRP News: <http://www.who.int/reproductivehealth/news/en/>

¹⁷ For further information, see: <http://www.ibpinitiative.org/>

¹⁸ For further information, see: <http://srhhivlinkages.org/>

¹⁹ Available at: <http://srhr.org/>

- lack of health management information systems (e.g. client cards, registers) designed to document and monitor recommended practices;
- lack of laws, policies and regulations to support safe and effective implementation;
- need for refinancing and re-budgeting to address the above-mentioned shortcomings.

Given the potential barriers noted above, a phased approach to adoption, adaptation and implementation of the guideline recommendations may be required. Various strategies will be applied to ensure that the people-centred approach and key principles that underpin this guideline are operationalized, and to address these barriers and facilitate implementation.

7.2.2 Monitoring and evaluating the impact of the guideline

It is critical that monitoring and evaluation systems are practical, not overly complicated, and collect information that is current, useful and can be readily applied. The implementation and impact of these recommendations will be monitored at the health service, regional and country levels, based on existing indicators. However, given the private space in which self-care is practised, alternative ways to assess the impact of the interventions need to be developed. Emphasis on use and uptake by vulnerable populations means that there will need to be meaningful engagement of affected communities.

In collaboration with the WHO Department of Health Metrics and Measurement (which leads the data collection and analysis for the WHO Global Health Observatory), the Department of Reproductive Health and Research will monitor and evaluate country- and regional-level data on health seeking behaviours and implementation of selected self-care interventions. These data will allow for a better understanding of the short-to-medium-term impact of self-care interventions on national policies of individual WHO Member States.

The WHO 13th General Programme of Work (GPW13) Impact Framework will also be used to monitor self-care interventions (1).



7.3 UPDATING THE GUIDELINE

This guideline uses a “living guideline” format, allowing for review of new research evidence to ensure that it can be brought to the GDG for review (see Chapter 1, section 1.4.4). This is the first version of this guideline; future updates will include topics, recommendations and good practice statements relevant to SRHR and noncommunicable diseases (NCDs), as well as other areas of health. A virtual GDG will be convened for formulating recommendations based on evidence tables prepared for the additional priority questions, followed by the preparation and release of the new version.

In accordance with the concept of WHO’s GREAT Network (Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge),²⁰ which employs a systematic and continuous process of identifying and bridging evidence gaps following guideline implementation, this guideline will be updated as new evidence becomes available.

The rapidly evolving nature of self-care interventions calls for a continuous review of the literature. An update to this guideline will likely be required within 18–24 months of dissemination of this edition, to accommodate either new evidence on existing recommendations or to develop new recommendations based on emerging evidence, including on new SRHR self-care interventions that may not have been available or identified during the discussions for the current version. The WHO Guideline Steering Group will continue to follow the research developments in self-care for SRHR, and additional colleagues from relevant departments will be brought in to expand the scope to NCDs and possibly other areas. An example of a new SRHR-related self-care recommendation might be the self-insertion of an intravaginal ring for HIV prevention and contraception. Several multipurpose technologies are in various stages of research and development, but are not yet available on the market. There are many areas for which no evidence was found or that are supported by low-quality evidence, and in these cases new recommendations or a change in the published recommendation, respectively, may be warranted. Any concern about the validity of a recommendation will be communicated promptly following approval from the WHO Guidelines Review Committee (GRC) of rapid guidance, and plans will be made to update the recommendation as needed in the next version(s) of the guideline.

²⁰ Further information available at: <https://greatnetworkglobal.org/>

All technical products developed during the process of developing this guideline – including full reports of systematic reviews, corresponding search strategies and dates of searches – will be archived for future reference and use. Where there are concerns about the validity of a recommendation based on new evidence, the systematic review addressing the primary question will be updated. To update the review, the search strategy used for the initial review will be applied. Any new questions identified following the scoping exercise will undergo a similar process of evidence retrieval, synthesis and application of the GRADE approach in accordance with the standards in the *WHO handbook for guideline development* (2014) (2).

The guideline development process identified a fair number of knowledge gaps, which are highlighted in Chapter 6 (Table 6.1). WHO aims to develop further guidance for SRHR and other health areas that would be likely to promote equity, be feasible to implement, and contribute to improvements in self-care, so that the appropriate recommendations can be included in future versions of this guideline, and can be adopted and implemented by countries and programmes.

REFERENCES FOR CHAPTER 7

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ANNEX 1: EXTERNAL EXPERTS AND WHO STAFF INVOLVED IN THE PREPARATION OF THIS GUIDELINE

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ANNEX 2: EXISTING RECOMMENDATIONS FOR NONCOMMUNICABLE DISEASES (NCDs)

EXISTING RECOMMENDATIONS ON SELF-CARE FOR CARDIOVASCULAR DISEASE, DIABETES AND CHRONIC RESPIRATORY DISEASE	
NCD REC 1	<p>Community interventions can complement primary health care. Structured training for community workers should be undertaken to aid the detection and ongoing management for NCDs.</p> <p><i>(weak recommendation, very low quality of evidence)</i></p>
NCD REC 2	<p>The use of highly structured lay led self-management patient programmes for self-care in NCDs is not recommended at the present time for LMIC.</p> <p><i>(weak recommendation, very low quality of evidence)</i></p>
NCD REC 3	<p>Health-care organizations should provide access to user-friendly, valid and reliable online information targeted at NCDs and their management. Online resources could provide some benefit.</p> <p><i>(weak recommendation, very low quality of evidence)</i></p>
NCD REC 4a	<p>Self-measurement to monitor blood pressure is recommended for the management of hypertension in appropriate patients where the affordability of the technology has been established.</p> <p><i>(strong recommendation, low quality of evidence)</i></p>
NCD REC 4b	<p>Self-monitoring of blood coagulation is recommended for appropriate patients treated with oral anticoagulation agents, where the affordability of the technology has been established.</p> <p><i>(weak recommendation, moderate quality of evidence)</i></p>
NCD REC 4c	<p>The use of self-monitoring of blood glucose in the management of patients with type 2 diabetes not on insulin is not recommended at the present time because there is insufficient evidence to support such a recommendation.</p> <p><i>(weak recommendation, moderate quality of evidence)</i></p>
NCD REC 4d	<p>People with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need.</p> <p><i>(weak recommendation, low quality of evidence)</i></p>
NCD REC 5a	<p>The use of telemonitoring for self-care in NCDs is not recommended at the present time, because there is insufficient evidence to support such a recommendation.</p> <p><i>(weak recommendation, low quality of evidence)</i></p>
NCD REC 5b	<p>The use of telehealth for self-care in NCDs is not recommended at the present time, because there is insufficient evidence to support such a recommendation.</p> <p><i>(weak recommendation, low quality of evidence)</i></p>
NCD REC 6a	<p>Self-monitoring of blood coagulation and self-augmentation of dosage in patients receiving oral anti-coagulation agents is recommended if affordable and according to an agreed action plan with a health professional.</p> <p><i>(weak recommendation, moderate quality of evidence)</i></p>

ANNEX 2 (continued)

EXISTING RECOMMENDATIONS ON SELF-CARE FOR CARDIOVASCULAR DISEASE, DIABETES AND CHRONIC RESPIRATORY DISEASE (continued)	
NCD REC 6b	Self-monitoring in asthma and COPD and self-adjustment of dosage is recommended according to an agreed action plan with a health professional. <i>(weak recommendation, very low quality of evidence)</i>
NCD REC 6c	Self-adjustment of diuretics based on body weight monitoring in heart failure is not recommended at the present time. <i>(weak recommendation, very low quality of evidence)</i>
NCD REC 6d	Self-monitoring and self-adjustment of insulin dosage is recommended in type 1 diabetes according to an agreed action plan with a health professional. <i>(weak recommendation, very low quality of evidence)</i>
NCD REC 7	Group education programmes, rather than individual education may offer a cost-effective strategy to deliver education in LMIC. <i>(weak recommendation, very low quality of evidence)</i>
NCD REC 8a	Appropriate patients could benefit from being educated on the benefits of cardiac rehabilitation, and can be encouraged to undertake rehabilitation exercise in the home setting. <i>(weak recommendation, very low quality of evidence)</i>
NCD REC 8b	Appropriate patients could benefit from being educated on the benefits of COPD rehabilitation, and encouraged to undertake rehabilitation exercise. <i>(weak recommendation, very low quality of evidence)</i>
NCD REC 8c	No single strategy to improve overall adherence is recommended over another. <i>(weak recommendation, very low quality of evidence)</i>
Remarks <ul style="list-style-type: none"> • These existing recommendations for self-care interventions for NCDs have been integrated into this guideline from Chapter 3 of <i>Package of essential noncommunicable (PEN) disease interventions for primary health care in low-resource settings</i> (WHO, 2013), available at: https://www.who.int/cardiovascular_diseases/publications/implementation_tools_WHO_PEN/en/ 	

COPD: chronic obstructive pulmonary disease; LMIC: low- and middle-income country

ANNEX 3: SCOPING REVIEW: WHO SELF-CARE DEFINITIONS

METHODS

The WHO Department of Reproductive Health and Research conducted a scoping review of definitions on self-care available in WHO tools and guidance. An initial database search in the WHO Institutional Repository for Information Sharing²¹ for “self-care” retrieved 1700 documents. After narrowing down to specific mentions of self-care, 922 WHO documents remained. These were entered into Excel and categorized by year and by topic. After removing documents which did not provide either a clear definition or explanatory narrative for self-care, 106 remained. These were read separately by three reviewers, including members of the systematic review teams for this guideline, who used qualitative coding to individually identify major themes across definitions and select their “top five” definitions, after which they discussed their findings to reach consensus on a working definition for this *Consolidated guideline on self-care interventions for sexual and reproductive health and rights*.

FINDINGS

Working definition

Our working definition for this guideline comes from a 2009 WHO regional working group in South-East Asia, whose definition for self-care in the context of primary health care has subsequently been cited many times in other WHO documents:



“Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health-care provider” (1).

Self-care is broad concept which also encompasses hygiene (general and personal), nutrition (type and quality of food eaten), lifestyle (sporting activities, leisure, etc.); environmental factors (living conditions, social habits, etc.), socioeconomic factors (income level, cultural beliefs, etc.) and self-medication (2).

Other common definitions for self-care in WHO documents included: non-professional care, “unorganized health activities and health-related decision-making by individuals, families, neighbors, friends, colleagues at work” (3); “utilization of all non-health professional resources, i.e. the individual himself or herself, members of the family, neighbours and other lay persons, for any health-related activity be it promotive, preventative, curative or rehabilitative” (4); and “Self -care ... is the primary health resource in the health care system. Included are informal health activities and health-related decision-making by individuals, families, neighbours, comprising self-medication, self-treatment, social support during illness, first aid, etc. Another term, ‘lay care’, describes all health care given by lay people to one another in both natural and organized settings” (5).

Key aspects of self-care definitions

Relationship with health system: One primary characteristic of self-care definitions across WHO documents was the relationship between self-care and the health system. Some defined self-care as independent of, or in opposition to, the health system. Others defined self-care as collaborative with, or part of, the health system. For example, some definitions considered self-care part of primary health care, or the first level, a building block or a domain of the health system, or as part of a continuum of health care. Some definitions described self-care as supported by the health system (or vice versa). Many definitions emphasized that self-care was not a substitute for, but rather a complement of, the health system, pointing out the co-production of care. Self-care was also described as essential to and simultaneous with the health system – a co-occurring phenomenon.

Who and where: Most definitions of self-care mentioned specific agents for self-care, usually referring to non-health-care professionals. Some definitions focused on the individual (“self”), but others included family members and larger organizational or community structures. Self-care was typically located at home, i.e. care that can be practised at home or a household process. Some definitions placed self-care in a “natural setting”, i.e. the normal context of people’s everyday lives. Self-care definitions also described the role of the health system in various ways. In some cases, the health system was to provide education (e.g. information, technology, techniques) so that people could carry out self-care.

²¹ <https://apps.who.int/iris/>

ANNEX 3 (continued)

Others emphasized the need for linkage to or support from the health system, especially when describing self-care as part of a continuum.

Scope: Definitions of self-care could be generally categorized through two dichotomies. First, self-care could be defined in terms of habits or activities of daily living or lifestyle, or in terms of management of illness, medication(s) or disease episodes. Some definitions related self-care to coping, social support or emotional aspects of health management. Second, self-care could be defined in terms of the ability to do something (i.e. empowerment, decision-making) or in terms of the actual activities themselves (i.e. actions). In all cases, self-care carried an element of active engagement. Self-care meant that individuals were actively monitoring and responding to a changing environment. One WHO document defined self-care as an “active, responsive, and flexible process of self-management” (6). Individuals engaged in self-care were willing, capable, informed and ready to do something for their own health.

Core principles: Fundamental principles for self-care include aspects of the individual (e.g. self-reliance, empowerment, autonomy, personal responsibility, self-efficacy) as well as the greater community (e.g. community participation, community involvement, community empowerment).

CONCLUSION

The working definition of self-care for this consolidated living guideline is:



The ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health-care provider.

The scope of self-care as described in this definition includes health promotion; disease prevention and control; self-medication; providing care to dependent persons; seeking hospital/specialist care if necessary; and rehabilitation including palliative care (7). Inherent in the concept is the recognition that whatever factors and processes may determine behaviour, and whether or not self-care is effective and interfaces appropriately with professional care, it is the individual person who acts (or does not act) to preserve health or respond to symptoms.

ANNEX 3 (continued)

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ANNEX 4: GLOSSARY

Adolescent	For the purposes of this guideline, adolescents are defined as individuals between the ages of 10 and 19 years old. Adolescents are not a homogeneous group; physical and emotional maturation comes with age, but its progress varies among individuals of the same age. Also, different social and cultural factors can affect their health, their ability to make important personal decisions and their ability to access services (1).
Adult	A person aged 18 or older (2).
Acceptability	All provision of health-care facilities, commodities and services must be acceptable to those who are their intended beneficiaries. They must be provided in a manner respectful of medical ethics and of the culture of individuals, minorities, peoples and communities; sensitive to gender and to life-cycle requirements; must be designed to respect confidentiality and improve the health status of those concerned. Countries should place a gender perspective at the centre of all policies, programmes and services affecting women's health, and should involve women in the planning, implementation and monitoring of such policies, programmes and services (3).
Accessibility	Under international human rights law, countries are required to ensure that health-care facilities, commodities and services are accessible to everyone. This includes physical and economic accessibility, as well as access to information. Human rights bodies have called on countries to eliminate the barriers people face in accessing health services, such as high fees for services, the requirement for authorization by spouse, parent/guardian or hospital authorities, distance from health-care facilities, and the absence of convenient and affordable public transport (3).
Accountability	Countries are accountable for bringing their legal, policy and programmatic frameworks and practices in line with international human rights standards. Further, effective accountability mechanisms are key to ensuring that the agency and choices of individuals are respected, protected and fulfilled, including when seeking and receiving health care. Effective accountability requires that individuals, families and groups, including women from marginalized populations, are made aware of their rights, including with regard to sexual and reproductive health, and are empowered to claim their rights (3).
Availability	Functioning health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the state. The characteristics of the facilities, goods and services will vary depending on numerous factors, including the state's developmental level. Countries must, however, address the underlying determinants of health, such as provision of safe and potable drinking water, adequate sanitation facilities, health-related education, hospitals, clinics and other health-related buildings, and ensure that trained medical and professional personnel are receiving domestically competitive salaries. As part of this core obligation, countries should ensure that the commodities listed in national formularies are based on the <i>WHO model list of essential medicines</i> , which guides the procurement and supply of medicines in the public sector (3).
Autonomy	Autonomy relates to the rights of individuals to self-determination in sexual health; rights that need to be recognized by the state and enabled by everyone – from partners and families to global institutions (4).
Children	According to Article 1 of the Convention on the Rights of the Child, "A child means every human being below the age of eighteen years unless, under the law applicable to the child, majority is attained earlier" (2).

ANNEX 4 (continued)

Comprehensive sexuality education (CSE)	CSE is a curriculum-based process of teaching and learning about the cognitive, emotional, physical and social aspects of sexuality. It aims to equip children and young people with knowledge, skills, attitudes and values that will empower them to: realize their health, well-being and dignity; develop respectful social and sexual relationships; consider how their choices affect their own well-being and that of others; and understand and ensure the protection of their rights throughout their lives (5).
Confirm	To issue a report on the status of a test for an STI (e.g. HIV, HPV), pregnancy or other health condition. Initially reactive test results, including reactive self-test results, need to be confirmed by a health-care provider and/or according to the national validated testing algorithms (6).
Digital health	The use of digital technologies for health. An overarching term that comprises both eHealth and mHealth, and emerging areas, such as the use of computing sciences in the fields of artificial intelligence, big data and genomics (7).
Digital health intervention	A discrete function of a digital technology to achieve health sector objectives. The classification of digital health interventions follows the different ways in which digital and mobile technologies are being used to support health system needs (7).
eHealth	The use of information and communications technology (ICT) in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research. mHealth is a component of eHealth (7).
Enabling environment	Attitudes, actions, policies and practices that stimulate and support the effective and efficient functioning of organizations, individuals and programmes or projects. The enabling environment includes legal, regulatory and policy frameworks, and political, sociocultural, institutional and economic factors (8).
Evidence to Decision (EtD) table	A framework to assist people making and using evidence-informed recommendations and decisions. Their main purpose is to help decision-makers use evidence in a systematic and transparent way. When used in a WHO guidelines context, EtD frameworks inform guideline development group (GDG) members about the comparative pros and cons of the interventions being considered, ensure that GDG members consider all the important criteria for making a decision, provide GDG members with a concise summary of the best available evidence about each criterion to inform their judgments, and help GDGs to structure and document their discussions, and to identify any reasons for disagreement, making the process and the basis for their decisions transparent (9).
Family planning	Family planning allows people to attain their desired number of children and determine the spacing of pregnancies. It is achieved through use of contraceptive methods and the treatment of infertility (10).
Fertility	The capacity to establish a clinical pregnancy (11).
Fertility awareness	The understanding of reproduction, fecundity, fecundability, and related individual risk factors (e.g. advanced age, sexual health factors such as sexually transmitted infections, and life-style factors such as smoking, obesity) and non-individual risk factors (e.g. environmental and work place factors); including the awareness of societal and cultural factors affecting options to meet reproductive family planning, as well as family building needs (11).
Fertility care	Interventions that include fertility awareness, support and fertility management with an intention to assist individuals and couples to realize their desires associated with reproduction and/or to build a family (11).

ANNEX 4 (continued)

Gender equality	Refers to equal chances or opportunities for groups of women and men to access and control social, economic and political resources, including protection under the law (such as health services, education and voting rights). Women and men have equal conditions to realize their full rights and potential to be healthy, contribute to health development and benefit from the results. Achieving gender equality requires specific measures designed to support groups of people with limited access to such goods and resources (12).
Harm or social harm	Any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt from one person to another, a person to themselves, or an institution to a person (6).
Health intervention	A health intervention is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions. Health interventions can be carried out by a broad range of providers, including lay people, ²² across the full scope of health systems; and includes interventions on: diagnostic, medical, surgical, mental health, primary care, allied health, functioning support, rehabilitation, traditional medicine and public health (13).
HIV self-testing (HIVST)	A process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts (6).
HIV status	Is the final report that is given to the patient; it is the final interpretation of the patient disease state and is based on a collection of testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or HIV-inconclusive (6).
HPV self-sampling (HPVSS)	A process where a woman who wants to know whether she has HPV infection uses a kit to collect a (cervico-)vaginal sample which is then sent for analysis by a laboratory. Collection methods include lavage, brush, swab and vaginal patch. While HPVSS cannot provide a diagnosis of cervical (pre-)cancer, it identifies those women at higher risk (14).
Human rights	Human rights are legal guarantees, equally applicable to everyone everywhere in the world, enshrined in international human rights documents. Human rights protect against actions that interfere with fundamental freedoms and human dignity, and support the agency of individuals and populations. The promotion of human rights requires governments and others to take active steps to put in place institutions and procedures that enable people to enjoy their guaranteed rights (15, 16, 17).
Infertility	A disease characterized by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with his/her partner. Fertility interventions may be initiated in less than 1 year based on medical, sexual and reproductive history, age, physical findings and diagnostic testing. Infertility is a disease that generates disability as an impairment of function (11).
Informed decision-making	Respect for individual dignity and for the physical and mental integrity of every person using a health-care facility means also providing each person the opportunity to make reproductive choices autonomously. The principle of autonomy, expressed through free, prior, full and informed decision-making, is a central theme in medical ethics, and is embodied in human rights law. In order to make informed decisions about their sexual and reproductive health, comprehensive information, counselling and support should be made accessible for all people without discrimination, including young people, people living with disabilities, indigenous peoples, ethnic minorities, people living with HIV, and transgender and intersex people. People should be able to exercise their choice from across a range of options but also be free to refuse any and all options (3).

²² This item was added – it did not appear as part of the definition provided in the cited source; this is an adapted definition.

ANNEX 4 (continued)

Intimate partner violence	Behaviour within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship, including acts of physical violence, sexual violence, emotional or psychological abuse and controlling behaviours (6).
Key populations	Groups who, due to specific higher-risk behaviours, are at increased risk of HIV irrespective of the epidemic type or local context. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people (6).
Lay health worker	Any person who performs functions related to health-care delivery and has been trained to deliver these services but has no formal professional or para-professional certification, nor a tertiary education degree (6).
Medically assisted reproduction (MAR)	Reproduction brought about through various interventions, procedures, surgeries and technologies to treat different forms of fertility impairment and infertility. These include ovulation induction, ovarian stimulation, ovulation triggering, all assisted reproductive technologies (ART) procedures, uterine transplantation, and intra-uterine, intracervical and intravaginal insemination with semen of husband/partner or donor (11).
mHealth	The use of mobile and wireless technologies to support health-sector objectives (7).
Non-discrimination	The human rights principle of non-discrimination obliges states to guarantee that human rights are exercised without discrimination of any kind based on race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, or other status such as disability, marital and family status, health status, place of residence, economic status, social situation, sexual orientation and gender identity. This obligation in connection with the right to health means countries are to ensure the availability, accessibility, acceptability and quality of services without discrimination (3).
Participation	Meaningful participation requires that individuals are entitled to participate in the decisions that directly affect them, including in the design, implementation and monitoring of health interventions. Under international human rights law, countries have an obligation to ensure active, informed participation of individuals in decision-making that affects them, including on matters related to their health. The International Conference on Population and Development (ICPD) Programme of Action reaffirms this core principle in relation to sexual and reproductive health, stating that “the full and equal participation of women in civil, cultural, economic, political and social life, at the national, regional and international levels, and the eradication of all forms of discrimination on grounds of sex, are priority objectives of the international community”. The Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) specifically requires countries to ensure that women have the right to participate fully and be represented in the formulation of public policy in all sectors and at all levels (3).
Patient engagement	To promote and support active patient and public involvement in health and health care and to strengthen their influence on health-care decisions, at both the individual and collective levels. Having real patients articulate their experiences and viewpoints helps those taking part in training to appreciate the patient perspective and the importance of preserving trust between clinicians and patients. These core values are essential to care that is compassionate, quality assured and, above all, safe. Exposure to patient stories during training is valuable and helps to motivate practitioners to improve safety. At an organizational level, patients and families can be engaged in the design or development of patient-centred processes and systems, for example as members of advisory committees (18).

ANNEX 4 (continued)

Patient experience	Patient experience encompasses the range of interactions that patients have with the health-care system, including their care from health plans, and from doctors, nurses and staff in hospitals, physician practices and other health-care facilities. As an integral component of health-care quality, patient experience includes several aspects of health-care delivery that patients value highly when they seek and receive care, such as getting timely appointments, easy access to information, and good communication with health-care providers (19).
Patient safety	Patient safety is the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment (20).
People-centredness	Providing care that is respectful of, and responsive to, individual preferences, needs and values, and ensuring that patient values guide all clinical decisions (21).
Point-of-care test (POCT)	Key elements of point-of-care tests are that they allow: (i) testing to be carried out at or near the person being tested, (ii) results to be returned to the person being tested during the same visit, and (iii) results of POCT to be used immediately for patient care and referral (22).
Pregnancy	A state of reproduction beginning with implantation of an embryo in a woman and ending with the complete expulsion and/or extraction of all products of implantation (11).
Privacy and confidentiality	The right to privacy means that an individual accessing health information and services should not be subject to interference with their privacy, and they should enjoy legal protection in this respect. Sexual and reproductive health involves many sensitive issues that are not widely discussed within families or communities, and health workers are often entrusted with very personal information by their patients. Confidentiality, which implies the duty of providers to not disclose or to keep private the medical information they receive from patients and to protect an individual's privacy, has an important role to play in sexual and reproductive health (3).
Psychosocial support	The term "psychosocial" refers to the close relationship between the individual and the collective aspects of any social entity. Psychosocial support can be adapted in particular situations to respond to the psychological and physical needs of the people concerned, by helping them to accept the situation and cope with it (23).
Quality	Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge; as well as the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. Fulfilment of human rights requires that health-care facilities, commodities and services be of good quality, including scientifically and medically appropriate. This requires, among other things, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation (3).
Quality assurance	Part of quality management focused on providing confidence among stakeholders that quality requirements will be fulfilled (6).
Self-administration	The process of a person administering a pharmacological substance or biomedical intervention to themselves.

ANNEX 4 (continued)

Self-care	<p>WHO's current working definition of self-care is "the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health-care provider" (24; see Annex 3). The scope of self-care as described in this definition includes health promotion; disease prevention and control; self-medication; providing care to dependent persons; seeking hospital/specialist care if necessary; and rehabilitation, including palliative care (25). Self-care is broad concept which also encompasses hygiene (general and personal); nutrition (type and quality of food eaten); lifestyle (sporting activities, leisure, etc.); environmental factors (living conditions, social habits, etc.); socioeconomic factors (income level, cultural beliefs, etc.); and self-medication (see below) (26).</p>
Self-medication	<p>Self-medication is the selection and use of medicines (including herbal and traditional products) by individuals to treat self-recognized illnesses or symptoms. Self-medication is one element of self-care (27).</p>
Serodiscordant couple	<p>A couple in which one partner is HIV-positive and one partner is HIV-negative (6).</p>
Social accountability	<p>Social accountability is "citizens' efforts at ongoing meaningful collective engagement with public institutions for accountability in the provision of public goods". This moves beyond community participatory approaches that impart information and generate demand, to those that empower and educate users to demand state obligated services, and that support health-service actors to recognize and act on these demands (28).</p>
Stigma	<p>Originally derived from a Greek word meaning a mark or stain, stigma refers to beliefs, attitudes, practices and social processes that label difference, enable discrimination, reduce opportunities and reproduce social inequalities. Stigma manifests in community norms (felt-normative stigma), mistreatment and acts of discrimination (enacted stigma), and can be internalized (self or internalized stigma) (29).</p>
Task sharing	<p>The rational redistribution of tasks and the increased scope of work among different cadres of health-care providers, including trained lay providers (6).</p>
Task shifting	<p>Task shifting involves the rational redistribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications to make more efficient use of the available human resources for health (30).</p>
Transgender	<p>An umbrella term for people whose gender identity and expression does not conform to the norms and expectations traditionally associated with the sex assigned to them at birth; it includes people who are transsexual, transgender or otherwise gender non-conforming. Transgender people may self-identify as transgender, female, male, transwoman or transman, trans-sexual or, in specific cultures, as <i>hijra</i> (India), <i>kathoey</i> (Thailand), <i>waria</i> (Indonesia) or one of many other transgender identities. They may express their genders in a variety of masculine, feminine and/or androgynous ways. Sexual risk practices differ among different subgroups within the transgender community. For example, sexual risk may be higher among transgender women (male to female) or transgender men (female to male) who have receptive anal intercourse with men than among transgender men or transgender women who have sex only with women (31). Transgender people are often highly vulnerable to stigma, discrimination and violence, and have specific health needs that necessitate a distinct public health response.</p>

ANNEX 4 (continued)

Vulnerable populations	Groups of people who are particularly vulnerable to health conditions in certain situations or contexts, due to socioeconomic factors, disabilities, legal status and unequal power dynamics. WHO defines vulnerability as the degree to which a population, individual or organization is unable to anticipate, cope with, resist and recover from the impacts of disasters. Vulnerable populations can include children, pregnant individuals, elderly people, malnourished people and those who are ill or immunocompromised (32).
Waste management	The collection, transportation, disposal or recycling and monitoring of waste.
Young people	Those between the ages of 10 and 24 (33).
Youth	Individuals between the ages of 15 and 24 (29).

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ANNEX 5: SUMMARY OF DECLARATIONS OF INTEREST (DOI) FROM THE GUIDELINE DEVELOPMENT GROUP (GDG) MEMBERS AND HOW THEY WERE MANAGED

NAME	EXPERTISE	DISCLOSURE OF INTEREST	CONFLICT OF INTEREST AND MANAGEMENT
Dr Kaosar Afsana	Research, sexual and reproductive health and rights (SRHR)	None declared	Not applicable
Dr Pascale Allotey	Health systems, SRHR, gender	None declared	Not applicable
Dr Elham Atalla	Sexual health, policy	None declared	Not applicable
Prof. Elizabeth Bukusi	Research, ethics, SRHR	None declared	Not applicable
Dr Laura Ferguson	Human rights, law	None declared	Not applicable
Dr Patricia J. Garcia	Human papillomavirus (HPV), sexually transmitted infections (STIs), women's health, policy	None declared	Not applicable
Dr Anita Hardon	SRHR, social science and implementation research	None declared	Not applicable
Mr Jonathan Hopkins	Integrated SRHR and HIV health services, homeless populations	None declared	Not applicable
Mr Denis Kibira	Social accountability, vulnerable populations, pharmaceutical policy	None declared	Not applicable
Dr Carmen Logie	Key populations, social science, HIV, STIs	None declared	Not applicable
Dr Patricia Mechael	Digital health technologies, policy	None declared	Not applicable
Dr Kevin Moody	Pharmacy, education, key populations, patient groups, HIV	None declared	Not applicable
Ms Daniella K. Munene	Pharmacy, programme manager	None declared	Not applicable
Prof. Ashraf Nabhan	Research, obstetrics/gynaecology, women's health	None declared	Not applicable
Ms Zelda Nompumelelo Nhlabatsi	Policy, family planning, maternal health	None declared	Not applicable
Prof. Gina Ogilvie	STIs, HIV, HPV, research	None declared	Not applicable
Dr Ash Pachauri	Climate change, environmental and planetary health, abortion, women's health, vulnerable populations, youth	None declared	Not applicable
Dr Michelle Remme	Health financing, SRHR, gender-based violence	None declared	Not applicable
Dr Iqbal H. Shah	Abortion, SRHR, social science research	None declared	Not applicable

ANNEX 5 (continued)

NAME	EXPERTISE	DISCLOSURE OF INTEREST	CONFLICT OF INTEREST AND MANAGEMENT
Dr Jaya Lakshmi Shreedhar	Advocacy, communications, journalism, tuberculosis and communicable diseases, noncommunicable diseases (NCDs)	None declared	Not applicable
Dr Viroj Tangcharoensathien	Health policy, key populations, health systems	None declared	Not applicable
Dr Tarek Turk	Youth, medicine, STIs, humanitarian setting	None declared	Not applicable
Dr Sheryl van der Poel	Infertility, research, normative guidance	Contributed to systematic review	Recused from discussion of recommendations around this topic
Dr Batoool Wahdani	Youth, medicine, family planning	None declared	Not applicable
Dr Allen Zhiwei Wu	STIs, HPV, education, research, policy	None declared	Not applicable

ANNEX 6: PRIORITY QUESTIONS AND OUTCOMES FOR THE INTERVENTIONS IDENTIFIED FOR THIS GUIDELINE

PICO: P = population; I = intervention; C = comparator; O = outcomes

PICO QUESTIONS (P–I–C)	PRIORITY OUTCOMES (O)
<p>PICO question 1: For individuals of reproductive age using injectable contraception, should self-administration be made available as an additional approach to deliver injectable contraception?</p> <p>P: Individuals of reproductive age using injectable contraception</p> <p>I: Provision of injectable contraception including self-administration options</p> <p>C: Provision of injectable contraception that does not include self-administration as an option (i.e. provider-administrated only)</p>	<ol style="list-style-type: none"> 1. Unintended pregnancy 2. Side-effects or adverse events (e.g. bleeding, skin site reactions, mental health problems) 3. Uptake of injectable contraception (initial use) 4. Continuation rate of injectable contraception (or, conversely, discontinuation) 5. Self-efficacy, knowledge and empowerment 6. Social harms (e.g. coercion, violence [including intimate partner violence, violence from family members or community members], psychosocial harm, self-harm), and whether these harms were corrected or had redress available
<p>PICO question 2: For individuals using oral contraceptive pills (OCPs), should OCPs be made available over the counter (OTC), i.e. without a prescription?</p> <p>P: Individuals using OCPs</p> <p>I: OTC availability of OCPs, or dispensing of OCPs by trained pharmacy personnel (pharmacy access)²³</p> <p>C: Availability of OCPs by prescription only</p>	<ol style="list-style-type: none"> 1. Uptake of OCPs (initial use) 2. Continuation of OCPs (or, conversely, discontinuation) 3. Adherence to OCPs (correct use) 4. Comprehension of instructions (product label) 5. Unintended pregnancy, side-effects, adverse events, or use of OCPs despite contraindications 6. Social harms (e.g. coercion, violence [including intimate partner violence, violence from family members or community members], psychosocial harm, self-harm), and whether these harms were corrected or had redress available 7. Client satisfaction
<p>PICO question 3: For individuals attempting to become pregnant, should home-based ovulation predictor kits (OPKs) be made available as an additional approach for fertility management?</p> <p>P: Individuals attempting to become pregnant</p> <p>I: Fertility management that includes home-based OPKs</p> <p>C: Fertility management that does not include home-based OPKs (i.e. clinician-led assessment of ovulation only, or no ovulation prediction)</p>	<p>Primary outcomes</p> <ol style="list-style-type: none"> 1. Time to pregnancy 2. Pregnancy <p>Secondary outcomes</p> <ol style="list-style-type: none"> 3. Live birth 4. Stress/anxiety 5. Social harms or adverse events (e.g. device-related issues, coercion, violence [including intimate partner violence, violence from family members or community members], psychosocial harm, self-harm, suicide, stigma, discrimination), and whether these harms were corrected or had redress available

²³ OTC availability of OCPs, i.e. without a prescription, includes (a) “off-the-shelf” direct access and (b) “behind-the-counter” pharmacy access requiring eligibility screening by trained pharmacy staff before dispensation.

ANNEX 6 (continued)

PICO: P = population; I = intervention; C = comparator; O = outcomes

PICO QUESTIONS (P–I–C)	PRIORITY OUTCOMES (O)
<p>PICO question 4: For individuals aged 30–60 years, should human papillomavirus self-sampling (HPVSS) be offered as an additional approach to sampling in cervical cancer screening services?</p> <p>P: Individuals aged 30–60 years</p> <p>I: Cervical screening services that include HPVSS</p> <p>C: Cervical screening services that do not include HPVSS (e.g. cervical screening by cytology, visual inspection with acetic acid [VIA] testing services, clinician-collected primary HPV testing)</p>	<p>Primary outcomes</p> <ol style="list-style-type: none"> 1. Uptake of cervical cancer screening services 2. Frequency of cervical cancer screening 3. Social harms or adverse events (e.g. device-related issues, coercion, violence [including intimate partner violence, violence from family members or community members], psychosocial harm, self-harm, suicide, stigma, discrimination, frequency of STI and HIV testing), and whether these harms were corrected or had redress available <p>Secondary outcome</p> <ol style="list-style-type: none"> 4. Linkage to clinical assessment or treatment of cervical lesions following a positive result
<p>PICO question 5: For individuals using sexually transmitted infection (STI) testing services, should self-collection of samples (SCS) be offered as an additional approach to deliver STI testing services?</p> <p>P: Individuals using STI testing services</p> <p>I: STI testing services that include SCS</p> <p>C: STI testing services that do not include SCS, or no STI testing services (i.e. no intervention)</p>	<p>Primary outcomes</p> <ol style="list-style-type: none"> 1. Uptake of STI testing services 2. Frequency of STI testing 3. Social harms or adverse events (e.g. device-related issues, coercion, violence [including intimate partner violence, violence from family members or community members], psychosocial harm, self-harm, suicide, stigma, discrimination, frequency of HIV testing), and whether these harms were corrected or had redress available <p>Secondary outcomes</p> <ol style="list-style-type: none"> 4. Case-finding (proportion of people who tested positive for an STI) 5. Linkage to clinical assessment or STI treatment following a positive test result 6. Sexual risk behaviour

ANNEX 7: LIST OF REVIEWS PUBLISHED IN A SPECIAL SUPPLEMENT OF THE BMJ: SELF CARE INTERVENTIONS FOR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS²⁴

TITLE OF MANUSCRIPT	AUTHORS
<i>Systematic reviews on effectiveness relating to the five new recommendations</i>	
REC 10: Self-administration of injectable contraception: a systematic review and meta-analysis (published 2 April 2019)	Kennedy CE, Yeh PT, Gaffield ME, Brady M, Narasimhan M
REC 11: Should oral contraceptive pills be available without a prescription? A systematic review of over-the-counter and pharmacy access availability (in press)	Kennedy CE, Yeh PT, Gonsalves L, Jafri H, Gaffield ME, Kiarie J, Narasimhan M
REC 12: Should home-based ovulation predictor kits be offered as an additional approach for fertility management for women and couples desiring pregnancy? A systematic review and meta-analysis (published 25 April 2019)	Yeh PT, Kennedy CE, van der Poel S, Matsaseng T, Bernard LJ, Narasimhan M
REC 21: Self-sampling for human papillomavirus (HPV) testing: a systematic review and meta-analysis (published 14 May 2019)	Yeh PT, Kennedy CE, De Vuyst H, Narasimhan M
REC 22: Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis (published 22 April 2019)	Ogale YP, Yeh PT, Kennedy CE, Toskin T, Narasimhan M
<i>Additional reviews (published 1 April 2019 unless otherwise noted)</i>	
Self care interventions to advance health and well-being: a conceptual framework to inform normative guidance	Narasimhan M, Allotey P, Hardon A
Self care interventions for sexual and reproductive health and rights: costs, benefits, and financing	Remme M, Narasimhan M, Wilson D, Ali M, Vijayasingham L, Ghani F, Allotey P
Sexual and reproductive self care among women and girls: insights from ethnographic studies	Hardon A, Pell C, Taqeban E, Narasimhan M
Self care interventions could advance sexual and reproductive health in humanitarian settings	Logie C, Khoshnood K, Okumu M, Rashid SF, Senova F, Meghari H, Kipenda CU
Safe and sustainable waste management of self care products	Pachauri A, Shah P, Almroth BC, Sevilla NPM, Narasimhan M
Human rights and legal dimensions of self care interventions for sexual and reproductive health (published 13 May 2019)	Ferguson L, Fried S, Matsaseng T, Ravindran S, Gruskin S

²⁴ Available at: www.bmj.com/selfcare-srhr.

ANNEX 8: GUIDELINE DEVELOPMENT GROUP (GDG) JUDGEMENTS RELATED TO THE NEW RECOMMENDATIONS

RECOMMENDATION	REC 10	REC 11	REC 12
Intervention	Self-administration of injectable contraception	Self-management with OTC oral contraceptives	Self-screening with OPKs for fertility regulation
Certainty of the evidence	<input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very low	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low <input checked="" type="checkbox"/> Very low	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low <input checked="" type="checkbox"/> Very low
Values and preferences	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Resource use	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input type="checkbox"/> Favours this option <input checked="" type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Equity	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Acceptability	<input type="checkbox"/> Favours this option <input checked="" type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Feasibility	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Balance of benefits versus disadvantages	<input checked="" type="checkbox"/> Benefits outweigh disadvantages <input type="checkbox"/> Benefits and disadvantages are balanced <input type="checkbox"/> Disadvantages outweigh benefits	<input checked="" type="checkbox"/> Benefits outweigh disadvantages <input type="checkbox"/> Benefits and disadvantages are balanced <input type="checkbox"/> Disadvantages outweigh benefits	<input checked="" type="checkbox"/> Benefits outweigh disadvantages <input type="checkbox"/> Benefits and disadvantages are balanced <input type="checkbox"/> Disadvantages outweigh benefits
GDG decision	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Conditional <input type="checkbox"/> Not recommended	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Conditional <input type="checkbox"/> Not recommended	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Conditional <input type="checkbox"/> Not recommended

ANNEX 8 (continued)

RECOMMENDATION	REC 21	REC 22A	REC 22B
Intervention	Self-sampling for HPV testing	Self-collection of samples for STI testing (chlamydia and gonorrhoea)	Self-collection of samples for STI testing (syphilis and trichomoniasis)
Certainty of the evidence	<input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very low	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Low <input type="checkbox"/> Very low	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low <input checked="" type="checkbox"/> Very low
Values and preferences	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Resource use	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Equity	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Acceptability	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Feasibility	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options	<input checked="" type="checkbox"/> Favours this option <input type="checkbox"/> Neither favours this option or other options <input type="checkbox"/> Favours other options
Balance of benefits versus disadvantages	<input checked="" type="checkbox"/> Benefits outweigh disadvantages <input type="checkbox"/> Benefits and disadvantages are balanced <input type="checkbox"/> Disadvantages outweigh benefits	<input checked="" type="checkbox"/> Benefits outweigh disadvantages <input type="checkbox"/> Benefits and disadvantages are balanced <input type="checkbox"/> Disadvantages outweigh benefits	<input checked="" type="checkbox"/> Benefits outweigh disadvantages <input type="checkbox"/> Benefits and disadvantages are balanced <input type="checkbox"/> Disadvantages outweigh benefits
GDG decision	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Conditional <input type="checkbox"/> Not recommended	<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Conditional <input type="checkbox"/> Not recommended	<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Conditional <input type="checkbox"/> Not recommended

For more information, please contact:

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