

WHO guideline on self-care interventions for health and well-being, 2022 revision



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Web Annex A. Global values and preferences survey report

<https://apps.who.int/iris/handle/10665/356986>

Web Annex B. GRADE tables

<https://apps.who.int/iris/handle/10665/356988>

The interactive web-based version of the full living guideline is available at <https://app.magicapp.org/#/guideline/Lr21gL>.

The English version of the complete WHO Guideline on self-care interventions for health and well-being can be downloaded here: <https://apps.who.int/iris/rest/bitstreams/1356501/retrieve>

SMART Guidelines on self-care interventions for antenatal care, family planning, HIV and other topics available under: <https://www.who.int/teams/digital-health-and-innovation/smart-guidelines>

The link to the main health topic page for WHO is as follows: https://www.who.int/health-topics/self-care#tab=tab_1

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FOREWORD

I am driven by the conviction that everyone has a right to health. But today, at least half the world's population has no access to essential health services. The provider-to-client model that is at the heart of health systems must be complemented with a self-care model through which people are enabled to make active, informed health decisions to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health worker. Many health issues can already be diagnosed and managed through self-care interventions, and the list continues to grow.

People have been practising self-care for millennia, and new diagnostics, medicines, and interventions, including digital technologies, are changing how health services can be delivered. Self-care and self-care interventions have also played a critical role in individual, community and national responses to the COVID-19 pandemic. In the context of overstretched health systems and shortages of qualified health workers, self-care interventions, prioritized by the World Health Organization (WHO), have contributed to improving health and well-being.

Self-care must work as an extension of the health system, so that while people are using self-care interventions, they can also access the health system and community support for further assistance when needed. It is also important that self-care occurs in a safe and supportive environment, to avoid the stigma, violence and negative health outcomes that can often occur when seeking care in isolation.

This guideline on self-care interventions is based on the core principles of universal health coverage, including a people-centred approach to health that views people as active decision-makers in their own health, not merely passive recipients of health services.

People-centred approaches to healthcare also support health literacy, including digital literacy, so that people can take charge of their own health with evidence-based self-care interventions. This guideline can play an important role in helping people both to access safe and effective self-care interventions and to avoid ones that may be dangerous or otherwise unhelpful.

The partnerships and experts who have contributed to the development of this guideline will also be important for its dissemination and implementation, particularly among underserved and marginalized populations who may have trouble accessing formal health systems.

I hope you will join me to promote this important guideline and support the efforts of WHO to implement self-care interventions for health.



A handwritten signature in black ink, which appears to read 'Tedros Adhanom Ghebreyesus'.

Dr Tedros Adhanom Ghebreyesus
Director-General
World Health Organization

PREFACE

Self-care interventions are playing a more prominent role in today's world with greater access through avenues such as digital technologies and the availability of over-the-counter medicines and diagnostics via pharmacies. The development of normative guidance from the World Health Organization (WHO) on self-care interventions acknowledges the important roles of individuals and communities in their own healthcare and the shift away from solely accessing health services through traditional health centres.

Further data and rigorous research continue to be needed to ensure a strong evidence base to promote the introduction, use and scale-up of self-care interventions. We urgently need to identify innovative research methodologies to better understand self-care and how it fits into individual, community and national-level healthcare. This need is in large part due to the challenges in collecting information on health practices at home.

Research is the foundation for learning, and monitoring, evaluating and improving these interventions, to ensure we are reaching the most underserved and marginalized communities with the right information and services, and positively impacting their health and well-being. Meaningful community engagement, including qualitative research methodologies to capture experiences and lived realities, can further strengthen the evidence base.

Building on the exciting momentum for self-care globally, there is an opportunity to expand the research in this field. Research has an important role in the implementation and scale-up of health programmes and interventions, including self-care. Partnerships will be instrumental in carrying out this research and using the information to inform and enhance self-care interventions.

By leveraging the framework, recommendations and good practices within this guideline, we can implement quality interventions and design research methodologies to support and further this rapidly growing field. This will be imperative to driving a sustainable pathway to achieving health for all.



Dr Soumya Swaminathan
Chief Scientist
World Health Organization

A handwritten signature in blue ink that reads "Soumya". The signature is fluid and cursive, with a long horizontal stroke at the end.

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ACRONYMS AND ABBREVIATIONS

Apgar	appearance, pulse, grimace, activity and respiration
CHW	community health worker
COMET	Core Outcome Measures in Effectiveness Trials
COVID-19	coronavirus disease 2019
CSE	comprehensive sexuality education
DALY	disability-adjusted life year
DMPA-IM	intramuscular depot medroxyprogesterone acetate
DMPA-SC	subcutaneous depot medroxyprogesterone acetate
EC	emergency contraception
ERG	External Review Group
GAH	gender-affirming hormone
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRC	Guidelines Review Committee
GVPS	Global Values and Preferences Survey
HELLP	haemolysis, elevated liver enzymes and low platelet count
HIV	human immunodeficiency virus
HPV	human papillomavirus
HRP	UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction
IPCHS	Integrated People-Centred Health Services framework
NCD	noncommunicable disease
OCP	oral contraceptive pill
OHCHR	Office of High Commission for Human Rights
OTC	over the counter
PHC	primary healthcare
LMICs	low- and middle-income countries
PICO	population, intervention, comparator, outcome
PrEP	pre-exposure prophylaxis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomized controlled trial
SDG	Sustainable Development Goal
SMART	standards-based, machine-readable, adaptive, requirements-based and testable
SMBG	self-monitoring of blood glucose
SMBP	self-monitoring of blood pressure
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
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Document Overview and Navigation Tools

HOW TO NAVIGATE THIS DOCUMENT:

 **Arrow buttons** – jump directly to different pages, sections, and external resources.

 **Home icon** – jump to this Overview page.

Throughout this document, icons will be located next to text denoting cross-cutting themes for implementation considerations of self-care interventions.



People-centredness



Human rights



Gender equality



Health workforce



Health financing

WHO GUIDELINE ON SELF-CARE INTERVENTIONS FOR HEALTH AND WELL-BEING

1. Introduction

2. Essential strategies for creating and maintaining an enabling environment for self-care

3. Recommendations and key considerations

4. Implementation and programmatic considerations for self-care interventions

5. Developing the research agenda for self-care interventions

6. Dissemination, applicability and updating of the guideline and recommendations

EXECUTIVE SUMMARY

BACKGROUND

Self-care interventions are among the most promising and exciting approaches to improve health and well-being, both from a health systems perspective and for the users of these interventions. Self-care interventions hold the promise to be good for everyone and to move us closer to realizing universal health. Self-care interventions have the potential to increase choice and autonomy when they are accessible, acceptable and affordable. They represent a significant push towards greater self-determination, 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 promote the active participation of individuals in their healthcare and are an exciting way forward to reach improved health outcomes by addressing various aspects of healthcare, as seen in Fig. 1.

A global shortage of an estimated 18 million health workers is anticipated by 2030, a record 130 million people are in need of humanitarian assistance, and there is the global threat of pandemics such as COVID-19. 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 healthcare out of their own pockets. There is, therefore, an urgent need to find innovative strategies that go beyond the conventional health-sector response. These interventions are also relevant for all three areas of the Thirteenth General Programme of Work of the World Health Organization

(WHO), as illustrated in Fig. 2. WHO recommends self-care interventions for every country and economic setting as critical components on the path to reaching universal health coverage (UHC), promoting health, keeping the world safe and serving the vulnerable.

Primary healthcare, universal health coverage and other global initiatives

Self-care interventions are increasingly being acknowledged in global initiatives, including for advancing primary healthcare. The three main elements of primary healthcare described in the 2018 Declaration of Astana are:

- 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;
- 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
- Empowering individuals, families and communities to optimize their health as advocates of policies that promote and protect health and well-being, as co-developers of health and social services and as self-carers and caregivers.

Primary healthcare is a fundamental component to achieving UHC, which will need a paradigm shift in health service delivery – and self-care interventions can

FIG. 1. IMPROVED OUTCOMES ASSOCIATED WITH SELF-CARE INTERVENTIONS

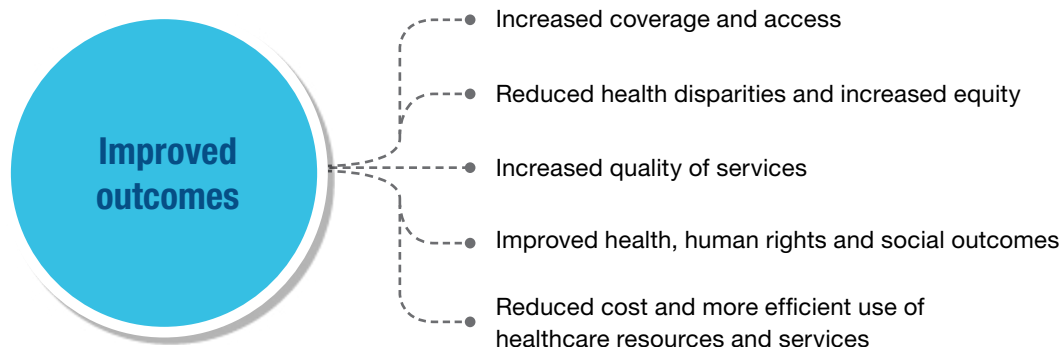


FIG. 2. STRATEGIC PRIORITIES AND TRIPLE-BILLION GOALS FROM THE WHO THIRTEENTH GENERAL PROGRAMME OF WORK



contribute substantially to making that shift. Self-care in support of UHC in turn supports target 3.8 of Sustainable Development Goal 3 (to ensure healthy lives and promote well-being for all at all ages).

Improving health and well-being

Health promotion enables people to increase their control over their own health. It covers a wide range of social and environmental interventions designed to benefit and protect individual people's health and quality of life by addressing and preventing the root causes of ill health, not just focusing on treatment and cure.

WHO recommends a range of self-care interventions for health promotion (see Fig. 3), including better nutrition and physical activity – but also essential enablers such as health literacy that provide a basis for health promotion.

Pandemics and humanitarian settings

In settings affected by conflict and humanitarian crises, existing health systems can rapidly become overstretched and there is often an unprecedented demand on individuals and communities to manage their own health. When quality self-care interventions are provided within the recommended framework or “enabling environment” (as described in Chapter 2), individuals and communities can benefit. During pandemics like COVID-19, self-care measures such as physical distancing, wearing masks and

good hygiene are recommended and practised globally as an essential part of the response. Self-care interventions are shifting the way healthcare is perceived, understood and accessed, and adding to the many medicines, diagnostics and other technologies available for people to use themselves.

Definition of self-care and self-care interventions

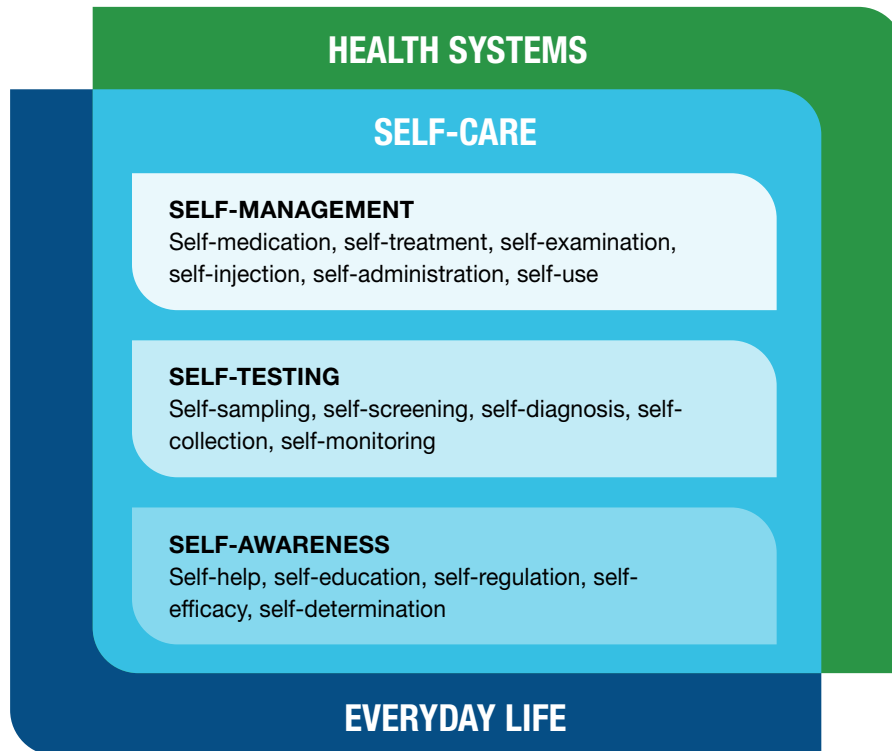
Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health worker. The scope of self-care in this definition includes health promotion, disease prevention and control, self-medication, giving care to dependent people, seeking hospital, specialist or primary care when needed, and rehabilitation, including palliative care.

Self-care interventions are tools that support self-care. These include evidence-based, high-quality drugs, devices, diagnostics and/or digital interventions that can be provided fully or partially outside formal health services and be used with or without a health worker.

Purpose and objectives of the guideline

The purpose of this guideline is to provide evidence-based normative guidance that will support individuals, communities and countries with quality health services

FIG. 3. SELF-CARE IN THE CONTEXT OF INTERVENTIONS LINKED TO HEALTH SYSTEMS



and self-care interventions based on primary healthcare strategies, comprehensive and 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 underserved populations and settings with limited capacity and resources in the health system;
- **good practice statements** on key programmatic, operational and service-delivery issues that need to be addressed to promote and increase the safe and equitable access, uptake and use of self-care interventions, including for advancing SRHR; and
- **key considerations** on specific topics to guide future research and guidelines processes.

Conceptual framework for self-care interventions

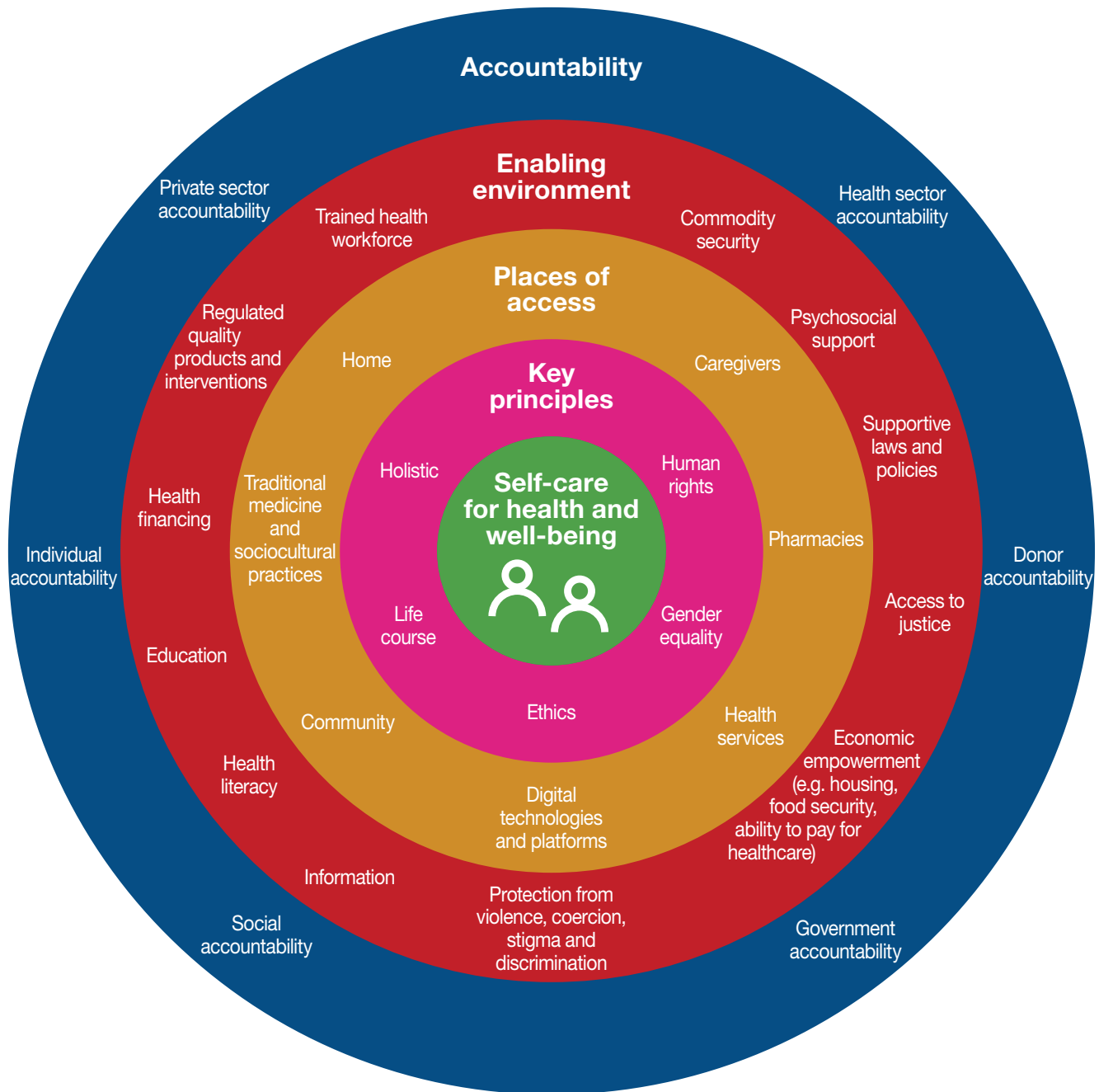
The conceptual framework provides a starting point for tackling the evolving field of self-care and identifying self-care interventions for future updates. The conceptual framework (see Fig. 4) illustrates core elements from both the “people-centred” and “health systems” approaches, which can support the 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.

This guideline is grounded in and advocates 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, and taking account of the environment within which they live.

Self-care interventions, if situated in an environment that is safe and supportive, are an opportunity to help to 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 the uptake of products and interventions that can improve the health and well-being of underserved and marginalized populations. 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.

FIG. 4. CONCEPTUAL FRAMEWORK FOR SELF-CARE INTERVENTIONS

Source: adapted with permission from Narasimhan et al. (doi:10.1136/bmj.l688).

Scope of this guideline

This guideline brings together new and existing WHO recommendations, good practice statements and key considerations on self-care interventions for health. The recommendations relate to specific health-related interventions (see Chapter 3) while the good practice statements relate to implementation considerations and more generally to creating and maintaining an enabling environment, particularly for underserved populations (see Chapter 4, which also contains two additional recommendations). This document builds on the 2019

guidance, which was the first such guideline published by WHO. The new recommendations in this guideline focus on self-care interventions that are considered to be in transition from provision by facility-based health workers to delivery using a self-care approach.

Where current WHO guidance exists, this document refers users to those other publications for further information, and to other relevant WHO tools and documents on programme activities.

Access, use and uptake of self-care interventions for underserved populations

Health inequities are endemic to every region of the world, with rates of disease significantly higher among the poorest and most marginalized individuals and communities.

The vulnerabilities of underserved individuals and communities might increase in many settings because of factors such as older age, which could lead to social isolation, or poverty, which could lead to people living in environments that are harmful to health. Not all individuals and communities, therefore, require the same level of support for access to and the uptake and use of self-care interventions. Safe and strong linkages between independent self-care and access to quality healthcare services for people who want or need them are critically important to avoid harm. Where self-care is not a positive choice but is prompted by fear or a lack of alternatives, it can increase vulnerabilities.

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 worker (or somewhere along that continuum) – can also change over time for each intervention and for different population groups. Ensuring the full implementation of human rights-based laws and policies through SRHR programmes is fundamental to health and human rights.

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 the delivery or promotion of self-care interventions. The secondary target audience is product developers. This new guideline is also expected to support the people 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 underserved 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 healthcare facilities.

Guideline development process

This guideline has been developed according to WHO standards and requirements for guideline development, and with the oversight of the WHO Guidelines Review Committee. All of the recommendations in this guideline have been developed by the Guideline Development Group (GDG) and facilitated by the guideline methodologist using the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation). Annex 2 of this document provides the full details of the methodology. In particular, section 2.4 of Annex 2 describes how the issues to be addressed and the specific recommendations and good practice statements to be included in this guideline were determined.

Developing the research agenda

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

Underpinning the focus of research on efficacy, safety, implementation and delivery will be the perspectives of individuals, collectives, communities and health workers, and/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 self-care 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 the people who participate in research and those who conduct it are paramount to creating a sustainable research environment. During the guideline development process and in-person GDG meeting, the GDG members identified important knowledge gaps that needed to be addressed through further primary research.

Chapter 5 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, and 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

The effective implementation of the recommendations, good practice statements and key considerations in this guideline is likely to need the reorganization of care and the redistribution of healthcare resources, particularly in low- and middle-income countries. The potential barriers are reviewed in Chapter 6. Various strategies will be applied to ensure that the people-centred approach and the key principles that underpin this guideline are operationalized, and to address barriers in a range of settings to facilitate the implementation of the guidance.

The implementation and impact of these recommendations will be monitored at the health-service, regional and country levels, based on existing indicators. Given the private space in which self-care is practised, though, alternative ways to assess the impact of the interventions need to be developed, with the engagement of the affected communities, and with a particular emphasis on the uptake and use by underserved populations.

Updating of the guideline

The recommendations, good practice statements, and key considerations published here represent a subset of prioritized self-care interventions for health. This guidance will be updated and expanded as new evidence becomes available and also depending on the progress in policies and programmes. This guideline is considered

a “living guideline”, which will allow the continual review of new evidence and information, so that appropriate guidance can be issued in a timely manner and adopted and implemented by countries and programmes.

Summary of the recommendations, good practice statements and key considerations

Table 1 presents the new and existing recommendations and the new key considerations on self-care interventions, covering the following topics: (i) improving antenatal, intrapartum and postnatal care; (ii) providing high-quality services for family planning, including infertility services; (iii) eliminating unsafe abortion; (iv) combating sexually transmitted infections (including HIV), reproductive tract infections, cervical cancer and other gynaecological morbidities; (v) promoting sexual health; and (vi) noncommunicable diseases, including cardiovascular disease and diabetes.

Table 2 presents the new and existing good practice statements and two new recommendations on self-care interventions, covering the following topics: (i) human rights, gender equality and equity considerations; (ii) financing and economic considerations; (iii) the training needs of health workers; (iv) population-specific implementation considerations; (v) digital health interventions; and (vi) environmental considerations.

Where the recommendations, good practice statements or key considerations are new, this is noted.



TABLE 1. RECOMMENDATIONS AND KEY CONSIDERATIONS FOR SELF-CARE INTERVENTIONS

Interventions	Recommendations and key considerations ^a
Improving antenatal, intrapartum and postnatal care	
Non-clinical interventions targeted at women to reduce caesarean sections	
Recommendation 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. <i>(Context-specific recommendation; low certainty evidence)</i>
Recommendation 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). <i>(Low to moderate certainty evidence)</i>



Interventions	Recommendations and key considerations ^a
Recommendation 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). <i>(Low to moderate certainty evidence)</i>
Recommendation 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. <i>(Low to moderate certainty evidence)</i>
Recommendation 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). <i>(Low to moderate certainty evidence)</i>
Self-administered interventions for common physiological symptoms	
Recommendation 2	When considering the educational interventions and support programmes, no specific format (e.g. pamphlet, videos, role play education) is recommended as more effective.
Interventions for nausea and vomiting	
Recommendation 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	
Recommendation 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	
Recommendation 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	
Recommendation 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	
Recommendation 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	
Recommendation 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.

Interventions	Recommendations and key considerations ^a
Self-administered pain relief for prevention of delay in the first stage of labour	
Recommendation 9	Pain relief for preventing delay and reducing the use of augmentation in labour is not recommended. <i>(Conditional recommendation; very low certainty evidence)</i>
Iron and folic acid supplements	
Recommendation 10a (new)	WHO recommends making the self-management of folic acid supplements available as an additional option to health worker-led provision of folic acid supplements for individuals who are planning pregnancy within the next three months. <i>(Strong recommendation; very low certainty evidence)</i>
Recommendation 10b (new)	WHO recommends making the self-management of iron and folic acid supplements available as an additional option to health worker-led provision of folic acid supplements for individuals during pregnancy. <i>(Strong recommendation; very low certainty evidence)</i>
Recommendation 10c (new)	WHO recommends making the self-management of iron and folic acid supplements available as an additional option to health worker-led provision of iron and folic acid supplements for individuals during the postnatal period. <i>(Strong recommendation; very low certainty evidence)</i>
Self-monitoring of blood pressure during pregnancy	
Recommendation 11 (new)	WHO suggests making the self-monitoring of blood pressure during pregnancy available as an additional option to clinic blood pressure monitoring by health workers during antenatal contacts only, for individuals with hypertensive disorders of pregnancy. <i>(Conditional recommendation; very low certainty evidence)</i>
Self-testing for proteinuria during pregnancy	
Key consideration 1 (new)	For pregnant individuals with non-proteinuric hypertension, there may be some benefit of home-based urine self-testing compared with inpatient care to detect proteinuria, but clinicians need to balance this with the additional burden placed on the individual.
Self-monitoring of blood glucose during pregnancy	
Recommendation 12 (new)	WHO recommends making self-monitoring of glucose during pregnancy available as an additional option to clinic blood glucose monitoring by health workers during antenatal contacts, for individuals diagnosed with gestational diabetes. <i>(Strong recommendation; very low certainty evidence)</i>
Women-held case notes to improve the utilization and quality of antenatal care	
Recommendation 13	WHO recommends that each pregnant woman carries their own case notes during pregnancy to improve the continuity and quality of care and their pregnancy experience.
Providing high-quality services for family planning, including infertility services	
Self-administration of injectable contraception	
Recommendation 14	Self-administered injectable contraception should be made available as an additional approach to deliver injectable contraception for individuals of reproductive age. <i>(Strong recommendation; moderate certainty evidence)</i>



Interventions	Recommendations and key considerations ^a
Self-management of contraceptive use with over-the-counter oral contraceptive pills	
Recommendation 15	Over-the-counter oral contraceptive pills (OCPs) should be made available without a prescription for individuals using OCPs. <i>(Strong recommendation; very low certainty evidence)</i>
Over-the-counter availability of emergency contraception	
Recommendation 16 (new)	WHO recommends making over-the-counter emergency contraceptive pills available without a prescription to individuals who wish to use emergency contraception. <i>(Strong recommendation; moderate certainty evidence)</i>
Self-screening with ovulation predictor kits for fertility regulation	
Recommendation 17	Home-based ovulation predictor kits should be made available as an additional approach to fertility management for individuals attempting to become pregnant. <i>(Strong recommendation; low certainty evidence)</i>
Condom use	
Recommendation 18	The 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.
Recommendation 19	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. <i>(Strong recommendation; moderate certainty evidence)</i>
Recommendation 20a	Provide up to one year's supply of pills, depending on the woman's preference and anticipated use.
Recommendation 20b	Programmes must balance the desirability of giving women maximum access to pills with concerns regarding contraceptive supply and logistics.
Recommendation 20c	The resupply system should be flexible, so that the woman can obtain pills easily in the amount and at the time she requires them.
Pregnancy self-testing	
Recommendation 21 (new)	WHO recommends making self-testing for pregnancy available as an additional option to health worker-led testing for pregnancy, for individuals seeking pregnancy testing. <i>(Strong recommendation; very low certainty evidence)</i>
Eliminating unsafe abortion	
Self-management of the medical abortion process in the first trimester	
Recommendation 22	Self-assessing eligibility for medical abortion is recommended within the context of rigorous research.

Interventions	Recommendations and key considerations ^a
Recommendation 23	Managing the mifepristone and misoprostol medication without the direct supervision of a health worker is recommended in specific circumstances. We recommend this option in circumstances where women have a source of accurate information and access to a health worker should they need or want it at any stage of the process.
Recommendation 24	Self-assessing the 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 worker should they need or want it at any stage of the process.
Post-abortion hormonal contraception initiation	
Recommendation 25	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 worker are strong, and where monitoring and follow-up can be ensured.
Recommendation 26	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.
Combating sexually transmitted infections (including HIV), reproductive tract infections, cervical cancer and other gynaecological morbidities	
Human papillomavirus (HPV) self-sampling	
Recommendation 27	HPV self-sampling should be made available as an additional approach to sampling in cervical cancer screening services for individuals aged 30–60 years. <i>(Strong recommendation; moderate certainty evidence)</i>
Self-collection of samples for STI testing	
Recommendation 28	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. <i>(Strong recommendation; moderate certainty evidence)</i>
Recommendation 29	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. <i>(Conditional recommendation; low certainty evidence)</i>
HIV self-testing	
Recommendation 30	HIV self-testing should be offered as an additional approach to HIV testing services. <i>(Strong recommendation; moderate certainty evidence)</i>
Self-efficacy and empowerment for women living with HIV	
Recommendation 31	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. <i>(Strong recommendation; low certainty evidence)</i>

Interventions	Recommendations and key considerations ^a
Pharmacy access to pre-exposure prophylaxis (PrEP) for HIV prevention	
Key consideration 2 (new)	Pharmacy initiation and continuation of PrEP: <ul style="list-style-type: none"> • WHO recommends offering oral PrEP and the dapivirine vaginal ring to individuals at substantial risk of HIV infection. • Equitable access to and the availability of PrEP, plus information about its use are imperative to ensure increased uptake. • Providing PrEP through pharmacies may present a unique opportunity for expanding access to PrEP in the community setting. • Any model of PrEP delivery through pharmacies should ensure adherence to WHO suggested procedures for initiating and maintaining PrEP, including HIV testing, creatinine testing and other tests and counselling as appropriate. • The decision to offer PrEP in pharmacies will require alignment with local laws and regulations, appropriate health system linkages and community engagement.
Promoting sexual health	
Lubricant use for sexual health	
Recommendation 32 (new)	WHO recommends making lubricants available for optional use during sexual activity, among sexually active individuals. <i>(Strong recommendation; moderate certainty evidence)</i>
Self-administration of gender-affirming hormones for transgender and gender-diverse individuals	
Key consideration 3 (new)	<ul style="list-style-type: none"> • The principles of gender equality and human rights in the delivery of quality gender-affirming hormones are critical to expanding access to this important intervention and reducing discrimination based on gender identity. • Transgender and gender-diverse people live within social, legal, economic and political systems that place them at high risk of discrimination, exclusion, poverty and violence. • Research is urgently needed to support evidence-driven guidance.
Noncommunicable diseases, including cardiovascular disease and diabetes	
Cardiovascular disease	
Self-measurement to monitor blood pressure	
Recommendation 33	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. <i>(Strong recommendation; low certainty evidence)</i>
Self-monitoring of blood coagulation	
Recommendation 34	Self-monitoring of blood coagulation is recommended for appropriate patients treated with oral anticoagulation agents, where the affordability of the technology has been established. <i>(Weak recommendation; moderate certainty evidence)</i>
Recommendation 35	Self-monitoring of blood coagulation and self-augmentation of dosage in patients receiving oral anticoagulation agents is recommended if affordable, and according to an agreed action plan with a health professional. <i>(Conditional recommendation; moderate certainty evidence)</i>

Interventions	Recommendations and key considerations ^a
Diabetes	
Self-monitoring of blood glucose	
Recommendation 36	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. <i>(Conditional recommendation; moderate certainty evidence)</i>
Recommendation 37	People with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need. <i>(Conditional recommendation; low certainty evidence)</i>

^a The strength of the recommendation and/or the certainty of the evidence are not specified for some of the existing recommendations because they were developed prior to the systematic use of GRADE methodology. When respective guidelines are updated using the GRADE framework, we will update the wording accordingly.



TABLE 2. RECOMMENDATIONS AND GOOD PRACTICE STATEMENTS ON THE IMPLEMENTATION AND PROGRAMMATIC CONSIDERATIONS OF SELF-CARE INTERVENTIONS

Interventions	Recommendations and good practice statements
Human rights, gender equality and equity considerations	
Good practice statement 1 (new)	All self-care interventions for health must be accompanied by accurate, understandable and actionable information, in accessible formats and languages, about the intervention itself and how to link to relevant community- or facility-based healthcare services, and the opportunity to interact with a health worker or a trained peer supporter to support decisions around, and the use of, the intervention.
Good practice statement 2 (new)	The provision of self-care interventions for health should increase clients' options about when and how they seek healthcare, including offering flexibility in the choice of interventions and in the degree and manner of the engagement with health services.
Good practice statement 3 (new)	Self-care interventions for health and their delivery mechanisms should be designed to accommodate the needs of all people across the gender spectrum, recognizing that there may be differences in the barriers that individuals and communities face accessing quality interventions, in their needs and priorities, in the nature of support they need, and in their preferred points of access.
Good practice statement 4 (new)	Countries should review and, where necessary, revise laws, policies and regulations to ensure that quality self-care interventions are made widely available in the community, that they are accessible to all without discrimination, through public, private and community-based health workers, and that they are acceptable to users.



Interventions	Recommendations and good practice statements
Financing and economic considerations	
Good practice statement 5	Good-quality health services and self-care interventions should be made available, accessible, affordable and acceptable to underserved and marginalized populations, based on the principles of medical ethics; the avoidance of stigma, coercion and violence; non-discrimination; and the right to health.
Training needs of health workers	
Good practice statement 6 (adapted)	Health workers should receive appropriate recurrent education to ensure that they have the competencies, underpinned by the required knowledge, skills and attitudes, to provide self-care interventions based on the right to health, confidentiality and non-discrimination.
Rational delegation of tasks and task sharing	
Good practice statement 7	Countries, in collaboration with relevant stakeholders, including patient groups and the community, should consider implementing and/or extending and strengthening the rational delegation of tasks to individuals, carers and communities, as members of the health team, in effective ways that lead to equitable health outcomes.
Good practice statement 8	Self-carers and caregivers who are not trained health workers can be empowered to manage certain aspects of healthcare under the responsibility of a health worker, particularly in relation to self-care and the use of self-care interventions, where appropriate and within the context of safe, supportive health systems.
Competency-based training of health workers	
Good practice statement 9 (adapted)	Countries should adopt a systematic approach to harmonized, standardized and competency-based training that is needs-driven and accredited so that health workers are equipped with the appropriate competencies for: <ul style="list-style-type: none"> • engaging in and supporting self-care practices that promote emotional resilience, health and well-being; • determining the extent to which an individual wishes to, and is able to, self-monitor and self-manage healthcare; • promoting access to and the correct use and uptake of self-care interventions; and • educating individuals for preparing and self-administering medications or therapeutics.
Population-specific implementation considerations	
Implementation considerations during humanitarian and pandemic crises	
Recommendation 38	WHO recommends prioritizing digital health services, self-care interventions, task sharing and outreach to ensure access to medicines, diagnostics, devices, information and counselling when facility-based provision of sexual and reproductive health services is disrupted.
Recommendation 39	WHO recommends maximizing occupational health and staff safety measures, including providing mental healthcare and psychosocial support and promoting self-care strategies.
Life-course approach	
Good practice statement 10	Sensitization about self-care interventions 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.

Interventions	Recommendations and good practice statements
Implementation considerations of underserved and marginalized populations	
Good practice statement 11 (adapted)	People from underserved and marginalized populations should be able to experience full, pleasurable sex lives and have access to a range and choice of reproductive health options.
Good practice statement 12 (adapted)	Countries should work towards implementing and enforcing anti-discrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against underserved and marginalized populations.
Good practice statement 13 (new)	Transgender and gender-diverse individuals who self-administer gender-affirming hormones require access to evidence-based information, quality products and sterile injection equipment.
Digital health interventions	
Good practice statement 14 (adapted)	Digital health interventions offer opportunities to promote, offer information about and provide discussion forums for self-care interventions.
Good practice statement 15 (adapted)	Client-to-provider telemedicine to support self-care interventions can be offered to complement face-to-face health services.
Good practice statement 16 (adapted)	Digital targeted client communication by health workers on the use of self-care interventions can help to implement monitor and evaluate health outcomes.
Environmental considerations	
Good practice statement 17	Safe and secure disposal of waste from self-care products should be promoted at all levels.
Good practice statement 18	Countries, donors and relevant stakeholders should work towards environmentally preferable purchasing of self-care products by selecting supplies that are less wasteful, can be recycled or produce less-hazardous waste products, or by using smaller quantities.

A LIVING GUIDELINE

This living guideline is also available in one user-friendly and easy-to-navigate online platform, which will allow for continual review of new evidence and information. The interactive web-based version of this living guideline is available at <https://app.magicapp.org/#/guideline/Lr21gL>.

SMART Guidelines (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) on self-care interventions for [antenatal care](#), [family planning](#), HIV and other topics is available under: <https://www.who.int/teams/digital-health-and-innovation/smart-guidelines>.

1.

Introduction



At a Glance

This chapter provides key background information about self-care and self-care interventions and an overview of the guideline, including brief summaries of how it was developed, the way it should be used and the scope of the guideline.

Background

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Objectives

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Living guideline approach

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Definitions of self-care and self-care interventions

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Scope

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Target audience

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Values and preferences

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Guideline development and compilation process

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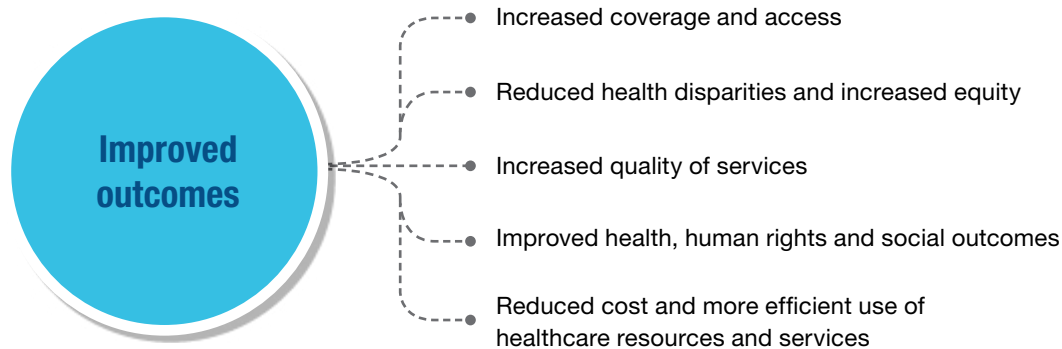
1.1 BACKGROUND

Self-care interventions are among the most promising and exciting new approaches to improving health and well-being, both from a health systems perspective and for the users of these interventions. Self-care interventions hold the promise of being good for everyone and moving us closer to realizing universal health. They have the potential to increase choice and autonomy when they are accessible, acceptable and affordable. People practise many forms of self-care, often learning from health professionals and applying medical and/or traditional treatments themselves. This has become especially important for everyone, everywhere in global health emergencies such as the COVID-19 pandemic and is especially important for individuals and communities whose health-seeking behaviour is constrained by costs or limited access to health facilities (1). For example, in rural north-east Thailand, 80% of self-reported uterus-related (*mot luuk*) 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 (2). It is important, therefore, to have evidence-based normative guidance to ensure that quality self-care interventions can provide more opportunities for individuals to make informed decisions regarding their health and healthcare.

Self-care interventions represent a significant push towards greater self-determination, self-efficacy, autonomy and engagement in health for self-carers and caregivers. While calculations of risks and benefits may be different in different settings and for different populations, with appropriate normative guidance and a safe and supportive enabling environment, self-care interventions can promote the active participation of individuals in their health, and are an exciting way forward to reach improved health outcomes via a number of mechanisms, as shown in Fig. 1.1.

FIG. 1.1. IMPROVED OUTCOMES ASSOCIATED WITH SELF-CARE INTERVENTIONS



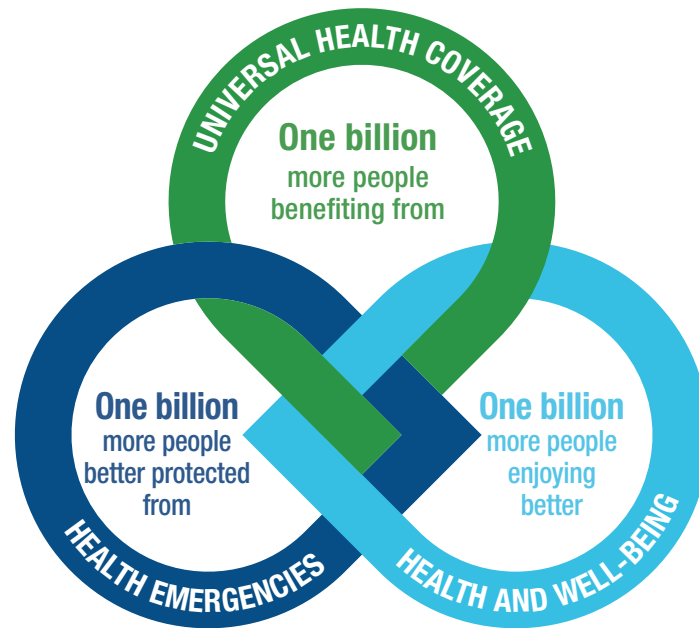
1.1.1 THE ROLE OF SELF-CARE INTERVENTIONS TO SUPPORT HEALTH SYSTEMS

A shortage of 18 million health workers is anticipated globally by 2030 (3), and a record 130 million people are in need of assistance under global threats that include humanitarian crises and pandemics such as COVID-19. 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 healthcare out of their own pockets (4). There is, therefore,

an urgent need to find innovative strategies that go beyond the conventional health sector response.

Self-care interventions are also relevant to all three areas of the Thirteenth General Programme of Work of the World Health Organization (WHO) (5), as illustrated in Fig. 1.2. WHO recommends self-care interventions for every country and economic setting as a critical component of the path to reach universal health coverage (UHC), promote health, keep the world safe and serve the vulnerable.

FIG. 1.2. WHO STRATEGIC PRIORITIES AND THE TRIPLE-BILLION GOALS IN THE THIRTEENTH GENERAL PROGRAMME OF WORK



1.1.2 PRIMARY HEALTHCARE, UNIVERSAL HEALTH COVERAGE AND OTHER GLOBAL INITIATIVES

Self-care interventions are increasingly being acknowledged in global initiatives, including to advance primary healthcare (6, 7). The Astana Declaration calls for the mobilization of all stakeholders – healthcare professionals, academics and researchers, 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 primary healthcare:

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, and 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 of policies that promote and protect health and well-being, as co-developers of health and social services and as self-carers and caregivers.

Table 1.1 outlines some examples of global initiatives in which self-care interventions play an important role.

Primary healthcare is a fundamental component to achieve UHC. Its achievement needs a paradigm shift in health service delivery, and self-care interventions can contribute substantially to making that shift. Self-care as part of primary healthcare represents a cornerstone of a sustainable health system in support of UHC, which is the target 3.8 of Sustainable Development Goal 3 (SDG 3) – to ensure healthy lives and promote well-being for all at all ages.

To assist countries in making progress towards UHC, WHO has developed the UHC Compendium – a website and database of health services and intersectoral interventions. This provides a strategic way to organize and present information and creates a framework for thinking about health services and health interventions (8). The database¹ spans the full spectrum of promotive, preventive, resuscitative, curative, rehabilitative and palliative services, plus a full complement of intersectoral interventions, including self-care.

¹ Available at <https://www.who.int/universal-health-coverage/compendium/database>

TABLE 1.1. EXAMPLES OF GLOBAL INITIATIVES THAT INCLUDE SELF-CARE INTERVENTIONS

Initiative	Interventions	Web address
Global action plan for the prevention and control of noncommunicable diseases, 2013–2020	Self-care strategies for improving health conditions such as cardiovascular disease and diabetes	https://www.who.int/publications/i/item/9789241506236
Global health sector strategy on HIV, 2016–2021	HIV self-testing to improve the coverage of testing for individuals and their partners	https://apps.who.int/iris/bitstream/handle/10665/246178/WHO-HIV-2016.05-eng.pdf
Global health sector strategy on sexually transmitted infections, 2016–2021	Self-collection of samples for the testing of sexually transmitted infections to improve testing and treatment, particularly for gonorrhoea, syphilis and chlamydia	https://apps.who.int/iris/bitstream/handle/10665/246296/WHO-RHR-16.09-eng.pdf;sequence=1
Global strategy to accelerate the elimination of cervical cancer as a public health problem	Self-sampling for human papillomavirus testing, to reach goals on cervical cancer screening and treatment	https://www.who.int/publications/i/item/9789240014107

1.1.3 IMPROVING HEALTH AND WELL-BEING

Health promotion enables people to increase their control over their own health. It covers a wide range of social and environmental interventions that address and prevent the root causes of ill health rather than just focusing on treatment and cure (9).

WHO promotes a range of self-care interventions for health promotion (see Fig. 1.3), including better nutrition and physical activity – but also essential enablers, such as health literacy, that are foundational to health promotion.

FIG. 1.3. HEALTH-PROMOTION TIPS FOR SELF-CARE PRACTICES


1.1.4 HUMANITARIAN CRISES

In settings affected by conflict and humanitarian crises, the existing health system can become rapidly overstretched and there is often an unprecedented demand on individuals and communities to manage their own health. When quality self-care interventions are provided within the recommended framework or

an enabling environment (as described in Chapter 2), individuals and communities can benefit. During pandemics, such as the COVID-19 one, self-care measures such as physical distancing, wearing masks and good hygiene have been recommended and are practised globally as an essential part of the response (see Fig. 1.4).

FIG. 1.4. EXAMPLE OF A WHO-RECOMMENDED SELF-CARE PRACTICE DURING THE COVID-19 PANDEMIC – HAND HYGIENE



Self-care interventions are shifting the way healthcare is perceived, understood and accessed, and adding to the many medicines, diagnostics and other technologies available for people to use themselves.

1.1.5 SUSTAINABLE DEVELOPMENT GOALS

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 in terms of both the coverage of quality 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, oblige us to anticipate an increase in the development, distribution and disposal of self-care products. The management of the related production, consumption and waste will need to be environmentally responsible. SDG 10 on reduced inequalities is of particular relevance to the key principles of ethics and human rights that 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 – all crucial aspects of an enabling environment for safe and effective health services, including self-care interventions. Box 1.1 lists the SDGs and targets relevant to this guideline.

BOX 1.1. RELEVANT SUSTAINABLE DEVELOPMENT GOALS 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 healthcare 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 healthcare 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 life-long 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

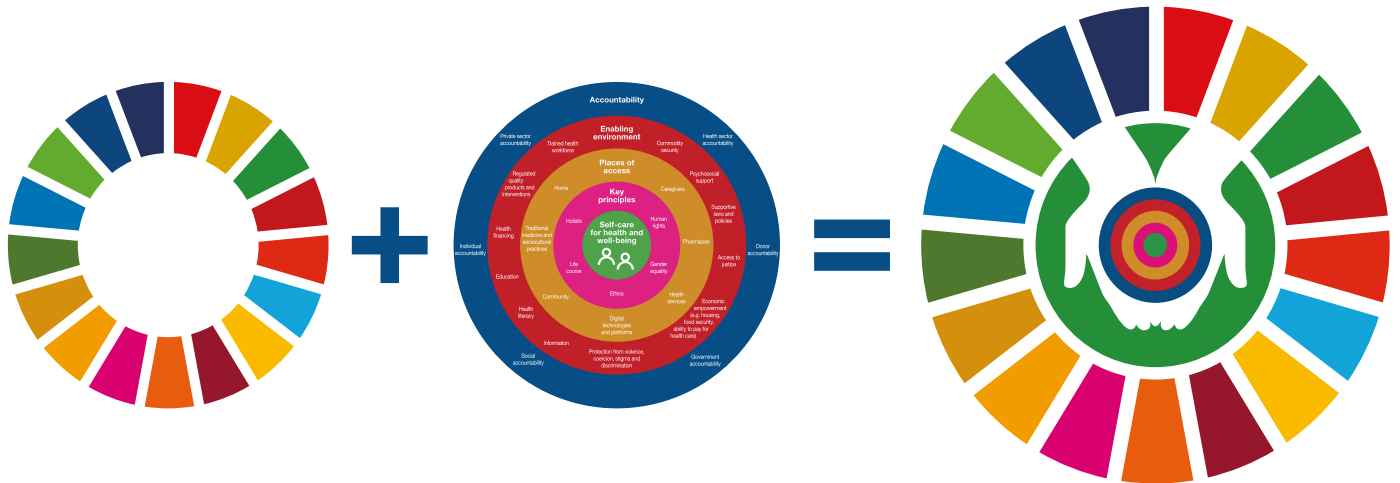
- **Target 16.6:** Develop effective, accountable and transparent institutions at all levels

Source: United Nations (10).

The self-care SDG logo (Fig. 1.5) was developed to promote this WHO guideline and related WHO/United Nations partner tools to support the implementation of self-care interventions for health. People-centredness is inherent in the concept of self-care, and this logo

symbolizes placing power over health and well-being in the hands of people in their roles as self-carers and/or caregivers. The image encompasses all the elements of the guideline reflected in the framework for self-care interventions (see Chapter 2).

FIG. 1.5. WHO SELF-CARE LOGO INCORPORATING THE SUSTAINABLE DEVELOPMENT GOALS



1.2 OBJECTIVES

The purpose of this guideline is to provide evidence-based normative guidance that will support individuals, communities and countries with quality health services and self-care interventions based on primary healthcare 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 health, with a focus on underserved populations and settings with limited capacity and resources in the health system;
- good practice statements on key programmatic, operational and service-delivery issues that need to be addressed to promote and increase safe and equitable access, and the uptake and use of self-care interventions for health; and
- key considerations on specific topics to guide future research and guidelines processes.

1.3 LIVING GUIDELINE APPROACH

In a fast-moving field, a “living guideline” approach allows for continual review of new evidence to inform further

versions of the guideline. This guideline will be updated frequently, on a rolling basis, and will be posted on a dynamic, user-friendly and easy-to-navigate web-based platform. The recommendations, good practice statements and key considerations presented in this publication build on the guideline published in 2019 and represent a subset of prioritized self-care interventions for health. Over time, in subsequent versions, WHO aims for this guideline to gradually include a broader set of self-care interventions.

This living guideline approach also facilitates the updating of existing recommendations as new evidence becomes available, and the inclusion of additional health domains that may not yet be reflected. Future guidance on self-care interventions in additional health areas will build on existing tools and guidance. For instance, a WHO package of essential noncommunicable disease interventions for primary healthcare 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 reliable online information.

Section 6.3 offers more detail about the living guideline approach.

1.4 DEFINITION OF SELF-CARE AND SELF-CARE INTERVENTIONS

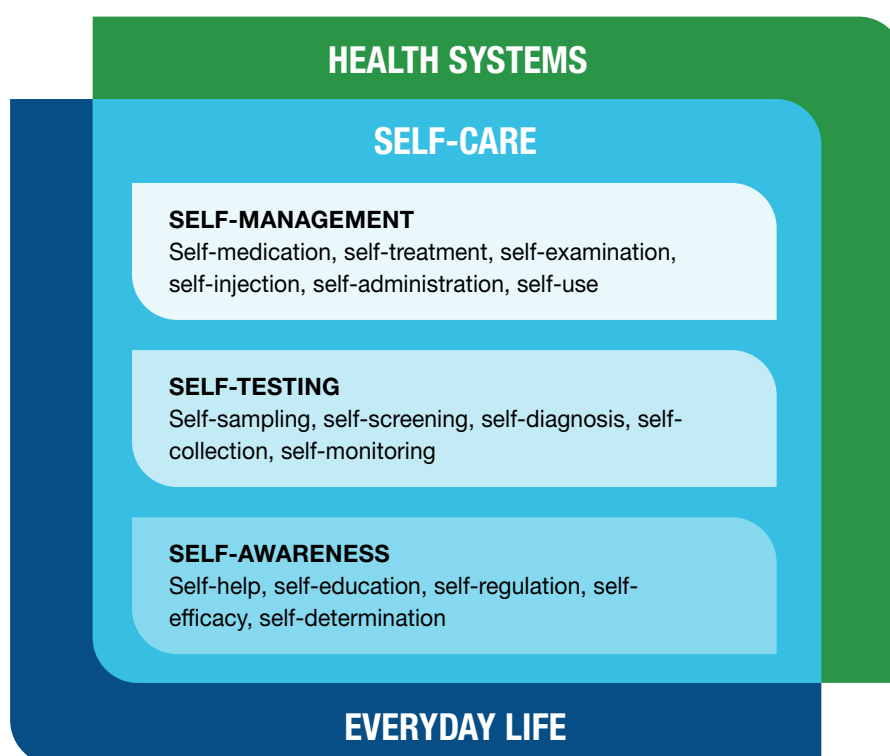
1.4.1 SELF-CARE

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 worker (11).

The scope of self-care thus includes health promotion, disease prevention and control, self-medication, providing care to dependent people, seeking hospital/specialist/primary care if needed, and rehabilitation, including palliative care (12).

This definition of self-care is based on a scoping review of WHO definitions of self-care (see Annex 3). It includes a range of self-care practices and approaches, as shown in Fig. 1.6.

FIG. 1.6. SELF-CARE IN THE CONTEXT OF INTERVENTIONS LINKED TO HEALTH SYSTEMS



Source: adapted with permission from Narasimhan et al. (13).

1.4.2 SELF-CARE INTERVENTIONS

Self-care interventions are tools that support self-care. These include evidence-based, high-quality drugs, devices, diagnostics and/or digital interventions that can be provided fully or partially outside formal health services and can be used with or without the direct supervision of healthcare personnel.

People can have good knowledge of some interventions, and feel comfortable using them independently from the outset. For other interventions, people need more guidance and support before they can accept and use them independently. Self-care interventions for health that need initiation by health workers, or their support, should be linked to the health system and supported by it (see Fig. 1.6).

Self-care interventions also support a continuum of care, as shown in Fig. 1.7, and a people-centred approach to health. This continuum of care applies to the users of self-care health interventions as individuals, but also to people in the role of caregiver. People might choose these interventions for positive reasons, which may include convenience, cost, empowerment or a better fit with values or daily lifestyles, or because the intervention may provide the desired options and choice. There might also be negative reasons, though – they might opt for self-care health interventions to avoid the health system, because of a lack of quality (e.g. discrimination from health workers) or lack of access (e.g. in humanitarian settings). While not ideal in these situations, self-care health interventions fulfil a particularly important role, as the alternative might be that people have no access at all.

FIG. 1.7. CONTINUUM OF CARE FOR SELF-CARE


1.4.3 CLASSIFICATION OF SELF-CARE INTERVENTIONS

The WHO classification of self-care interventions categorizes the different ways in which they are used to support people's needs and health system challenges (14). Even though many self-care interventions directly target individuals and caregivers and offer alternative means of seeking and obtaining care, they often operate at the broader health system level. As such, this classification is primarily health-system focused, analysing how self-care interventions can be applied as strategies to meet health system challenges. In turn, the system responses to these strategies help to meet people's self-care needs by supporting and improving the health of individuals downstream. Targeted primarily at public health audiences, this classification provides a structure with the objective of promoting an accessible and bridging language for researchers, policy-makers, donors and health programme planners to articulate the functionalities of the implementation of self-care interventions.

1.5 SCOPE

1.5.1 SCOPE OF THIS GUIDELINE

Building on the 2019 guideline, this guideline brings together new and existing WHO recommendations, key considerations and good practice statements on self-care interventions for health. These relate either to specific health-related interventions (see Chapter 3) or to creating and maintaining an enabling environment, particularly for underserved populations (see Chapter 4). The new

PERSONAL DETERMINANTS

- Knowledge
- Health literacy
- Daily choices (hygiene, safe sex, risk avoidance, nutrition/diet, work-life balance, adherence to treatment)

SITUATIONAL, ECONOMIC, EMOTIONAL AND SOCIAL DETERMINANTS

- Peer-to-peer actions
- Support
- Counselling
- Engagement in health decisions

HEALTH SYSTEMS DETERMINANTS

- Identify opportunities to promote self-care
- Provide written or visual materials
- Support development of action/calendar/follow-up plan with increased severity of health condition
- Promote tools, interventions, information for improved autonomy
- Support caregivers

recommendations focus on self-care interventions that are considered to be in transition from provision by facility-based health workers to delivery using a self-care approach.

Where current WHO guidance exists, this document refers readers to those other publications for further information, and to other relevant WHO tools and documents on programme activities.

All of the new and existing recommendations in this guideline are summarized in the summary tables in the executive summary and described in detail in Chapters 3 and 4.

1.5.2 ACCESS, USE AND UPTAKE OF SELF-CARE INTERVENTIONS FOR UNDERSERVED POPULATIONS

Health inequities are endemic to every region of the world, with rates of disease significantly higher among the poorest and most marginalized individuals and communities. The vulnerabilities of underserved individuals and communities can lead to social isolation, poverty and people living in environments that are harmful to health. Not all individuals and communities require the same level of support for access, use and uptake of self-care interventions. Safe and strong linkages between independent self-care and access to quality healthcare for people who want or need it are important to avoid harm. Where self-care is not a positive choice, but prompted by fear or a lack of alternatives, this can increase any vulnerabilities.



Furthermore, not all interventions are situated in the same space between users themselves and health workers. The use and uptake of self-care interventions is organic, and the shift in responsibility – between full responsibility for the user and full responsibility for the health worker (or somewhere along that continuum) – can change over time for each intervention and for different population groups.

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

1.5.3 SELF-CARE FOR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS

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” (15), sexual and reproductive health 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 sexual and reproductive health programmes is fundamental to health and human rights. Table 1.2 outlines the key components of a human rights approach to self-care interventions.



TABLE 1.2. HUMAN RIGHTS APPROACH TO SELF-CARE INTERVENTIONS

Human rights standard	Relevance to self-care interventions for sexual and reproductive health and rights
The right to health, including the availability, accessibility, acceptability and quality of information, goods and services	The ability of the user to engage in 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	The 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 the liability falls for inaccurate or false information
The right to informed decision-making	The availability of accurate, accessible, clear and 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 need additional consideration where self-care interventions are accessed outside the health system
The right to accountability	Accountability includes that 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

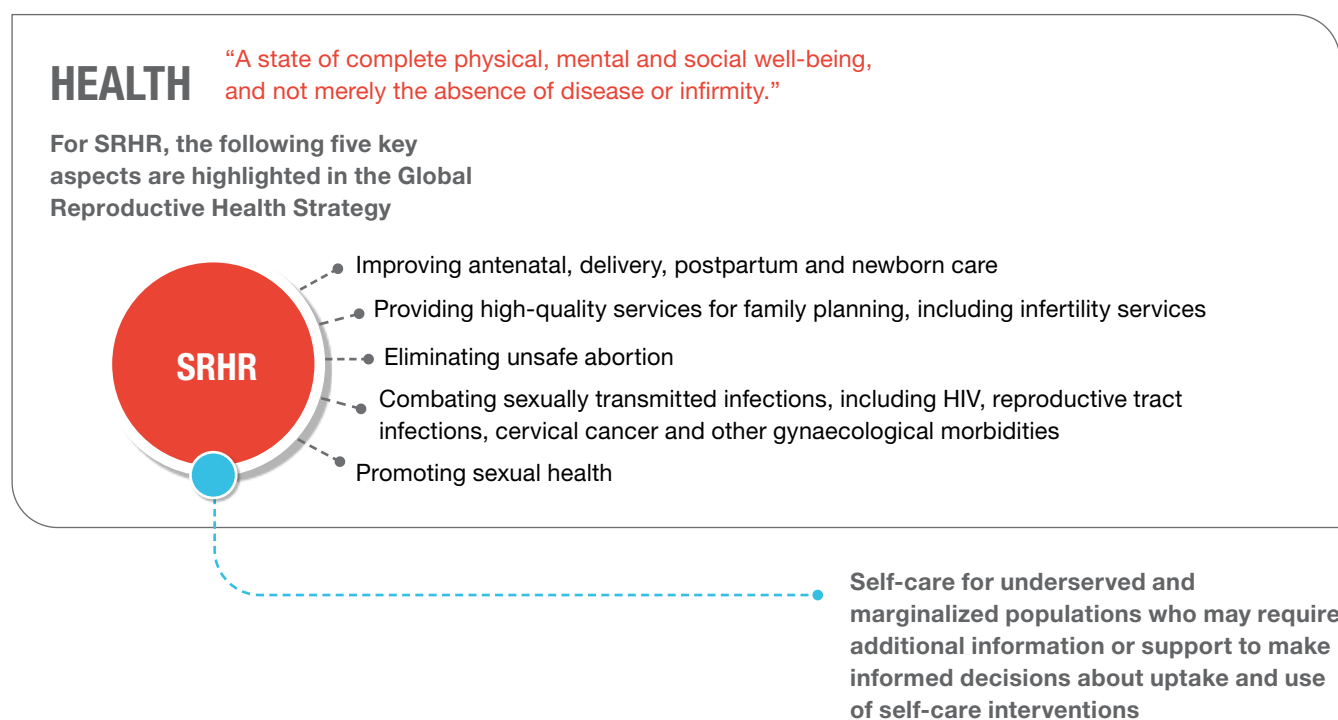
The comprehensive approach to SRHR endorsed by WHO Member States in the 2004 Global Reproductive Health Strategy covers five key areas (see Fig. 1.8) – plus several cross-cutting areas such as gender-based violence (16).



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 underserved people (e.g. people with disabilities). 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.

FIG. 1.8. SCOPE OF SELF-CARE INTERVENTIONS FOR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS (SRHR)



1.6 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 the delivery or promotion of self-care interventions.

Secondary target audience:

- product developers.

This new guideline is also expected to support:

- people affected by the recommendations, i.e. people 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 underserved 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 healthcare facilities.

1.7 VALUES AND PREFERENCES

Building on 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 (17)* – a global survey on self-care interventions ran online. Available in English, French

and Spanish, this Global Values and Preferences Survey (GVPS), was available from October 2020 to May 2021.

A total of 1350 people from 113 countries responded to the survey, including health workers (36% of respondents). There was good regional representation: 26% of respondents were in Africa, 18% in South Asia, 27% in Europe, 23% in the Americas and 13% in the Western Pacific. The respondents ranged in age from 18 to 70 years and had a diverse range of backgrounds, including individuals of diverse sexual orientation and gender identity and expression (18%), young people between 18 and 29 years of age (46%), and people aged 50 years and older (16%).

The limitations of the GVPS included that the survey was most likely to reach people who were able to locate and access it online, and it was accessible only to people who could read English, French or Spanish. The strengths of the survey included 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.

The GVPS results were presented at the Guideline Development Group (GDG) meeting. 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).

1.8 GUIDELINE DEVELOPMENT AND COMPILATION PROCESS

This guideline has been developed according to WHO standards and requirements for guideline development, based on the *WHO handbook for guideline development, second edition (18)*, and with the oversight of the WHO Guideline Review Committee.

All of the recommendations in this guideline have been developed by the GDG, facilitated by the guideline methodologist using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (19). See Annex 2, and section A2.4 in particular, which describes how the issues to be addressed and the specific recommendations and good practice statements to be included in this guideline were determined.

In the remainder of this document, Chapter 2 describes the essential strategies for creating and maintaining an enabling environment for self-care. Chapter 3 presents the recommendations, and Chapter 4 provides the good practice statements relating to implementation considerations. Chapter 5 offers a list of research gaps and priorities, as identified by the GDG, that need further study. Finally, Chapter 6 describes the plans for the dissemination, application, monitoring and evaluation, and updating of the guideline and recommendations.

BOX 1.2 A LIVING GUIDELINE

This living guideline is also available in one user-friendly and easy-to-navigate online platform, which will allow for continual review of new evidence and information. The interactive web-based version of this living guideline is available at <https://app.magicapp.org/#/guideline/Lr21gL>.

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2.

Essential strategies for creating and maintaining an enabling environment for self-care



At a Glance

This chapter describes the core elements of the WHO conceptual framework for self-care interventions and their importance in supporting the introduction, access, uptake and scale-up of self-care interventions.

People-centred approach for health and well-being p. 17

Key principles p. 17

Safe and supportive enabling environment p. 19

Characteristics of an enabling environment p. 22

Places to access and/or deliver self-care interventions p. 24

Accountability p. 24

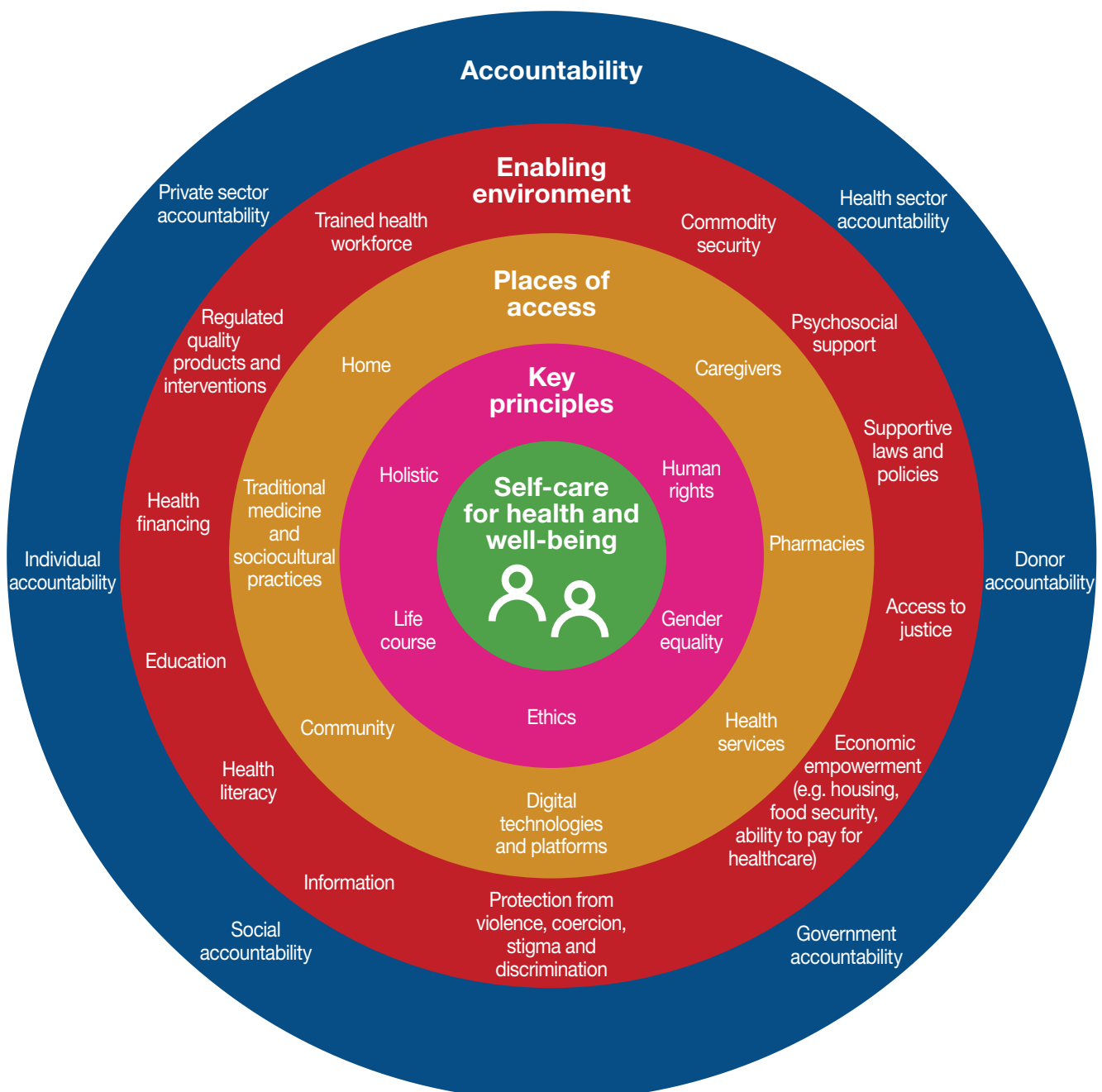


2.1 BACKGROUND

Ensuring that the environment in which self-care interventions can be made available is safe and appropriate must be key to any strategy for introducing and/or scaling-up these interventions. These strategies 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. The conceptual framework informing this guideline is designed to draw systematic attention to the key areas for creating and maintaining an enabling environment for self-care to ensure that self-care interventions reach users with all the necessary checks and balances in place to support their rights and needs.

The conceptual framework presented in Fig. 2.1 illustrates core elements from both people-centred and health systems approaches that can support the introduction, access, uptake and scale-up of self-care interventions for health (1). The people-centred approach to health and well-being lies at the core of this framework (green circle) and is underpinned by key principles (pink ring). The framework then shows key places of access to, and delivery of, self-care interventions (mustard ring), the key elements of a safe and supportive enabling environment (red ring), and accountability at different levels (blue ring).

FIG. 2.1. CONCEPTUAL FRAMEWORK FOR SELF-CARE INTERVENTIONS



Source: adapted with permission from Narasimhan et al. (1).

2.2 PEOPLE-CENTRED APPROACH FOR HEALTH AND WELL-BEING



This guideline is grounded in, and advocates, a strengthened, comprehensive, people-centred approach to health and well-being, including for sexual and reproductive health and rights (SRHR) and noncommunicable diseases (NCDs). People-centredness means taking a holistic approach to the care of each person, and taking account of the environment in which they live and their individual circumstances, needs and desires across their whole life course. People-centred health services are delivered using an approach to healthcare that consciously adopts the perspectives of individuals, families and communities.



A people-centred approach (2, 3):

- 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 that examine harmful gender norms and support gender equality;
- ensures 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 healthcare;
- recognizes the strengths of individuals as active agents in 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 framework for integrated people-centred health services calls for a fundamental shift in the way health services are funded, managed and delivered (2). The framework's vision is that "all people have equal access to quality health services that are co-produced 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" (2).

The World Health Organization (WHO) recommends five interwoven strategies that need to be implemented to

achieve the framework. Application of the approach can build robust and resilient health services, which are critical for progress towards universal health coverage (UHC) and fulfilling the Sustainable Development Goals (2).

2.3 KEY PRINCIPLES

A systematic consideration of the key principles outlined in this section, in the context of a well-functioning health system and a safe and supportive enabling environment, will help to ensure better health for all in the provision of self-care interventions. This guideline's key principles are designed to draw systematic attention to key areas of potential concern, to inform actions that might militate against these negative impacts and ensure a supportive and responsive health system and broader enabling environment.

2.3.1 HOLISTIC APPROACH

A holistic approach to health encompasses issues that go beyond simple access to biomedical interventions and their uptake. Adopting a holistic approach to health means 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.

Within a people-centred approach, a holistic view of health demands that attention is given beyond a specific disease or health condition. Health is interrelated with nature and nurture and evolves over time, so ensuring a holistic approach to it can better reflect its complex and dynamic elements (4). A holistic approach to self-care interventions is thereby one that is relevant to a range of health topics, including SRHR and NCDs, infectious diseases and noncommunicable diseases, including mental health.

2.3.2 ETHICAL CONSIDERATIONS

Health ethics add the dimension of value-orientated considerations, such as equity and its impact on healthcare delivery for underserved populations. Leveraging an ethical framework emphasizes well-being and not just the absence of disease. An ethical framework can help us to better understand how user autonomy could promote or challenge one or more dimensions of well-being. It can help us to assess, for instance, criteria on the capacity of individuals to make health decisions or to use a self-care intervention (5).

An ethical approach should inform all decisions about self-care interventions, underpinned by the principles of fairness and equity (6). This includes respect for medical ethics within health services, and goes beyond doing so, to ensuring an ethical approach anywhere that self-care interventions are accessed and used outside the health system. The enabling environment to support the introduction of self-care interventions must be ethical by making sure that healthcare optimizes the risk–benefit ratio in all interventions, respects individuals’ rights to make autonomous and informed decisions, safeguards privacy, protects the most underserved, and ensures equitable distribution of resources.

2.3.3 LIFE-COURSE APPROACH



Socioeconomic conditions throughout people’s lives shape health outcomes, disease risk, health-seeking behaviour and needs, and influence people’s use and uptake of self-care interventions (6). Healthy people often maintain their health and well-being at home and engage or re-engage with the health system at discrete stages of their lives. Self-care interventions should meet the health needs and aspirations of potential users at all stages of the life course. This helps to ensure that the needs of different age groups are considered and that people’s health needs and priorities over time are taken into account for access to and the use of self-care interventions.



The benefits of considering such a life-course approach include increased delivery efficiency, decreased overall costs, improved equity in the uptake of services, better health literacy and self-care, increased satisfaction with care, improved relationships



between patients and health workers, and an improved ability to respond to healthcare crises. As each stage in a person’s life exerts influence on the next stage, it is important to use self-care interventions at all stages (7).

2.3.4 HUMAN-RIGHTS AND GENDER-EQUALITY APPROACHES

An integrated approach based on human rights and gender equality lies at the heart of ensuring the dignity and well-being of individuals. Laws, policies and interventions should address gender inequalities, including harmful gender norms and stereotypes, unequal power in intimate relationships, and women’s and gender-diverse individuals’

relative lack of access to and control over resources. All 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. The promotion of gender equality is central to facilitating access to self-care interventions for all people 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 the safe, effective, affordable and acceptable method 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 partners with the best chance of having a healthy infant (6).

The United Nations Committee on Economic, Social and Cultural Rights has 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” (8). It says the right to SRH entails a set of entitlements, including unhindered access to a whole range of healthcare facilities, goods, services and information (8). These ensure – for all people – the full enjoyment of the right to SRH under Article 12. Showing respect for individual dignity and for physical and mental integrity includes giving each person the opportunity to make autonomous reproductive choices (9–11). 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 (12). This holds particular relevance in the context of self-care interventions, as people may rely on publicly available information rather than healthcare professionals to make appropriate decisions when selecting and using self-care interventions. 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” (13).

The programme of action of the 1994 International Conference on Population and Development highlighted SRH issues within a human rights framework (14). It defined reproductive rights as follows.

Reproductive 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 (14, 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 SRH cannot be achieved and maintained without respect for and protection of certain human rights. The application of existing human rights to sexuality and SRH constitutes sexual rights. Sexual rights protect all people's rights to fulfil and express their sexuality and enjoy SRH, with due regard for the rights of others and within a framework of protection against discrimination (15).



WHO has recognized certain human rights to be particularly integral to the promotion and protection of SRHR (16). As such, these human rights are equally applicable to self-care interventions for SRHR. Centred around the user, Table 1.2 in Chapter 1 outlines the relevance of these human rights standards to the

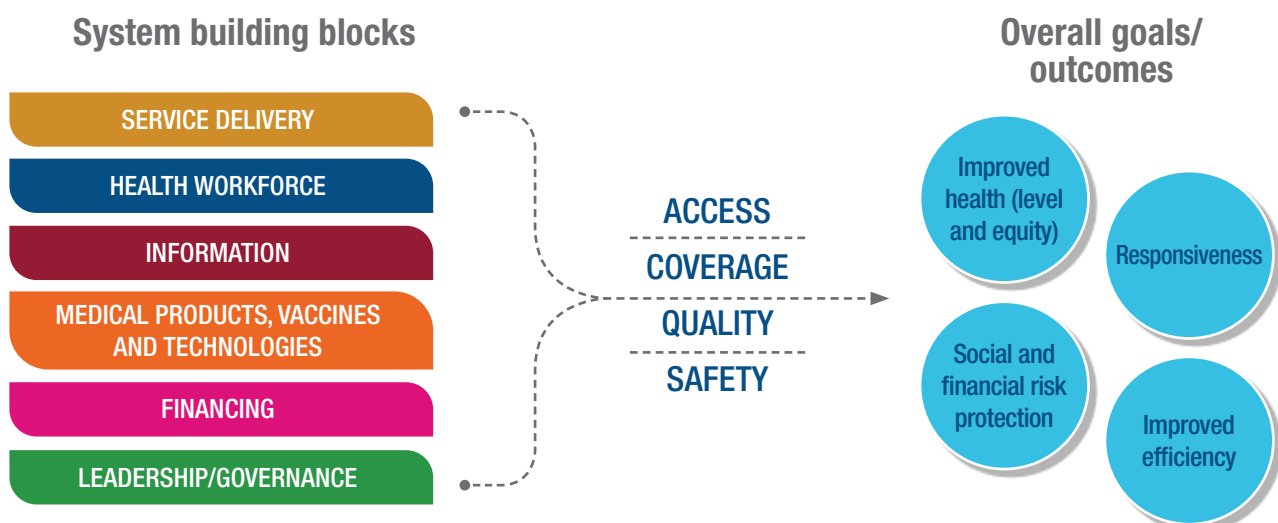
adoption and provision of self-care interventions. These human rights standards and principles are critical to ensuring the appropriate roll-out of self-care interventions (17). SRHR outcomes are not equal for people throughout the world, neither across nor within countries. Many of these disparities, which are rooted in underlying social determinants, are avoidable and unacceptable (18).

2.4 SAFE AND SUPPORTIVE ENABLING ENVIRONMENT

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 marginalized and underserved populations. The successful introduction and/or scale-up of self-care interventions therefore requires systematic attention to all aspects of the health system, and to the broader environment within which self-care interventions are delivered (6).

Self-care interventions must be an adjunct to, rather than a replacement for, direct interaction with the health system, and this may need the boundaries of the health system to be reconceptualized. 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 healthcare, self-care interventions may need more – not less – support from the health system (17). Drawing on the WHO health system framework (19), every health system building block (see Fig. 2.2) needs to be adapted to ensure its adequacy for effective self-care interventions.

FIG. 2.2. WHO HEALTH SYSTEM FRAMEWORK



Source: WHO (19).

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 in using them, and to ensure that they seek support from health workers when needed. This is further explored in section 2.4.7, with the potential users of self-care interventions placed at the centre of all considerations of how the health system might have to respond.

2.4.1 SERVICE DELIVERY

Service 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 the availability of and access to health services that meet or exceed the minimum quality standards is a key function of a health system (20). 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 healthcare. Service delivery is organized to provide an individual with a continuity of care across the network of services, health conditions and levels of care, and over the life course.

2.4.2 THE HEALTH WORKFORCE

The WHO global competency and outcomes framework for UHC is relevant to the provision of health interventions across promotive, preventative, curative, rehabilitative and palliative health services, and it can be used by health workers at the primary healthcare level with a pre-service training pathway of 12–48 months (21). The framework focuses on the competencies (integrated knowledge, skills and behaviours) needed to provide interventions, and has relevance to both pre-service and in-service education and training. To maximize the opportunities to promote and facilitate self-care interventions, it is important that training for health workers incorporates communication to enable informed decision-making; the clarification of values; collaborative practice; and empathetic and compassionate approaches to care (21).



The delivery of care and health services should be accomplished in a people-centred and non-judgemental way, allowing everyone, when they are willing and able, 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, demand some engagement with the health

system, and, as such, it is critical that the attitudes and behaviours of health workers are inclusive and non-stigmatizing and that they promote safety, including patient safety and equality. Health workers and managers of



healthcare facilities – whether in the public or the private sector – are responsible for delivering services appropriately and meeting standards based on professional ethics and internationally agreed human rights principles. Health workers and health services need to include the role that people take up when practising self-care outside of any initiation by the health system – acknowledging self-care when developing and supporting a holistic, health management plan.

2.4.3 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 (6). 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. Pictures and other visual materials are useful in overcoming language barriers and literacy issues. Mobile phones, tablets and other information and communications technologies offer new opportunities to deliver health information.

Health information should be available to and used by health workers to address the clinical and non-clinical aspects of self-care. 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 health and well-being and their interactions with the health system. Patient information leaflets, for example, are a legal requirement in many countries, and they must be designed to ensure that patients can make informed decisions about the safe and effective use of the products and interventions they describe. Capturing information about self-care interventions may require the expansion of health management information systems beyond the traditional confines of the health system.

2.4.4 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 Fig 2.3) (22). The national regulatory authorities (i.e. the government) determine which medical products, vaccines and

technologies can enter the local market. The uninterrupted delivery of services and of the implementation of interventions must be enabled by the availability of all the necessary medical products and technologies; this includes supplies that might be accessed outside

traditional health services (e.g. through pharmacies or online). Even though most self-care interventions are likely to be used outside the healthcare setting, the quality of the products and technologies must be appropriately regulated (see section 2.4.6).

FIG. 2.3. PROCESSES TO GUARANTEE ACCESS TO APPROPRIATE, SAFE AND QUALITY SELF-CARE INTERVENTIONS



Source: adapted from WHO (23).

The security of reproductive health commodities 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 and managing their delivery. Ensuring this security involves planning, implementation, and the monitoring and evaluation of supply chain processes at the programme level. It also demands broader policy advocacy, the management of procurement issues, devising costing strategies, multi-sectoral coordination and addressing contextual considerations. Enabling and strengthening in-country capacity for the security of reproductive health commodities is an essential step in guarding against shortfalls in much-needed reproductive health supplies (24).

2.4.5 FINANCING



Using self-care approaches and technologies to deliver certain healthcare 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 (25). 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.

2.4.6 LEADERSHIP AND GOVERNANCE – THE REGULATORY ENVIRONMENT

With self-care interventions encompassing many different products and places of access, the regulation of a wide range of actors is necessary. 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 (26). Regulation is key in this context, and it is critical that this balances ensuring quality and safety against ensuring access. The detection and correction of any undesirable trends and distortions – any negative impacts or unintended uses of self-care interventions – is also important. The regulatory system also has a role in identifying and preventing 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 (27, 28).

2.4.7 LINKS BETWEEN HEALTH SYSTEMS AND COMMUNITIES



To ensure the safe and effective provision of self-care interventions, mechanisms must be put into place to overcome any barriers to service uptake and use, and any barriers to continued engagement with the health system. These barriers occur at the individual, interpersonal, community and societal levels. They may include challenges such as, among others, social exclusion and marginalization, criminalization, stigma, and gender-based violence and gender inequality.

Strategies are needed across health system building blocks (see Fig. 2.2) to improve the availability, accessibility, acceptability, affordability, uptake, equitable coverage, quality, effectiveness and efficiency of self-care interventions as well as links to services. If barriers to such improvements are left unaddressed, they could undermine health, even where self-care interventions are available; removing them is a critical part of creating an enabling environment for self-care interventions.

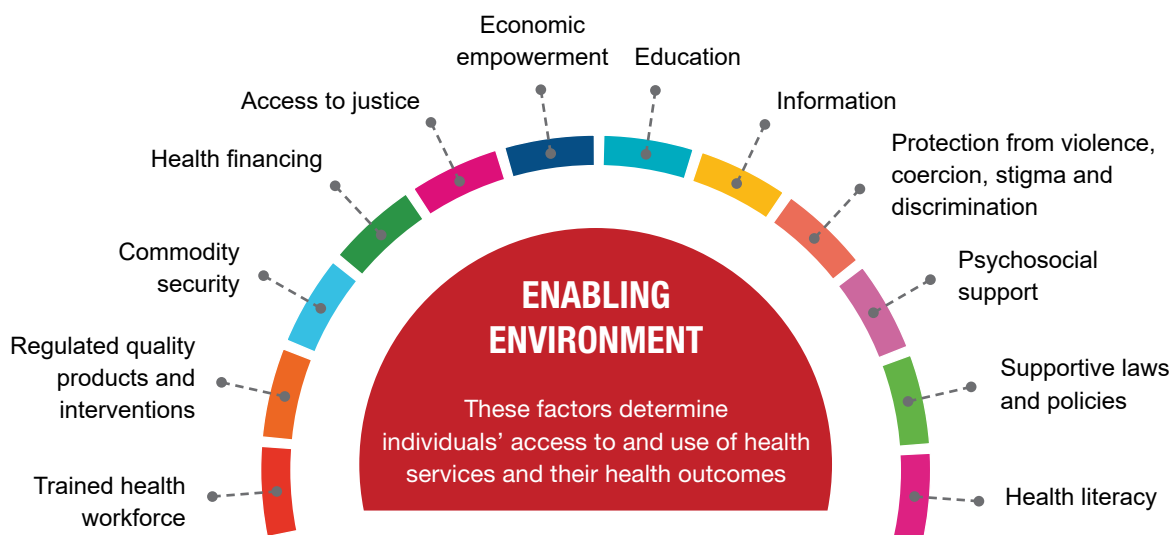
In the context of self-care interventions, bridges between health systems and communities take on particular

importance for ensuring safe, informed and appropriate use of these interventions. This should include outreach to provide information on the traditional options available as well as on the self-care interventions, and how and where to seek support from health services whenever needed, including outreach to communities that may be unaware of new technological advances in self-care products.

2.5 CHARACTERISTICS OF THE ENABLING ENVIRONMENT

The environment around the health system and the individual plays a crucial role in shaping a person's access to and use of health services as well as their health outcomes (see Fig. 2.4). The importance of, for example, the social determinants of SRHR, as manifested in the laws, institutional arrangements and social practices that prevent individuals from effectively enjoying their SRHR, is well documented (9). The importance of the enabling environment is particularly true for self-care interventions, since these are mostly accessed and/or used outside formal health services. This environment must, therefore, be conducive to the realization of health and well-being.

FIG. 2.4. CHARACTERISTICS OF THE ENABLING ENVIRONMENT AFFECTING SELF-CARE INTERVENTIONS



2.5.1 ACCESS TO JUSTICE

Policies and procedures are needed to ensure that all people can safely report, seek redress for, and prevent further 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. The primary considerations in facilitating access to justice must include safety, confidentiality, and choice and autonomy in terms of whether or not an individual wants to report a violation. Users should be able to access a functional system of remedy; in the case of rights violations (e.g. discrimination), such a system provides a way to seek legal redress, by which users can hold duty-bearers, including health workers, accountable for their actions or inactions. A system could also provide other forms of redress and accountability, as formal legal systems may present too high a barrier for an individual seeking redress and prevention of further



harm. Where appropriate, health workers can facilitate access to justice by offering to support clients who want to report violations to the police. Access to justice, redress and the prevention of further harm may take different forms, in particular for communities and individuals who face marginalization and criminalization.

2.5.2 ECONOMIC EMPOWERMENT

Livelihood insecurity, poverty and a lack of resources to meet key needs and expenses contribute to greater vulnerability and poor health outcomes. Socioeconomic vulnerabilities can make it difficult for people to exercise their human rights, such as in situations where individuals are dependent on violent or abusive partners or transactional sex to ensure that their own and/or their



dependants' basic needs are met. There is a risk that self-care interventions shift the costs of care from the health system to the individual (see section 2.4.5), which could exacerbate access inequities. Interventions focused on economic empowerment, poverty reduction and resource access, such as housing and food support, therefore have the potential to improve access to healthcare and to improve health outcomes for all.

2.5.3 EDUCATION

Education, particularly secondary education, is important for empowering people in their health and well-being, and has repeatedly been found to be associated with a wide range of better health outcomes as well as improved

knowledge of how to maintain good health (29, 30). The central role of comprehensive sexuality education (CSE), for example, in empowering young people to take responsible and informed decisions about their sexuality and relationships is well documented (31). Ensuring access to education, including CSE, for all will support informed decision-making about care-seeking and self-care interventions.

2.5.4 PROTECTION FROM VIOLENCE, COERCION, STIGMA AND DISCRIMINATION

Violence can take various forms, including physical aggression, forced or coerced sexual contact, psychological abuse, and controlling behaviours by an intimate partner (32). 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 (32, 33). Violence may undermine people's ability to make and enact health-promoting decisions in their sexual and reproductive life, or to access and use SRH services, including self-care interventions. Further, the negative psychological outcomes of violence may inhibit self-care (34).

The risks of violence that may be affecting people must be considered and mitigated when self-care interventions are used. Efforts to address violence in this context must involve other sectors along with the health sector. While appropriate action around violence could help to 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, transgender and gender-diverse individuals, sexually diverse persons, people who use drugs, and people engaged in sex work.



Stigma and discrimination, both enacted and perceived, can create barriers to accessing SRH services, with important implications for health-seeking behaviours and outcomes. This can be true for certain SRH services in particular, such as abortion, and for specific populations, such as adolescents, transgender and gender-diverse individuals, and people with disabilities. Protecting against such stigma and discrimination is a critical part of the enabling environment for self-care interventions, to ensure equitable access to services for all who need them, without fear of reprisals for seeking information or connecting with health services. This may need intervention at multiple levels, from individuals to communities as well as people working in health facilities and services.

2.5.5 PSYCHOSOCIAL SUPPORT

Early, adequate and tailored psychosocial support (see the definition in Annex 4) helps individuals and communities to heal psychological wounds and rebuild social structures after an emergency or a critical event. It can help to 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 to cope better and become reconciled to everyday life, (iii) help people to resume their regular lives, and (iv) meet community-identified needs (35).

2.5.6 SUPPORTIVE LAWS AND POLICIES

The legal and policy environment shapes the availability of health services and programmes, and the degree to which they are responsive to individuals' needs and aspirations. Laws and public policies are also key tools with which to influence the 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 (36). The barriers created by, for example, the criminalization of adult same-sex consensual sexual conduct and other behaviours, 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 needed to promote access to self-care interventions without compromising quality or safety is a critical area for action to realize SRHR.

2.5.7 HEALTH AND DIGITAL LITERACY

Health literacy is essential to make the most informed choices regarding health for self-carers and caregivers. Improving health literacy in populations provides the foundation on which citizens are enabled to play an active role in improving their own health, to engage successfully with community action for health, and to push governments to meet their responsibilities for health and health equity. Improving people's health literacy can allow them to better interpret, understand and act on health information for better self-care. Health literacy also helps individuals to distinguish between incorrect and correct information. Ideally, a health-literate individual is able to seek and assess the health information they need; to understand and follow instructions for self-care, including administering complex daily medical regimens; to plan and achieve the lifestyle adjustments needed to improve their health; to make informed, positive health decisions; to know how and when to access healthcare when this is needed; and to share health-promoting activities with

others, and address health issues in the community and society (37).

When digital platforms are used for self-care interventions, digital literacy – proficiency in operating digital devices and platforms – needs to be considered. The uptake of self-care interventions delivered through digital channels may be affected by different levels of digital literacy. Some populations, such as adolescents and youth, may have higher levels, so self-care interventions delivered through digital or mobile devices may be more appealing to them (38, 39).

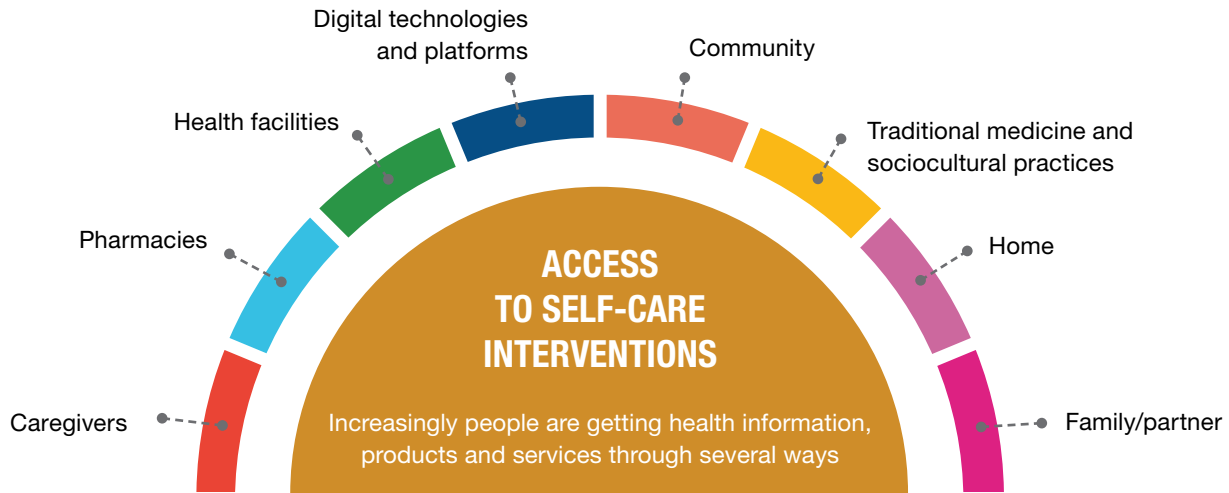
2.6 PLACES OF ACCESS TO SELF-CARE INTERVENTIONS

Increasingly, people access health information, products and services outside formal health facilities (6). Self-care interventions can be accessed through several avenues, giving individuals more choice and improving individual autonomy. Much self-care is done at home, and self-care interventions are often accessed through pharmacies or via digital platforms (such as telehealth or through mobile applications). The places of access to these interventions also include health facilities (such as hospitals, specialized clinics or care homes) and delivery can also be via the community, caregivers or traditional health practitioners (see Fig. 2.5).

2.7 ACCOUNTABILITY

From a human rights perspective, accountability means ensuring the fulfilment of the obligations of government policy-makers and other duty bearers to the rights holders who are affected by their decisions and actions. From an ethics perspective, accountability is about answerability, liability, and the expectation that blameworthy individuals or organizations will be held accountable for their actions (6).

Accountability for self-care interventions is shared among several different sectors and should be considered at all levels – local, national, regional and global. The enabling environment to support self-care interventions must be governed through shared accountability to ensure quality of care and better health outcomes. Self-care interventions require accountability across several fronts of the health system for their fully ethical and appropriate provision (6). Self-care interventions should not be stand-alone products or cause further health system fragmentation but should rather be linked to the health system and supported by it (6). This ensures that the health system remains accountable and can determine how to appropriately interact with and support the implementation of self-care interventions (6).

FIG. 2.5. PLACES OF ACCESS TO SELF-CARE INTERVENTIONS


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3.

Recommendations and key considerations



At a Glance

This chapter presents new and existing evidence-based WHO recommendations on self-care interventions as well as new key considerations on priority areas and interventions that are promising, but require additional research.

Improving antenatal, intrapartum and postnatal care p. 30

Providing high-quality services for family planning, including infertility services p. 40

Eliminating unsafe abortion p. 46

Combating sexually transmitted infections (including HIV), reproductive tract infections, cervical cancer and other gynecological morbidities p. 47

Promoting sexual health p. 50

Addressing noncommunicable diseases, including cardiovascular diseases and diabetes p. 55

Recommendations and key considerations are identified throughout the chapter by these icons:



New
recommendations



Existing
recommendations



Key
considerations



This chapter presents the World Health Organization (WHO) recommendations that have been newly developed and published for the first time in this guideline, alongside the existing recommendations previously published in other WHO guidelines. In addition to the recommendations, which were reached through the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach, this chapter also presents new, adapted or existing good practice statements. For this guideline, the Guideline Development Group (GDG) formulated several key considerations to guide and inform future research and guidelines processes for those questions for which neither recommendations nor good practice statements had been developed. For these questions, the decision not to make a recommendation was largely driven by the limited or non-existent evidence of effectiveness for the self-care option of the intervention. Nonetheless, the GDG deemed that the scarcity of knowledge related to self-care for these critically important topics warranted foregrounding, and the key considerations are presented alongside the recommendations and good practice statements.

The recommendations concern health interventions that reflect the priority areas of the 2004 WHO Global Reproductive Health Strategy. The recommendations are numbered in Table 1 of the executive summary, and given greater detail in the following sections 3.1–3.5. The new and existing recommendations are presented in boxes along with 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 A2.5 of Annex 2), followed by any remarks, including any key considerations highlighted by the GDG. For existing recommendations, the remarks are limited to the title, year of publication and the weblink for the original source guideline.

For each of the new recommendations, which address new topic areas or replace previous recommendations, additional information is presented in this order:

- Background information about the intervention;
- Summary of evidence and the considerations of the GDG, including results on the effectiveness of the intervention (the balance of benefits and risks) and explanations about the certainty of the evidence and the strength of the recommendation, plus information on resource use, feasibility and equity implications, and the acceptability of the intervention to end users and health workers (i.e. relative to end users' and health workers' values and preferences). A rationale underpinning the decisions leading to each recommendation is provided.

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

The key considerations relate to four priority guideline questions for which the GDG judged there to be insufficient evidence to make a recommendation and for which best practice remained uncertain. For each new key consideration, additional information is presented in this order:

- Background information;
- Summary of the important issues noted by the GDG with respect to the question, and the identification of critical research gaps to support future decision-making.

The recommendations presented are particularly suited to low- and middle-income countries (LMICs), where self-care interventions offer innovative strategies that go beyond a conventional health sector response. This is because a well-functioning health system – staffed with trained health workers, supported by a well-maintained infrastructure and a reliable supply of medicines and technologies, backed by adequate funding, strong health plans and evidence-based policies – is the reality in very few countries.

3.1 IMPROVING ANTENATAL, INTRAPARTUM AND POSTNATAL CARE

Despite effective interventions for the prevention or treatment of virtually all the life-threatening maternal complications, and the important progress that has been made in the last two decades, about 295 000 women died during or following pregnancy and childbirth in 2017 (1). It has been established that implementing timely and appropriate evidence-based antenatal care practices can save lives. Crucially, antenatal care is also an opportunity to communicate with and support women, families and communities at a critical time in the course of a woman's life. A positive pregnancy experience is defined as maintaining physical and sociocultural normality, maintaining a healthy pregnancy for mother and baby (including preventing or treating risks, illness and death), having an effective transition to positive labour and birth, and achieving positive motherhood (including maternal self-esteem, competence and autonomy) (2). Services include a package of interventions, including advice and support for individuals 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 (3).



3.1.1 EXISTING RECOMMENDATIONS ON SELF-CARE DURING ANTENATAL CARE AND DELIVERY

	Recommendation
Recommendation 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. <i>(Context-specific recommendation; low certainty evidence)</i>
Recommendation 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). <i>(Low to moderate certainty evidence)</i>
Recommendation 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). <i>(Low to moderate certainty evidence)</i>
Recommendation 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. <i>(Low to moderate certainty evidence)</i>
Recommendation 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). <i>(Low to moderate certainty evidence)</i>
Recommendation 2	When considering the educational interventions and support programmes, no specific format (e.g. pamphlet, videos, role play education) is recommended as more effective.
Recommendation 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.
Recommendation 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.
Recommendation 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.
Recommendation 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.
Recommendation 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.

	Recommendation
Recommendation 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.
Recommendation 9	Pain relief for preventing delay and reducing the use of augmentation in labour is not recommended. <i>(Conditional recommendation; very low certainty evidence)</i>
Recommendation 13	WHO recommends that each pregnant woman carries their own case notes during pregnancy to improve the continuity and quality of care and their pregnancy experience.

3.1.2 ADDITIONAL EXISTING GUIDANCE ON SELF-CARE INTERVENTIONS DURING ANTENATAL AND INTRAPARTUM CARE

WHO also recommends the use of home-based records for the care of pregnant women, mothers, newborns and children to complement facility-based records and to improve care-seeking behaviours, male involvement and support in the household, maternal and child home-care practices, infant and child feeding, and communication between health providers and women/caregivers (4).

Qualitative evidence suggests that women from a variety of settings are likely to favour carrying their case notes, because it offers more opportunity to acquire pregnancy and health-related information, and because of the sense of empowerment this brings. For paper-based systems,

health-system planners also need to ensure that case notes are durable and transportable. Health systems that give women access to their case notes through electronic systems need to ensure that all pregnant women have access to the appropriate technology and that attention is paid to data security. Furthermore, policy-makers should involve stakeholders to discuss the important considerations with respect to the type, content and implementation of home-based records.

In the context of developing SMART (standards-based, machine-readable, adaptive, requirements-based and testable) guidelines (5), WHO released guidance and tools for health workers' digital tracking and decision support during antenatal care contacts, which include components of self-care interventions from the 2019 guideline (6).



3.1.3 NEW RECOMMENDATIONS ON IRON AND FOLIC ACID SUPPLEMENTS DURING ANTENATAL CARE AND DELIVERY

	Recommendation
Recommendation 10a (new)	WHO recommends making the self-management of folic acid supplements available as an additional option to health worker-led provision of folic acid supplements for individuals who are planning pregnancy within the next three months. <i>(Strong recommendation; very low certainty evidence)</i>
Recommendation 10b (new)	WHO recommends making the self-management of iron and folic acid supplements available as an additional option to health worker-led provision of folic acid supplements for individuals during pregnancy. <i>(Strong recommendation; very low certainty evidence)</i>
Recommendation 10c (new)	WHO recommends making the self-management of iron and folic acid supplements available as an additional option to health worker-led provision of iron and folic acid supplements for individuals during the postnatal period. <i>(Strong recommendation; very low certainty evidence)</i>

Remarks:

- Early linkage to antenatal and postnatal care is essential.
- Information on how to monitor possible side-effects and harms (e.g. iron toxicity due to overdosing; child poisoning) is essential.
- Folic acid is to be taken up to 12 weeks gestation.

Background

The use of iron and folic acid supplements during pregnancy is an effective and recommended intervention to reduce maternal anaemia, puerperal sepsis, low birthweight and preterm birth (3, 7). The use of folic acid supplements is recommended as early as possible during pregnancy, and ideally prior to pregnancy, to prevent neural tube defects (3, 8). Postpartum use of iron supplements (either alone or with folic acid) may also reduce the risk of anaemia in settings with a high prevalence of maternal anaemia (9).

Despite the efficacy of these supplements, the use of iron and folic acid supplementation during pregnancy is not reaching its potential impact, because of a lack of consistent use; this is attributed to a range of issues, including supply and demand factors (10–14), side-effects, cost and access.

Promoting over-the-counter or home-use folic acid or iron and folic acid supplementation when planning a pregnancy (before pregnancy), during pregnancy and/or postpartum (after delivery) may help to expand the delivery of micronutrient supplements beyond the clinical care setting and ultimately improve maternal, fetal and newborn health outcomes.

Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group selected to compare the self-management of iron and folic acid, or folic acid supplements with provider-initiated provision in relation to pregnancy.

The PICO (population, intervention, comparator, outcome) questions were:

- Should individuals who are planning pregnancy self-manage the use of folic acid supplements or be offered only provider-led management of such supplements?
- Should pregnant individuals self-manage the use of iron and folic acid supplementation as per international guidance (currently either a daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid, or an

intermittent [e.g. weekly] dose of 120 mg of elemental iron and 2.8 mg of folic acid) or be offered only provider-led management of such supplements (3)?

- Should postnatal individuals self-manage the use of iron (with or without folic acid) supplementation for at least three months after delivery as per international guidance (currently either a daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid, or an intermittent [e.g. weekly] dose of 120 mg of elemental iron and 2.8 mg of folic acid) or be offered only provider-led management of such supplements (10)?

A systematic review was conducted of the extant literature in three areas relevant to these questions: the effectiveness of the intervention on maternal and/or fetal and newborn outcomes in the pre-pregnancy, pregnancy or postpartum periods; the values and preferences of end users; and the cost and/or cost-effectiveness of the intervention during pre-pregnancy, pregnancy and postpartum periods. The review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (15). The protocol was published at PROSPERO, the international prospective register of systematic reviews (registration number CRD42020205548). The systematic review has been published in a peer-reviewed journal (16).

Results

Of 2587 unique citations identified, no studies met the inclusion criteria. The articles were excluded generally because they lacked the outcomes of interest, lacked comparison groups or focused on supplement use in general and did not specifically look at folic acid or iron and folic acid supplementation. Lastly, no articles presented cost or cost-effectiveness data.

Certainty of the evidence for the recommendation

No direct evidence was identified and the overall certainty of the evidence was very low.

Rationale for the strength and the direction of the recommendation

The GDG noted that that this intervention was already widely used in many countries with no major concerns or controversy. Harms related to possible toxicity or poisoning were discussed and the GDG agreed that health literacy and education around this self-care intervention would be an important component to promote its correct use. The question of how best to build health literacy, however, was an important research gap that should be addressed. The GDG deemed that, overall, the balance of large benefits and trivial harms was in favour

of making self-management an additional choice for individuals. Given the likely impact on improving equity and accessibility if self-management is made available as an additional choice to individuals, the GDG made a strong recommendation.

Resource use



No direct cost evidence was identified in this review.

Lower costs of supplements in general, however, have been shown to increase uptake. When private facilities factor in the costs of access to antenatal care, the costs of supplements may be lower here. In low-income countries, cost is largely dependent on packaging. The GDG discussed that costs for iron and folic acid supplements were generally low, but that there may be additional costs for the end user to reach the place of purchase.

Feasibility

All GDG members agreed that this recommendation was feasible given that iron and folic acid supplementation was already available in many places globally.

Equity and human rights



No major equity or human rights issues were foreseen if iron and folic acid supplementation were made available as an additional option to

provision through the healthcare system. The GDG agreed that, despite insufficient information, there was a 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.

Acceptability of the intervention: values and preferences of end users and health workers



No studies were included in the values and preferences review. Indirect evidence from studies suggests that the facilitators of supplement use in general (not specific to folic acid or iron and folic acid) include convenient supply, cost/affordability, health worker messaging and personal risk perception. Barriers to use include poor communication with health workers, scepticism about the effectiveness and necessity of supplements, and perceptions of the supplement itself. It is important to note, though, that these facilitators and barriers were only found for those end users who were currently pregnant.

As described in Chapter 1, section 1.7, a Global Values and Preferences Survey (GVPS) was also conducted among health workers and potential end users on their values and preferences in relation to this and other interventions covered by the new recommendations in this guideline.



The results show that more health workers than people in the general population are aware of iron and folic acid supplementation. Convenience and cost were the top reasons for use. Most health workers had provided iron and folic acid supplements, although slightly fewer were comfortable with it. Pharmacies were identified as the top choice of location for access.



3.1.4 NEW RECOMMENDATION ON SELF-MONITORING OF BLOOD PRESSURE DURING PREGNANCY

	Recommendation
Recommendation 11 (new)	WHO suggests making the self-monitoring of blood pressure during pregnancy available as an additional option to clinic blood pressure monitoring by health workers during antenatal contacts only, for individuals with hypertensive disorders of pregnancy. <i>(Conditional recommendation; very low certainty evidence)</i>

Background

Hypertensive disorders of pregnancy are among the leading causes of pregnancy-related mortality and morbidities for women and adolescent girls and their newborns, particularly in LMICs, affecting around 10% of all pregnant individuals globally (17–19). Hypertension in pregnancy can also lead to long-term disability such as chronic hypertension in women and adolescent girls, and

pre-eclampsia, which can result in a range of morbidities in newborns, including low birth weight and respiratory distress syndrome (20–22). Early hypertensive treatment and timely delivery can prevent morbidity and, potentially, mortality (23). Improving the management of hypertension during pregnancy is thus an essential aspect of quality care for maternal and neonatal health.

Routine antenatal care visits generally include blood pressure measurement, but blood pressure changes may be missed between visits. The self-monitoring of blood pressure (SMBP), a strategy in which patients take a more active role in their own healthcare by measuring their own blood pressure, may be particularly useful in settings where access to and resources for conventional antenatal care are limited.

SMBP has been reviewed extensively for the general hypertensive population (i.e. not just in pregnancy). SMBP compared with clinic-based monitoring is associated with improved hypertension control (24–26), although its impact depended on the specific outcomes that were assessed or implemented (27).

Two recent reviews reported mixed benefits of SMBP compared with clinic-based monitoring for multiple maternal and neonatal outcomes among pregnant and postpartum individuals (28, 29), suggesting that home-based monitoring may not be inferior to receiving provider-administered care. However, less is known about SMBP specifically for pregnant individuals and their newborns (30).

A recent review found that SMBP had limited impact on improving blood pressure control unless accompanied by certain co-interventions (31).

Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group decided to examine whether SMBP should be made available in addition to clinic check-ups among individuals with hypertensive disorders of pregnancy.

The PICO question was:

- Should SMBP among individuals with hypertensive disorders of pregnancy be made available in addition to clinic check-ups?

A systematic review was conducted of peer-reviewed journal publications in any location or language. It included literature in three areas relevant to this question: the effectiveness of the intervention, the values and preferences of end users and health workers, and cost information. The included studies on pregnant individuals with hypertension (gestational hypertension, chronic hypertension and pre-eclampsia) compared individuals who were self-monitoring blood pressure (either by the pregnant individual or by another layperson, such as a family member) with those whose blood pressure was monitored in the clinic by health workers during antenatal care contacts only. The studies measured one or more of the

following maternal outcomes: maternal mortality or near miss; eclampsia or pre-eclampsia (for those without pre-eclampsia prior to entering the study); long-term risk or complication (stroke, cardiovascular outcomes, chronic kidney disease, or chronic hypertension); autonomy (self-efficacy, self-determination, empowerment); HELLP syndrome (haemolysis, elevated liver enzymes and low platelet count); caesarean section; antenatal hospital admission; adverse pregnancy outcomes (spontaneous abortion, premature rupture of membranes, placental abruption); device-related issues (e.g. test failure; problems with manufacturing, packaging, labelling or instructions for use); follow-up care with appropriate management; mental health and well-being (e.g. anxiety, stress, self-harm); social harms (stigma, discrimination, intimate partner violence); and neonatal outcomes (stillbirth or perinatal death; birthweight/size for gestational age; Apgar [appearance, pulse, grimace, activity and respiration] score) (see Annex 6 for further details of the PICO questions).

The review followed PRISMA guidelines (15), and the protocol was published at PROSPERO (registration number CRD42021233839), and the systematic review in a peer-reviewed journal (32).

Results

The systematic review included 1794 unique references, of which 91 were retained for the full-text review. Six studies were ultimately included in the effectiveness review, seven in the values and preferences review, and one in the cost review. Of the six studies in the effectiveness review, one randomized controlled trial (RCT) and five observational studies were included. All the studies were from high-income countries, and they compared daily SMBP using an automated blood pressure monitor, recorded on paper or submitted via app, with routine care at antenatal visits (one study) and routine care at prenatal visits (two studies).

Two observational studies found that SMBP had no impact on maternal morbidity. The RCT found that SMBP was associated with higher caesarean section rates among pregnant individuals with chronic hypertension (risk ratio: 2.01, 95% confidence interval: 1.22–3.30), but was associated with no difference among those with gestational hypertension; found no difference in the pre-eclampsia rate among pregnant women with either chronic or gestational pre-eclampsia (risk ratio: hypertension; no impact on antenatal hospital admissions; no impact on stillbirth or perinatal death); and found that SMBP was associated with lower birthweight and a higher rate of infants being born small for their gestational age among pregnant individuals with chronic hypertension (although this was not a statistically significant difference), but had no impact among those with gestational hypertension.

No quantitative comparative data were identified from either the RCTs or the observational studies related to maternal mortality or near miss; long-term risk or complications (e.g. stroke, cardiovascular outcomes, chronic kidney disease or chronic hypertension); autonomy (measured by self-efficacy, self-determination, empowerment); HELLP syndrome; device-related issues; follow-up care with appropriate management; mental health and well-being (e.g. anxiety, stress, self-harm); social harms (e.g. stigma, discrimination, intimate partner violence); or Apgar score.

Certainty of the evidence for the recommendation

The available evidence was of moderate to very low certainty overall.

Rationale for the strength and the direction of the recommendation

The GDG made a conditional recommendation in favour of the intervention. In the wording of the recommendation, the GDG emphasized that the intervention should be made available as an additional approach, with early linkage to and continuation of antenatal care, and accompanied by comprehensive information and guidance on the interpretation of blood pressure readings and actions required for SMBP.

Resource use



There was evidence that, compared with usual care, SMBP during pregnancy decreased costs for the overall health system, in part due to fewer clinic visits. A study in the United Kingdom of Great Britain and Northern Ireland found that, among hypertensive pregnant women using an automated blood pressure machine linked to paper notes, the health system would see greater weekly savings per patient among those using SMBP, compared with those using a smartphone app or traditional monitoring.



The GDG agreed that costs would vary by health system and the cost of the device. It also acknowledged that, if the individual was unable to read the blood pressure monitor and the blood pressure readings, inaccurate readings would also incur a cost.

Feasibility

All GDG members agreed that this recommendation was feasible but noted that considerations around literacy, counselling and reinforcement/mentorship were incorporated for implementation.

Equity and human rights

The GDG agreed that, despite insufficient information, there was potential for this self-care intervention to

improve equity because it provided choice to the individual, fostered participation in their own care and can promote the right to privacy.

Acceptability of the intervention: values and preferences of end users and health workers

Overall, seven studies from four countries were included in the values and preferences review. There were three qualitative studies, three quantitative studies and one mixed-methods study. The included studies were generally among pregnant individuals with, or at risk of, hypertensive disorders. One study examined the values and preferences of health workers. All seven studies took place in high-income countries (in Europe, North America and Oceania).

The evidence suggested that most end users found SMBP highly satisfactory or acceptable. They cited various factors for liking self-monitoring, including the device's ease of use, the convenience and the ability to help them to feel empowered and less anxious or stressed.

Barriers included some variations in end users' perceptions of ease of use, and some users perceived the SMBP device to be uncomfortable and noisy.

The practice of SMBP created the impression that end users were taking a greater role in self-care on blood pressure, pregnancy and health through taking the initiative and using the device. The resulting sense of empowerment helped to alleviate anxiety. Despite SMBP reducing the number of care visits, many patients whose SMBP devices enabled them to communicate with their health worker (i.e. through apps for remote monitoring and telehealth) expressed being even more connected to their care team.

Women generally agreed that they would continue to use SMBP and would recommend others to do the same.



Health workers acknowledged the convenience and comfort of clients monitoring at home and were generally in favour of SMBP, but some expressed concerns that SMBP may induce anxiety or falsely reassure women about their health.

As described in Chapter 1, section 1.7, a GVPS was also conducted among health workers and potential end users to survey their values and preferences in relation to this and other interventions covered by new recommendations in this guideline. Most participants in the GVPS were aware of SMBP and had used it. Convenience and cost were the main factors important to the decision.



3.1.5 KEY CONSIDERATIONS FOR SELF-TESTING FOR PROTEINURIA

	Recommendation
Key consideration 1	For pregnant individuals with non-proteinuric hypertension, there may be some benefit of home-based urine self-testing compared with inpatient care to detect proteinuria, but clinicians need to balance this with the additional burden placed on the individual.

Background

Pre-eclampsia is generally diagnosed in pregnant individuals who have an onset of hypertension and subsequent proteinuria (greater than normal amounts of protein in urine) during pregnancy (33). About a third of individuals with new-onset proteinuria after their 20th week of pregnancy may ultimately contract pre-eclampsia (34).

Measuring proteinuria early in pregnancy can help to identify individuals who are at high risk of pre-eclampsia and related complications, including preterm delivery and fetal malformations (35). Screening for proteinuria is typically through dipstick urinalysis, which needs a small sample of clean urine and gives a result rapidly (36).

Dipstick urinalysis is typically done at the point of care during routine prenatal visits; however, emerging research suggests that screening can also be done through self-testing (37). Given that pre-eclampsia is a significant cause of maternal and perinatal morbidity and mortality, affecting between 2% and 8% of pregnancies worldwide, self-testing for proteinuria may be useful to help to identify the risk of pre-eclampsia in pregnant women, increase end-user empowerment and reduce the burden on the health system.

Summary of evidence and considerations

The WHO Guideline Steering Group decided to examine whether self-testing for proteinuria during pregnancy should be available in addition to clinic check-ups.

The PICO question was:

- Should self-testing for proteinuria during pregnancy be available in addition to clinic check-ups?

A systematic review assessed three areas relevant to this topic: (i) effectiveness of the intervention, (ii) values and preferences of end users and health workers, and (iii) cost information. The PRISMA guidelines (15) were followed, and the protocol was published at PROSPERO (registration number CRD42021233845) and the systematic review in a peer-reviewed journal (38).

Results

Of the 334 unique records, 20 were retained for full-text review, two studies were included in the values and preferences review and none in the cost review. The studies included pregnant women with non-proteinuric hypertension and the comparison was with the provision of proteinuria testing during inpatient care. Most studies were from high-income countries.

Overall, there was no statistically significant difference between self-testing and clinic-based testing for proteinuria in any of the outcomes for which data were available. In general, both the women and their health worker approved of self-testing for reasons including that it gave the women a greater role in self-care and reduced their visits to clinics, although some health workers emphasized the need to train end users for proper testing and appropriate follow-up actions.

The GDG agreed that the sense of self-empowerment, ownership of care and decreased frequency of clinic visits were important considerations for making self-testing available for proteinuria. However, the GDG questioned the clinical utility of urine dipstick testing, in part due to the lack of a gold standard for the diagnosis of proteinuria in pregnancy. Urine dipstick testing for this use has several limitations, including variability in urine concentration, which depends on fluid status, the time of day during which the test takes place, and whether the subject has urinated prior to testing. Furthermore, the GDG noted that clinical guidelines highlighted the need for information beyond the presence of proteinuria to diagnose and manage complications of pregnancy, as non-proteinuric hypertensive disease is a recognized entity that has outcomes quite similar to those of pre-eclampsia.

Nonetheless, the GDG agreed that the evidence showed that self-testing for proteinuria was not harmful. Further studies would be needed to assess whether self-testing for proteinuria as part of routine prenatal care could improve pregnancy outcomes.

Feasibility

The GDG agreed that there was evidence for the feasibility and acceptability of self-testing for proteinuria and that it generally did not negatively impact the maternal and neonatal health outcomes. However, the GDG agreed that more research in resource-limited settings was needed.

Equity and human rights

Despite the recognized limitations, initial proteinuria testing based on dipstick urinalysis with follow-up tests as indicated may help to triage patients appropriately in resource-limited settings, although the value added by routine proteinuria testing via urine dipsticks may be limited in well-resourced settings. The testing method remains a standard tool for testing for proteinuria in the setting of LMICs, where the affordability of testing is a key issue.

Acceptability of the intervention: values and preferences of end users and health workers

Two quantitative feasibility studies for self-testing urine for proteinuria during pregnancy, one from the

United Kingdom (37) and the other from the United States of America (USA) (39), found that most pregnant women were highly satisfied with self-testing for proteinuria or preferred it over in-clinic testing. Ease of use was the common reason across the two studies for liking self-testing.



Most of the surveyed health workers saw self-testing for proteinuria as a way for women to detect pre-eclampsia early, to empower themselves and to save time and money (37). Close to 80% believed that self-testing would enhance their usual care provision, although about 70% also reported that they would repeat urinalysis despite women self-testing. Health workers also raised concerns, though, about pregnant individuals' aptitudes and suitability for self-testing, their abilities to act appropriately on any positive results, and whether self-testing might increase the demand for urgent clinic-based services.



3.1.6 NEW RECOMMENDATION ON SELF-MONITORING OF BLOOD GLUCOSE DURING PREGNANCY

	Recommendation
Recommendation 12 (new)	WHO recommends making self-monitoring of glucose during pregnancy available as an additional option to clinic blood glucose monitoring by health workers during antenatal contacts, for individuals diagnosed with gestational diabetes. <i>(Strong recommendation, very low certainty evidence)</i>

Background

Gestational diabetes mellitus is defined as glucose intolerance resulting in clinical hyperglycaemia with onset or first recognition during pregnancy (40, 41). Hyperglycaemia during pregnancy is associated with adverse maternal and newborn health outcomes, both short-term and long-term ones.

The self-management of gestational diabetes through lifestyle changes (diet and exercise) is considered the first-line treatment by many clinical professional associations, including the American Diabetes Association and the International Diabetes Federation. One component of the self-management of gestational diabetes is self-monitoring of blood glucose levels, which is used clinically to monitor the effectiveness of lifestyle modification, guide the intensification of treatment and inform antenatal care.

Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group decided to examine self-monitoring of blood glucose (SMBG) in addition to clinic check-ups among individuals with gestational diabetes.

The PICO question was:

- Should self-monitoring of blood glucose among pregnant individuals with gestational diabetes be made available in addition to clinic check-ups?

The extant literature was reviewed in three areas relevant to this question: effectiveness of the intervention, values and preferences of end users and health workers, and cost information. The review followed PRISMA guidelines (15),

and the protocol was published at PROSPERO (registration number CRD42021233862) and the systematic review in a peer-reviewed journal (42).

The review examined the evidence for SMBG compared with monitoring by a health worker within the antenatal care (clinic) setting. Although many products, devices and apps can be used to self-monitor blood glucose, SMBG was defined as the home-based use of finger-prick devices, continuous glucose monitoring (including real-time), flash glucose monitoring or a urine dipstick for glucose testing.

Results

Of the 1871 unique records, 78 were retained for full-text review. Six studies were ultimately included in the effectiveness review, five in the values and preferences review and one in the cost review. None of the studies compared SMBG with clinic surveillance of blood glucose, but three RCTs that compared SMBG with no treatment for gestational diabetes mellitus were included in the analysis. The two larger RCTs (around 500 individuals in each arm) compared the clinical and healthcare utilization outcomes with SMBG, as part of a package of interventions for gestational diabetes treatment, against those with routine care during antenatal contacts; the third, smaller RCT compared pregnancy and psychosocial outcomes with SMBG versus periodic monitoring during prenatal visits.

The GDG agreed that, while no studies directly compared SMBG with monitoring in the antenatal clinic setting, the results highlighted the value of SMBG as part of a larger programme of treatment for gestational diabetes mellitus.

Pregnant individuals found SMBG acceptable, and they recognized benefits that included convenience, ease of use and increased confidence.

The potential drawbacks of SMBG as part of the treatment of gestational diabetes mellitus include increased healthcare use. One small study suggested potential cost savings for SMBG among people with insulin-dependent diabetes during pregnancy; however, no studies examined out-of-pocket costs to individuals compared with health system costs.

All studies included in the meta-analysis were conducted in high-income countries.

Certainty of the evidence for the recommendation

The available evidence was of very low certainty overall.

Rationale for the strength and the direction of the recommendation

The GDG made a strong recommendation in favour of the intervention, and emphasized in the wording of this recommendation that the intervention should be made available as an additional approach and accompanied by comprehensive information and guidance on SMBG, including on blood glucose readings.

Resource use



No studies investigated the economic effects of SMBG in people with gestational diabetes mellitus. One study done in the USA reported the economic effects of SMBG being done by women with insulin-dependent diabetes during pregnancy, thus providing indirect evidence for SMBG for gestational diabetes mellitus. Patients in the group using a reflectance colorimeter (for SMBG) spent an average of 1.3 days in hospital, at a total average cost of over US\$ 590, compared with the control group (conventional outpatients) being hospitalized for an average 3.8 days, at an average cost of more than US\$ 1700. Only two of the nine patients in the SMBG group needed to be admitted, compared with five of the nine patients in the control group.



The GDG agreed that costs would vary by health system.

Feasibility

All GDG members agreed that this recommendation was feasible but noted that considerations around literacy, counselling and reinforcement/mentorship should be incorporated for implementation.

Equity and human rights

The GDG agreed that, despite insufficient information, there was potential for this self-care intervention to improve equity because it provided choice to the individual, fostered participation in their own care and could promote the right to privacy.

Acceptability of the intervention: values and preferences of end users and health workers

The review included five studies from Asia, Europe and North America (all high- or upper-middle-income countries) – three quantitative studies, one RCT with qualitative in-depth interviews and one qualitative study (43–48).

All the feasibility studies for specific blood glucose management systems found that most individuals

supported SMBG. The reasons for liking SMBG included health benefits, convenience, ease of use and increased confidence/control/motivation/self-awareness. End users saw SMBG as a supplement to, not a replacement for, contact with health professionals. Reasons for disliking SMBG included the challenge of incorporating it into daily life and the frustration if self-monitoring conflicted with hospital advice. Health workers acknowledged the convenience of patients monitoring their blood glucose at home and trusted SMBG devices, but were wary of technical problems.

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

Family planning is essential for promoting the well-being and autonomy of individuals, couples, their families and their communities. Quality care in family planning is paramount for ensuring progress towards achieving high standards of health for all. The following are five elements of quality of care in family planning (49):

- the choice of a wide range of contraceptive methods;
- evidence-based information on the effectiveness, risks and benefits of different methods;
- competent, trained health workers;
- relationships between health workers and end users based on respect for informed choice, privacy and confidentiality; and
- the appropriate constellation of services being available in the same locality.

Individuals with an unmet need for contraception who report not wanting any more children or wanting to delay the next child may have an unintended pregnancy. Unintended pregnancies remain an important public health issue. Globally every year, 74 million women living in LMICs have unintended pregnancies; this leads to 25 million unsafe abortions and 47 000 maternal deaths every year.

WHO recommends self-care interventions as ways to improve people's contraceptive options and their choices of place to access these. Such self-care interventions include self-injectable contraception and the over-the-counter availability of oral contraception (50).



3.2.1 EXISTING RECOMMENDATIONS ON SELF-CARE WITH USE OF CONDOMS AND ORAL CONTRACEPTIVES

	Recommendation
Recommendation 14	Self-administered injectable contraception should be made available as an additional approach to deliver injectable contraception for individuals of reproductive age. <i>(Strong recommendation; moderate certainty evidence)</i>
Recommendation 15	Over-the-counter oral contraceptive pills (OCPs) should be made available without a prescription for individuals using OCPs. <i>(Strong recommendation; very low certainty evidence)</i>
Recommendation 17	Home-based ovulation predictor kits should be made available as an additional approach to fertility management for individuals attempting to become pregnant. <i>(Strong recommendation; low certainty evidence)</i>
Recommendation 18	The 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.
Recommendation 19	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. <i>(Strong recommendation; moderate certainty evidence)</i>

	Recommendation
Recommendation 20a	Provide up to one year's supply of pills, depending on the woman's preference and anticipated use.
Recommendation 20b	Programmes must balance the desirability of giving women maximum access to pills with concerns regarding contraceptive supply and logistics.
Recommendation 20c	The resupply system should be flexible, so that the woman can obtain pills easily in the amount and at the time she requires them.

3.2.2 ADDITIONAL EXISTING GUIDANCE ON SELF-CARE IN FAMILY PLANNING

The WHO guidance *Medical eligibility criteria for contraceptive use* 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 and barrier methods, including condoms (male latex, male polyurethane and female condoms), the diaphragm (with spermicide) and the cervical cap (51).

The guidance notes: "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 document provides further guidance on the use of barrier methods depending on the user's personal characteristics and reproductive history, cardiovascular disease, rheumatic diseases, neurological conditions, depressive disorders, reproductive tract infections and

disorders, HIV/AIDS, other infections, endocrine conditions, gastrointestinal conditions, anaemias and drug interactions, plus additional comments.

Regarding barrier methods, the guidance 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."

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



3.2.3 NEW RECOMMENDATIONS ON OVER-THE-COUNTER AVAILABILITY OF EMERGENCY CONTRACEPTION

	Recommendation
Recommendation 16 (new)	WHO recommends making over-the-counter emergency contraceptive pills available without a prescription to individuals who wish to use emergency contraception. <i>(Strong recommendation; moderate certainty evidence)</i>

Background

Access to emergency contraception (EC) varies around the world. In some countries, EC is available over the counter (so without the need for a prescription). This includes both off-the-shelf availability (with no screening)

and behind-the-counter pharmacy access (requiring eligibility screening by trained pharmacy staff) (52). In other countries, there is no over-the-counter access, and a prescription from a health worker is required (52).

The 2019 guideline included a recommendation on over-the-counter oral contraceptive pills informed by a systematic review that showed they may result in higher continuation rates and limited contraindications among users, and were generally supported by patients and health workers (53). This review and recommendation did not include over-the-counter delivery of EC. EC is effective in preventing pregnancy if used within five days of sexual intercourse, and may be used in situations such as unprotected intercourse, having concerns about possible contraceptive failure or incorrect use, and sexual assault. With an estimated 44% of pregnancies globally being unintended (52), making oral contraceptive pills, including EC, easier to access in more settings could contribute to reducing this proportion.

Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group decided to examine whether emergency contraceptive pills could be made available without a clinician's prescription.

The PICO question was:

- Should emergency contraceptive pills be made available without a clinician's prescription?

A systematic review was conducted of the extant literature in three areas relevant to this question: effectiveness of the intervention, values and preferences of end users and health workers, and cost information. The review followed PRISMA guidelines (15), and the protocol was published at PROSPERO (registration number CRD42021231625) and the systematic review in a peer-reviewed journal (54).

Results

The systematic review included 2581 unique references, of which 129 were retained for full-text review. Nineteen studies (in 21 articles) were ultimately identified that met the inclusion criteria for the effectiveness review, 55 values and preferences studies, and three cost studies. The 19 studies in the effectiveness review comprised one RCT and 18 observational studies. The studies came from eight countries, all high-income settings. Most of the studies presented data on EC uptake, changes in sexual and reproductive health (SRH) practices and behaviour, or abortion. Only one study assessed side-effects, adverse events or social harms.

Four ecological studies from the USA assessed the impact of pharmacy-access EC on abortion rates per 1000 women. These studies found no difference in overall abortion

rates with pharmacy-access EC. Two of these studies, however, identified significant decreases among younger age groups: a decrease of 1.6 abortions per 1000 women aged 18 and 19 years ($P < 0.05$) (55), and a decrease of 1.97 per 1000 among women aged 15–19 years ($P < 0.01$) (56). Given the unique barriers faced by younger women accessing prescription-only EC in many settings, it may be that increased access to over-the-counter EC has unique benefits for younger women.

While many studies found that women valued the privacy and control offered by over-the-counter EC, two studies found that women were concerned about having limited interaction with health workers in true over-the-counter delivery. In both of these studies, while there was widespread support for prescription-free EC (between 78% and 100% support), a large proportion of women expressed a preference for behind-the-counter modalities that allowed for interaction with a health worker.

In many settings, over-the-counter EC is offered as one of an array of options, including receiving EC from behind the counter, via prescription or on store shelves (truly over the counter). One study included in the effectiveness review used a blended modality: women could choose whether to obtain EC from a health worker. This study found no difference between groups, and an overall high level of knowledge of EC use, although pharmacy-access EC resulted in higher use and satisfaction. Given this and the findings about the effectiveness of over-the-counter EC, blended delivery modalities in which users can choose where and how to access EC may be most responsive to a range of user preferences.



Health workers expressed concern that providing EC over the counter might not allow sufficient education or counselling, including about how to use the contraceptive correctly and counselling about other routine SRH services (including the use of other contraceptives, and screening for cervical and breast cancers and STIs). No studies assessing correct use in over-the-counter versus prescription-only delivery modalities were identified. One study from the United Kingdom, however, found no significant difference in the correct knowledge (as distinct from the correct use) of EC between women receiving EC on prescription versus over-the-counter, with correct knowledge higher than 90% for both groups. Another included study found no significant difference between over-the-counter and prescription delivery in the percentage of end users reporting that they had received adequate information about EC. Future research should investigate this further, to

assess whether correct knowledge of EC translates to correct use in over-the-counter modalities. Research in LMICs is also needed.

Certainty of the evidence for the recommendation

The available evidence was of moderate certainty overall.

Rationale for the strength and the direction of the recommendation

The GDG made a strong recommendation in favour of the intervention. The GDG put the emphasis on equity, which is supported by the increased availability made possible by over-the-counter access, and on high feasibility, given that the intervention is already available in many countries.

Resource use



Results from cost studies of over-the-counter EC suggest making it available through pharmacy access in North America should result in lower costs for the health sector (for both private insurance and public payers). Three modelling studies met the inclusion criteria for the cost review. Two of these were from the USA and one was from Canada. All examined the impact of pharmacy-access EC (not truly over the counter) and found that it was expected to lead to lower health sector costs across a range of assumptions. No studies examined other sector costs, patient and family costs or productivity impacts. The lack of data on the cost impacts for patients and families will be important to consider as over-the-counter EC access expands.



The GDG agreed that over-the-counter EC was cheap in many places, noting that government subsidies should be retained when distribution is transferred to an over-the-counter approach. The GDG expressed concerns that the burden of payment may fall to end users themselves if their health insurance did not cover over-the-counter availability, thus risking a decrease in accessibility. On the other hand, this intervention may 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.

Feasibility

The GDG agreed that the intervention was feasible, given that over-the-counter EC was already in use in many countries.

Equity and human rights



The GDG agreed that this intervention was likely to increase access, reduce discrimination and support human rights, especially among adolescent girls and young women, and among individuals of diverse sexual orientation and gender identity and

expression. This was because the availability of EC might remove the need to see a health worker and/or to get third-party permission – from a parent, partner or spouse. Attention to context is important, however, as in some countries EC may not be sold to unmarried individuals or be readily available over the counter, but rather behind the counter. The evidence suggests that providing EC over the counter may be cost-saving and responsive to users' preferences, while introducing no negative sexual and reproductive health and rights (SRHR) outcomes.

Acceptability of the intervention: values and preferences of end users and health workers

Overall, 55 studies from 33 countries were included in the values and preferences review. There were 38 quantitative studies (all cross-sectional surveys), 11 qualitative studies and six mixed-methods studies. Twenty-one studies included end users, 33 studies included pharmacists or other health workers or professional stakeholders, and one study included both groups.

Of the included studies, most were in the USA (19 studies) and the United Kingdom (eight), followed by Sweden (five), Canada (four), Australia (three), India (three), South Africa (two) and the Democratic People's Republic of Korea (two). One study was conducted in each of these countries: Austria, Barbados, Belgium, Bulgaria, Czechia, the Democratic Republic of the Congo, France, Germany, China, Hong Kong Special Administrative Region, Hungary, Indonesia, Jamaica, Kazakhstan, Lithuania, Nicaragua, Norway, Pakistan, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Slovakia and Spain.

Support for over-the-counter EC among end users in the values and preferences studies varied widely within and across countries, ranging from 12% support among college students in India to 100% among women who used over-the-counter EC in Sweden. End users broadly supported over-the-counter EC because they thought it offered improved access/availability, convenience, more-flexible hours (particularly weekend hours), confidentiality/privacy/anonymity and reduced cost. End users also anticipated that over-the-counter delivery would offer less opportunity for judgement from a health worker and greater control for women.

End users who did not support over-the-counter EC expressed concern about a potential lack of privacy or increased cost, and preferred more-personal contact with a health worker for support and information. They also expressed some concerns about increased risk behaviour. One study noted this concern was for others, not for users

themselves: the individuals participating in the study, all of whom were EC users, did not believe that their own behaviour would be shaped by EC use.



In the values and preferences studies among pharmacists and other health workers and professionals, support for over-the-counter EC ranged widely. In quantitative surveys, support from pharmacists ranged from 16% in South Dakota, USA, to 97% in San Francisco, USA. Among doctors, support was generally lower, ranging from 6.1% in the Democratic People's Republic of Korea to 68.9% in Canada. Health workers supported over-the-counter EC for broadly similar reasons to those of end users. Some studies found that health workers had concerns about side-effects, including the inability to communicate about side-effects in over-the-

counter delivery modalities and concerns about long-term impacts of repeated EC use. In contrast, one study found that health workers supported over-the-counter delivery because they thought that EC had relatively few side-effects.

Health workers were also found to have concerns about increased risk behaviour, misuse or repeated use of EC, and communication. Specifically regarding communication, health workers were concerned about discouraging the use of other contraceptives and thought that over-the-counter delivery might preclude delivery of necessary education and counselling. In some studies, health workers had religious or moral concerns about over-the-counter delivery. One study found that these concerns were more common among health workers who believed EC was a form of abortion.



3.2.4 NEW RECOMMENDATION ON PREGNANCY SELF-TESTING

	Recommendation
Recommendation 21 (new)	WHO recommends making self-testing for pregnancy available as an additional option to health worker-led testing for pregnancy, for individuals seeking pregnancy testing. <i>(Strong recommendation; very low certainty evidence)</i>

Background

Urine tests for pregnancy measure the presence of human chorionic gonadotropin and are widely used to detect pregnancy in both home and clinical settings. While urine pregnancy self-tests are available over the counter in many high- and middle-income settings, in many LMICs, they may be financially inaccessible to most people outside of public health services, or unavailable altogether, leading individuals with the sole option of health facility-based blood tests to confirm pregnancy. Most countries in the WHO Eastern Mediterranean Region, for example, have pregnancy self-testing widely available in private pharmacies, particularly in urban settings, and these are used mainly by people with higher socioeconomic resources, due to cost and knowledge (57).

Providing pregnancy tests for home use may have a range of benefits for different populations. In Madagascar, randomized trial data have shown that providing pregnancy tests to community health workers (CHWs) for home distribution can increase both engagement in antenatal care services (54) and in contraceptive services, since a negative pregnancy test is necessary before initiating some contraceptive methods (58). Home pregnancy tests have been shown to be an acceptable and feasible option for follow-up among couples undergoing

assisted reproduction (59). There is also evidence supporting the efficacy, safety and acceptability of urine pregnancy tests instead of an ultrasound to confirm the effectiveness of a medical abortion (60, 61).

Many people in resource-constrained settings are not able to decide whether to have children, or how many children to have and when; increased access to self-care interventions such as pregnancy self-tests could support such people's health decision-making. More widespread efforts to provide pregnancy self-tests that can be used at home or in a place of choice could also support the increased autonomy of individuals and the multiple programmatic approaches to advance SRHR.

Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group decided to examine the effect of increasing the availability of pregnancy self-tests.

The PICO question was:

- Should self-testing for pregnancy be available as an additional option to clinic-based testing?

A systematic review was conducted of peer-reviewed journal articles in publications from any location and in any language examining the effectiveness of pregnancy self-testing, the values and preferences of end users and health workers, and the cost. Standardized methods were used to search, screen and code the studies to be included. A meta-analysis was conducted using random-effects models, and the findings were summarized in GRADE tables. The review followed PRISMA guidelines (15), and the protocol was published at PROSPERO (registration number CRD42021231656) and the systematic review in a peer-reviewed journal (62).

Results

The systematic review included 414 unique references, of which 62 were retained for full-text review. Overall, six studies – five RCTs and one observational study – met the inclusion criteria for the effectiveness review. Four RCTs, conducted in a diverse range of countries (Austria, Finland, India, Norway, Sweden, the Republic of Moldova, Uzbekistan and Viet Nam), were conducted among individuals receiving medical abortion. These four RCTs randomized clients to either abortion follow-up with home pregnancy testing and a phone call, or abortion follow-up with a traditional clinic visit, usually with ultrasound confirmation of successful termination. The fifth RCT, conducted in Madagascar, randomized CHWs to receive pregnancy tests to use with their clients versus the standard care, which the authors said had historically been pregnancy testing available only at clinics.

The RCTs provided data for two outcomes: appropriate clinical follow-up, and gestational age at pregnancy awareness (knowledge of pregnancy) and at presentation for antenatal care or abortion. The non-randomized observational study provided data for the same outcomes but under appropriate clinical follow-up only.

Appropriate clinical follow-up was assessed in the four post-abortion RCTs by loss to follow-up, meaning the client did not return for their follow-up visit or was not able to be contacted by phone. In the meta-analysis, there was no significant difference between the study arms in loss to follow-up (risk ratio: 0.479, 95% confidence interval: 0.155–1.480). Heterogeneity was substantial, with an I-squared of 87. Stratification by high-income countries versus LMICs did not yield meaningful differences; no further stratifications were available.

The GDG agreed that, given the ubiquity of self-testing for pregnancy in many settings, it was not surprising that this intervention had not been studied widely in a comparative way except in specific circumstances. The evidence presented and the experience of the GDG members supported the need for broader access to pregnancy self-testing.

Certainty of the evidence for the recommendation

The available evidence was of very low certainty overall.

Rationale for the strength and the direction of the recommendation

The GDG made a strong recommendation in favour of the intervention. Given the ubiquity of self-testing for pregnancy in many settings and the positive findings in post-abortion care and CHW programmes, the GDG felt there was evidence that the wider use of home pregnancy tests could have beneficial outcomes within health systems (58, 63–66). However, the lack of data from a wider swathe of users limits the conclusions that can be drawn about the public health benefits of this intervention.

Resource use



No studies presented primary data examining cost-effectiveness, a cost-utility analysis or the cost versus benefit of pregnancy self-testing. Costs of pregnancy self-tests vary by setting and specific product, but should generally fall within the range of those for other over-the-counter products. Considerations of cost should include not only the cost of the test to the end user, but also the full range of health-sector costs (e.g. costs due to delayed pregnancy care), other sector costs, and productivity impacts (e.g. labour and workforce issues). Creative ways of expanding access to pregnancy self-testing within existing healthcare systems, such as using CHWs, would benefit from including cost and cost-effectiveness assessments.

Feasibility

All GDG members agreed that this recommendation was feasible.

Equity and human rights

The GDG agreed that pregnancy self-testing was acceptable and valued by end users. Expanded use in the health system, including by CHW programmes, may lead to improved SRH outcomes and SRHR. Ensuring universal access to pregnancy self-testing may encourage women to seek early antenatal care, contributing to better health outcomes for parents, newborns and children.

Acceptability of the intervention: values and preferences of end users and health workers

Overall, 16 studies were identified in the values and preferences review. There were 12 quantitative studies (all cross-sectional surveys) and four qualitative studies. For populations, six studies included general pregnancy test users or volunteers, while 12 studies followed individuals after they received a medical abortion with at-home follow-up including a home pregnancy test. No studies were identified with health workers or other stakeholders. The studies were conducted in diverse locations: USA (five), United Kingdom (three), India (two), Viet Nam (two), and one each in Austria, Finland, France, Norway, the Republic of Moldova, Saudi Arabia, South Africa, Sweden, Tunisia and Uzbekistan.

Among individuals having medical abortions, the evidence indicated that most individuals receiving home management with a pregnancy test said they would prefer this option in the future; this ranged from 76.1% (the Republic of Moldova and Uzbekistan) to 98.5% (South Africa). In two trials with clinic comparison groups, home management was still the preferred option among participants in the clinic groups. When participants were asked, clear majorities across the studies said they found home management acceptable and would recommend it to a friend.

The GDG agreed that the reasons why individuals considered pregnancy tests included getting quick results, convenience, confidentiality/privacy, cost and accuracy, and that availability and access to pregnancy tests could shape individuals' relationships with their bodies, and their social roles, relationships and responsibilities. The GDG also acknowledged the potential harms of going to a clinic

for pregnancy testing brought by the interpretations that could be made about the individual being pregnant and having sex; thus a self-test for pregnancy would reduce stigma and increase user autonomy.

3.3 ELIMINATING UNSAFE ABORTION²

Medical abortion care encompasses the management of various clinical conditions, including spontaneous and induced abortion (in both viable and non-viable pregnancies), incomplete abortion, intrauterine fetal demise, and post-abortion contraception. The medical management of abortion generally involves either a combination of mifepristone and misoprostol or a misoprostol-only regimen.

Medical abortion care plays a crucial role in safe, effective and acceptable abortion care. In both high- and low-resource settings, the use of medical methods of abortion has contributed to task sharing and the more efficient use of resources. Medical abortion care reduces the need for surgical abortion and offers a non-invasive and highly acceptable option to pregnant individuals (67).

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. Self-assessment



and self-management approaches can be empowering for individuals, and help to triage care, leading to a more optimal use of healthcare resources. The self-management of medical abortion is recommended by WHO (67).



3.3.1 EXISTING RECOMMENDATIONS ON SELF-CARE IN MEDICAL ABORTION AND POST-ABORTION CONTRACEPTION

	Recommendation
Recommendation 22	Self-assessing eligibility for medical abortion is recommended within the context of rigorous research.
Recommendation 23	Managing the mifepristone and misoprostol medication without the direct supervision of a health worker is recommended in specific circumstances. We recommend this option in circumstances where women have a source of accurate information and access to a health worker should they need or want it at any stage of the process.

² 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 healthcare. These recommendations are not an endorsement of self-use by women without access to information or a trained health worker/healthcare facility as a backup. All women should have access to health services should they want or need them.

	Recommendation
Recommendation 24	Self-assessing the 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 worker should they need or want it at any stage of the process.
Recommendation 25	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 worker are strong, and where monitoring and follow-up can be ensured.
Recommendation 26	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.

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

STIs are among the most common communicable diseases and affect the health and lives of women, men and babies worldwide. People with STIs also face stigma, stereotyping and shame, and are vulnerable to gender-based violence. Globally every year there are an estimated 357 million new infections of four curable STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis. Many STIs, including chlamydia, gonorrhoea, hepatitis B, herpes, HIV and syphilis, can also be transmitted from mother to child during pregnancy and childbirth.

The self-collection of samples to test for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* is recommended by WHO as an additional approach to deliver STI testing services, as is, where appropriate, the self-collection of samples to test for *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* (68).

HIV infection attacks the body's immune system, specifically the white blood cells called CD4 cells. HIV can be diagnosed using simple and affordable rapid diagnostic tests, and WHO recommends HIV self-tests. It is important that HIV testing services follow the five Cs: consent, confidentiality, counselling, correct results and connection with treatment and other services.

Cervical cancer is the fourth most common cancer in women. In 2020, an estimated 604 000 women were diagnosed with cervical cancer worldwide, and about 342 000 women died from the disease. Almost all cervical cancer cases (99%) are linked to infection with high-risk human papillomavirus (HPV), an extremely common virus transmitted through sexual contact. Effective primary prevention (HPV vaccination) and secondary prevention (screening for and treating precancerous lesions) will prevent cervical cancer in most cases. When diagnosed, cervical cancer is one of the most successfully treatable forms of cancer, as long as it is detected early and managed effectively. WHO recommends self-sampling for HPV as an essential means to improve screening for cervical cancer (69).



3.4.1 EXISTING RECOMMENDATIONS ON SEXUALLY TRANSMITTED INFECTIONS, INCLUDING HIV, AND CERVICAL CANCER

	Recommendation
Recommendation 27	HPV self-sampling should be made available as an additional approach to sampling in cervical cancer screening services for individuals aged 30–60 years. (<i>Strong recommendation; moderate certainty evidence</i>)
Recommendation 28	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. (<i>Strong recommendation; moderate certainty evidence</i>)
Recommendation 29	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. (<i>Conditional recommendation; low certainty evidence</i>)
Recommendation 30	HIV self-testing should be offered as an additional approach to HIV testing services. (<i>Strong recommendation; moderate certainty evidence</i>)
Recommendation 31	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. (<i>Strong recommendation; low certainty evidence</i>)



3.4.2 KEY CONSIDERATIONS ON ACCESS TO PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION

	Recommendation
Key considerations 2 (new)	<ul style="list-style-type: none"> • WHO recommends offering oral pre-exposure prophylaxis (PrEP) and the dapivirine vaginal ring to individuals at substantial risk of HIV infection. • Equitable access to and the availability of PrEP, plus information about its use are imperative to ensure increased uptake. • Providing PrEP through pharmacies may present a unique opportunity for expanding access to PrEP in the community setting. • Any model of PrEP delivery through pharmacies should ensure adherence to WHO suggested procedures for initiating and maintaining PrEP, including HIV testing, creatinine testing and other tests and counselling as appropriate. • The decision to offer PrEP in pharmacies will require alignment with local laws and regulations, appropriate health system linkages and community engagement.

Background

PrEP is the use of antiretroviral drugs by individuals not infected with HIV to prevent the infection. PrEP may be taken either in a daily oral pill (generally containing tenofovir plus emtricitabine), as driven by events (i.e. at the time of sex), or in the form of a dapivirine ring; recent data suggest that long-acting injectable PrEP may soon be added as another option.

WHO recommends that people at substantial risk of HIV infection should be offered PrEP as an additional preventive choice and as part of a combination approach to prevention (70).

Summary of evidence and considerations

The WHO Guideline Steering Group decided to examine over-the-counter pharmacy delivery of PrEP as a possible means to increase access.

A systematic review was conducted to address two PICO related questions: whether PrEP initiation should happen in pharmacies, and whether PrEP continuation should happen in pharmacies.

- Should PrEP initiation be available following screening by a pharmacist, without a prescription?
- Should PrEP continuation be available from a pharmacist, without a prescription?

The extant literature was reviewed in three areas relevant to answering these questions: effectiveness of the intervention, the values and preferences of end users and health workers, and cost information. The review followed PRISMA guidelines (15), and the protocol was published at PROSPERO (registration number CRD42021231650) and the systematic review in a peer-reviewed journal (71).

Results

No articles met the inclusion criteria for the effectiveness review, neither for PrEP initiation nor for its continuation. However, seven case studies presenting non-comparative data from PrEP pharmacy programmes demonstrated the feasibility of this model in the USA. Eleven studies reported values and preferences. In Kenya, South Africa and the USA, potential PrEP clients generally supported access through pharmacies, although some expressed a preference for access through clinics. One study of actual PrEP pharmacy clients found that all would “definitely recommend” the programme. Six studies found that pharmacists were generally supportive of offering PrEP; one study including doctors found more limited backing, while one study of diverse stakeholders in Kenya found broad support. Three studies reported cost data that indicated clients’ willingness to pay in Kenya and the USA, and indicated the initial sustainability of a clinic financial model in the USA.

With the increasing roll-out of PrEP across regions, more evidence from safety monitoring may reduce laboratory monitoring requirements. Adaptations to PrEP delivery have been made during the COVID-19 pandemic to support the continuation of PrEP delivery, such as the use of HIV self-testing, and virtual platforms and telemedicine for support. Future implementation research could explore how these strategies could be incorporated into a future PrEP pharmacy model. Attention will need to be given, though, to ensuring there is no increase in negative outcomes if PrEP is made available with reduced laboratory test monitoring.

Resource use



Two of the case studies presented data about health-sector costs and patient or family costs, and one study on values and preferences also examined the willingness to pay for PrEP. Both the case studies were conducted in the USA. For health-sector costs, one clinic reported that it recouped start-up costs in nine months. Financial sustainability was dependent on the ability of pharmacists to bill insurance plans for their services. For patient and family costs, 98% of patients paid nothing in one study for their PrEP; in another, participants were split in their willingness to pay US\$ 20 or US\$ 60 quarterly for PrEP visits. Finally, one study in Kenya found that over half of participants were willing to pay for PrEP; 78% said the maximum they would pay for a month’s supply was less than US\$ 5.

Feasibility

GDG members agreed that the provision of oral PrEP through pharmacies had been demonstrated to be feasible in the USA, and acceptable to end users and stakeholders in multiple settings. Feasibility may also rely on the laboratory capacity of pharmacies or links to a laboratory network.

Equity and human rights

The GDG agreed that health equity for underserved and marginalized populations would improve with increased access and coverage of this proven and effective HIV prevention intervention. However, the limited evidence on effectiveness and the lack of data from LMICs call for further research.

Acceptability of the intervention: values and preferences of end users and health workers

For the values and preferences review, 11 studies were identified – eight were conducted in the USA, two in Kenya and one in South Africa. Seven of the studies used quantitative methods – generally cross-sectional surveys – while four used qualitative methods – generally in-depth interviews.

Many of the included studies did not describe in-depth reasons for users being for against pharmacy PrEP. In the USA, men who had sex with men emphasized the importance of privacy and confidentiality, and of pharmacies having welcoming staff. One study in South Africa (72) highlighted the role of subgroup differences, finding that preferences for pharmacy PrEP differed between women, men who had sex with men, and men who had sex with women. These differences align

with previous findings about user preferences for PrEP delivery more broadly (73, 74). Further, even within each of these groups, user preferences may be shaped by the geographical, economic and sociocultural context.

The review found that pharmacy delivery of PrEP was highly acceptable among marginalized groups such as Black men who have sex with men in the south of the USA. The GDG thought that individuals from key populations often faced critical barriers to accessing PrEP through more traditional modalities, and that pharmacy PrEP may be an important additional option to reach them. Understanding the perspectives of underserved individuals and communities, such as transgender people or people who use drugs, who may be excluded from research on PrEP, is also critical.



Evidence from health workers indicated mixed support for pharmacy-access PrEP. Some health workers had concerns about the additional time associated with a new task, although one of the included case studies found that workflow disruption was minimal. Concerns about insufficient training and skills to provide PrEP were common. While guidelines for PrEP and clinical requirements at visits vary across settings, pharmacists need, at a minimum, training and supervision to provide HIV and creatinine clearance testing along with pregnancy testing, STI screening and other tests depending on setting. Along with training and supervision, strategies to support access to laboratories – whether on site or elsewhere – will be key to offering PrEP through pharmacies.

3.5 PROMOTING SEXUAL HEALTH

Promoting sexual health is one of the five priority areas of the WHO Reproductive Health Strategy (75). WHO’s working definition of sexual health is the “state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity”. Sexual health, when viewed affirmatively, needs a positive and respectful approach to sexuality and sexual relationships, and the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence (76).

Sexual health-related issues are wide-ranging and encompass sexual orientation and gender identity, sexual expression, relationships and pleasure. The ability of people to achieve sexual health and well-being depends on their:

- access to comprehensive, good-quality information about sex and sexuality;
- knowledge about the risks they may face and their vulnerability to adverse consequences of unprotected sexual activity;
- ability to access sexual healthcare; and
- ability to live in an environment that affirms and promotes sexual health.

3.5.1 EXISTING GUIDANCE ON SEXUALITY EDUCATION

The 2018 publication by the United Nations Educational, Scientific and Cultural Organization, *International technical guidance on sexuality education: an evidence-informed approach*, offers a new definition of comprehensive sexuality education (CSE) (see Glossary, Annex 4) and a description emphasizing that it is a process to empower children and young people. Taken as a whole, the publication constitutes the recommended set of CSE topics and guidance on effective delivery and on the key considerations for understanding the evolving field of CSE (77).

The section on delivering effective CSE programmes includes 14 recommendations on effective curriculum development, including 10 on designing and implementing CSE programmes, three on the monitoring and evaluation of CSE programmes, and 10 key principles for scaling up CSE (77).

3.5.2 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, done in Washington, DC, 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 expressed being encouraged by the physician)” (78).

3.5.3 EXISTING GUIDANCE ON SELF-CARE IN RELATION TO INTIMATE PARTNER VIOLENCE AND SEXUAL VIOLENCE

Self-care can be inhibited by the negative psychological outcomes of violence. Violence against women tends to increase during every type of wide emergency, as it

did during the COVID-19 pandemic (79). Older women, women with disabilities, sexual and gender minorities and populations (of all genders) affected by conflict or humanitarian crises are also particularly vulnerable. Access to good-quality care and the ability to self-care may be affected for these individuals and communities.

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 the care of injuries and the prevention of STIs, and guidance for strengthening positive coping methods after a violent event (see Box 3.1) (80).

BOX 3.1. PLANS THAT CAN BE RECOMMENDED TO SURVIVORS FOR SELF-CARE AFTER SEXUAL ASSAULT OR VIOLENCE

After a 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 healthcare 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 sexually transmitted infections

- Discuss the signs and symptoms of sexually transmitted infections (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 their STI/HIV status has been determined at the visit at three or six months.

Follow-up

- Plan follow-up visits at two weeks, one month, three months and six months after the assault.

After violence

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

Encourage survivors to:

- build on their 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
- do relaxing activities to reduce anxiety and tension
- keep a regular sleep schedule and avoid sleeping too much
- do 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 (80).



3.5.4 NEW RECOMMENDATION ON LUBRICANT USE FOR SEXUAL HEALTH

	Recommendation
Recommendation 32 (new)	WHO recommends making lubricants available for optional use during sexual activity, among sexually active individuals. <i>(Strong recommendation; moderate certainty evidence)</i>

Background

The use of lubricants during sex may result in improved sexual health and well-being, including for individuals experiencing vaginal dryness associated with menopause (81), individuals experiencing dyspareunia (pain during sexual intercourse or other sexual activity that involves vaginal penetration) (81), or people having anal sex (82). Lubricants may also facilitate optimal sexual function and pleasure for sexually active individuals – across genders, regardless of specific health conditions – and may improve sexual relationships.

A wide range of lubricant products is available on the market globally, and they are used during both anal and vaginal sexual activity. While lubricant use may be generally helpful, substandard products used as lubricants could result in adverse health outcomes.

Summary of evidence and considerations for the new recommendation

The WHO Guideline Steering Group decided to examine the use of lubricants during or prior to sex to improve sexual health and well-being.

The PICO question was:

- Does use of lubricants during or prior to sex result in improved sexual health and well-being?

A systematic review of peer-reviewed publications was conducted to understand the effectiveness of the intervention, the values and preferences of end users and health workers, and cost information. Specifically, studies in the systematic review compared lubricant use during sexual activity with no lubricant use. The outcomes of interest in this review included: vaginal dryness; pain during vaginal/anal penetration; sexual arousal dysfunctions (female sexual arousal dysfunction, male erectile dysfunction); sexual desire, arousal, lubrication, orgasm, satisfaction and pleasure; vaginal discharge and bacterial vaginosis; side-effects (irritation, infections [yeast,

reproductive tract infection, STI, urinary tract infection]); STIs/HIV (incidence, prevalence, transmission, etc.); self-efficacy, self-determination, autonomy and empowerment around sexual health and sexuality (confidence, communication with partners, self-esteem); and other adverse events or social harms (e.g. coercion, violence [including intimate-partner violence, violence from family members or community members, etc.], psychosocial harm, self-harm, etc.), and whether these harms were corrected or redress was available for them.

The review followed PRISMA guidelines (15) and the protocol was published at PROSPERO (registration number CRD42020208976). The systematic review has been published in a peer-reviewed journal (82).

Results

The systematic review included 7578 unique references, 60 of which were identified for full-text review. Seven studies ultimately met the inclusion criteria for the effectiveness review; this included two RCTs and five observational studies. The two RCTs were conducted in the USA and Zimbabwe, and the observational studies were conducted in Australia and the USA.

The studies included in the review provided data on several outcomes of interest, specifically: sexual desire, arousal, lubrication, orgasm, satisfaction and pleasure; STIs and HIV; and vaginal dryness or pain during vaginal or anal penetration. One RCT among sexually active adult women in stable heterosexual partnerships in the USA found that lubricant use was associated with improved female sexual well-being. Additionally, another RCT, conducted in Zimbabwe among sexually active women, found that lubricant use did not affect the incidence of HPV. Lastly, one observational study among self-identified gay and bisexual men in the USA found that lubricant use was associated with a lower degree of pain during both insertive and receptive sex. Similarly, another observational study among female breast cancer survivors in Australia found that the use of lubricants was associated with lower

dyspareunia (genital pain during sexual intercourse) and lower sexual discomfort.

No quantitative comparative data were identified – neither from the RCTs nor from the observational studies – related to sexual arousal dysfunctions, vaginal discharge and bacterial vaginosis, side-effects such as irritation or infections (yeast, reproductive tract infection, urinary tract infection), or other side-effects, adverse events or social harms.

Certainty of the evidence for the recommendation

The available evidence was of moderate certainty overall.

Rationale for the strength and the direction of the recommendation

The GDG made a strong recommendation in favour of the intervention.

Resource use



No direct cost evidence was identified in this review. However, the GDG noted that the availability and costs of lubricants varies by setting. For policymakers, financial implications needs to be acknowledged. In addition, the GDG discussed the potential costs related to social harms that users may incur when purchasing lubricants.

Feasibility

All GDG members agreed that this recommendation was feasible, given that lubricants were already available in many places globally. However, there may be legal concerns in some areas, and lubricants may be less accessible in rural areas.

Equity and human rights



There were no major equity or human rights issues foreseen if lubricants were made available for optional use during sexual activity. The GDG agreed that health equity would be increased if lubricants were more widely available and used during sexual activity, including by increasing respect and improving sexual health and well-being.

Acceptability of the intervention: values and preferences of end users and health workers

Overall, 22 studies were included in the values and preferences review. Of these studies, 13 were quantitative (nine of which were cross-sectional) and eight were qualitative studies. Almost half were conducted in high-income countries, four in upper-middle-income countries, three in lower-middle-income countries, and one in a low-

income country. The country with the most studies was the USA (nine), followed by South Africa (four), Zimbabwe (three) and Australia (two). One study was conducted in each of these countries: Canada, Peru, Thailand, Uganda, the United Republic of Tanzania and Zambia. All studies were on the values and preferences of end users of lubricants, and no studies were identified on the values and preferences of health workers.

Populations included in these studies varied widely, including heterosexual people, men who have sex with men, HIV-infected and HIV-uninfected individuals, individuals with dyspareunia, and clients of STI services.

Overall, support for the use of lubricants was positive, ranging from 55% to 100% support in the studies. In general, water-based lubricants were preferred to no lubricants or oil-based lubricants. There were varied preferences for the odour, taste, flavour, colour and smell of the lubricants.

The reasons why individuals liked lubricants or would choose to use them ranged widely, and included comfort, reduced dryness/pain/discomfort, increased pleasure (for themselves or their partners); their partner's preference; the ease of orgasm (e.g. ability to orgasm, time needed to orgasm, quality of orgasm); preference for sex to feel more wet; curiosity; enhanced foreplay; clean, fast, easy insertion; reduced risk of tearing the vulva/vagina/anus; easier to feel aroused, increased readiness for sex; reciprocity; reduced chance of condoms drying out/breaking; and making condom use more enjoyable. The GDG acknowledged that the benefits of lubricants were many and varied, but that in general it was important for individuals to have the option to use lubricants.

The reasons why individuals disliked lubricants or would choose not to use them also ranged widely, and included that: lubricants were perceived as sticky, slippery, wet, messy, runny, gooey, burning, itchy, leaky (a nuisance), or too quick to try; that lubricants were expensive, unavailable or inaccessible; that individuals were not prepared when in the heat of the moment, or that lubricant use interrupted sexual interaction; that individuals or their partners preferred dry sex or preferred to use non-commercial products (e.g. saliva, pre-cum) instead; or that participants perceived that lubricants were only for older people, or that they did not think they needed to use lubricant. The GDG also acknowledged that there were some unknowns about the content and quality of lubricants.



3.5.5 KEY CONSIDERATIONS FOR USE OF SELF-ADMINISTRATION OF GENDER-AFFIRMING HORMONES FOR TRANSGENDER AND GENDER-DIVERSE INDIVIDUALS

	Recommendation
Key considerations 3 (new)	<ul style="list-style-type: none"> • The principles of gender equality and human rights in the delivery of quality gender-affirming hormones are critical to expanding access to this important intervention and reducing discrimination based on gender identity. • Transgender and gender-diverse people live within social, legal, economic and political systems that place them at high risk of discrimination, exclusion, poverty and violence. • Research is urgently needed to support evidence-driven guidance.

Background

Holistic care for transgender and gender-diverse individuals is critical, yet too often unavailable. Health systems must be designed to support individuals to seek the interventions they desire in affirming their gender identity. Support for gender-affirming interventions should be part of an overall supportive structure that ensures that no additional harm, marginalization, stigma or discrimination is caused to transgender and gender-diverse individuals, who are too often ill-served by healthcare systems.

Gender-affirming hormone therapy is a gender-affirming intervention that enables the acquisition of secondary sex characteristics more aligned with an individual's gender identity or expression (83). Ideally, gender-affirming hormone therapy would take place in the context of a supportive healthcare system. Many transgender and gender-diverse individuals do not have access to such a supportive system, however.

There are several possible ways in which individuals could self-administer hormones, for example through self-injection, or self-application of creams, gels, patches and suppositories. Expanding access to the self-administration of gender-affirming hormones may help to support a rational distribution of tasks across clients and health workers, thus potentially expanding the ability of the healthcare system to offer access to the benefits of such therapy.

For clients, self-administration may be more efficient and convenient, offering the possibility of fewer health-facility visits; more private; and more empowering, facilitating greater control for clients over their bodies and health. It may also enable the safer use of such therapies in settings where transgender and gender-diverse individuals face discrimination and violence.

Summary of evidence and considerations

The WHO Guideline Steering Group decided to examine whether the self-administration of gender-affirming hormones should be made available in addition to provider administration.

The PICO question was:

- Should self-administration of gender-affirming hormones be made available in addition to health worker administration?

The extant literature was reviewed in three areas relevant to this question: effectiveness of the intervention, values and preferences of end users and health workers, and cost information. The review followed PRISMA guidelines (15), and the protocol was published at PROSPERO (registration number CRD42021231648) and the systematic review in a peer-reviewed journal (84).

Results

The search yielded 3792 unique references, of which 30 were retained for full-text review. However, no studies met the inclusion criteria for the effectiveness or cost reviews.

The GDG recognized that the concept of self-administration versus health worker administration was complex and encompassed a range of different situations. In particular, administration is more easily defined for injectables or implants – where the health provider potentially knows what is being injected and the dose. In contrast, self-administration could raise risks in terms of the hormone used and/or how the injection is done. For oral or topical forms of hormone delivery, health workers may prescribe the hormones but are unlikely to routinely watch individuals take their hormone pills or apply their gel or patch. Furthermore, there may also be important

differences between the self-initiation, maintenance or self-administration of gender-affirming hormones that are initiated within healthcare settings.

The GDG noted that no comparative studies were identified from the review of effectiveness, and judged the balance of benefits and harms for self-administration of gender-affirming hormone versus provider administration to be uncertain at the time, and that a recommendation in favour of self-administration could not be made. The GDG further noted the support for the self-administration of gender-affirming hormone by people seeking affirmation, based on the review of values and preferences.

Members of the GDG discussed the potential harms facing transgender and gender-diverse individuals. GDG members identified the following from their own experiences, research, practice, observations and knowledge of the literature: the ubiquitous stigma and discrimination experienced by transgender individuals, the deleterious mental health effects, including depression and suicide, and the threats and high incidence of violence against transgender communities, including incidents of murder.

Given the need to ensure equitable, good-quality access to healthcare for all underserved communities, and to address potential harms as much as possible, the GDG determined to formulate a good practice statement regarding access to appropriate evidence-based services for transgender and gender-diverse individuals (see Chapter 4). Further research is needed, and the GDG identified this area as one of the most urgent topics to be explored further. The GDG noted that a research-prioritization process may identify the topic – such as the self-administration of gender-affirming hormones (perhaps with attention to the route of administration, e.g. topical versus injectable) as an additional option to provider administration – when appropriate guidance, infrastructure, resources, information and quality products are available. Attention may also need to be given to the processes of self-initiation versus self-administration following provider-supervised initiation. Where gender-affirming hormones are being used totally outside the health system, harm-reduction approaches might usefully be studied to minimize the risks.

Feasibility



The GDG discussed feasibility, noting that self-administration was widely practised among transgender and gender-diverse individuals, with many procuring gender-affirming hormones illegally online, in clubs or directly from pharmacies, with little or no quality control of the products, posing a risk of significant harm to the user. The GDG also noted that a lack of ongoing

provider monitoring for individuals taking gender-affirming hormones may result in negative effects going undetected and unaddressed.

Equity and human rights



Globally, transgender and gender-diverse individuals live within social, legal, economic and political systems that place them at high risk of discrimination, exclusion, poverty and violence, and “familiar models of professional healthcare” – such as clinical guidelines – “are not adequate to these issues across much of the world; social action and organizing are required” (85).



The principles of gender equality and human rights in the delivery of quality gender-affirming hormones are critical to expanding access to this important intervention and reducing gender discrimination based on gender identity. These needs extend more generally, too, to the provision of gender-affirming care across all health services and to ensuring a legal environment supportive of transgender people’s rights and health.

Acceptability of the intervention: values and preferences of end users and health workers

Five studies were identified that met the inclusion criteria for the values and preferences review. All were peer-reviewed articles. Two were conducted in the USA, one in Brazil, one in Thailand and one in the United Kingdom. All studies of values and preferences focused on the self-administration of unprescribed hormones, not on prescribed hormones used within a supportive healthcare system.

Four studies – from the USA (two), Brazil (one) and the United Kingdom (one) – found that individuals seeking gender-affirming hormone therapy may self-manage because of challenges finding knowledgeable and non-stigmatizing health workers; a lack of access to appropriate services; exclusion by, and discomfort with, health workers; cost; and a desire for a faster transition. One study in Thailand found that perspectives were shaped by restrictive legislation, few transgender-specific services or guidelines, inappropriate provider–patient communication, and medical knowledge gaps.

3.6 NONCOMMUNICABLE DISEASES, INCLUDING CARDIOVASCULAR DISEASES AND DIABETES

All patients with noncommunicable diseases can have some level of self-care (86). Self-care strategies for noncommunicable diseases include both self-care and self-management. Inherent in this concept is the recognition that, whatever factors and processes may determine

behaviour (such as staying fit and healthy, both physically and mentally, avoiding hazards such as smoking, and improving the management of long-term health conditions) – and whether or not self-care is effective and interfaces appropriately with professional care – it is the individual who

acts (or does not act) to preserve their health or respond to their symptoms (87). Self-care implementation strategies should therefore reflect the coexistence and complexity of noncommunicable diseases, aim to avoid vertical programmes and focus on an integrated healthcare strategy.



3.6.1 EXISTING RECOMMENDATIONS ON CARDIOVASCULAR DISEASES AND DIABETES

	Recommendation
Recommendation 33	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. <i>(Strong recommendation; low certainty evidence)</i>
Recommendation 34	Self-monitoring of blood coagulation is recommended for appropriate patients treated with oral anticoagulation agents, where the affordability of the technology has been established. <i>(Weak recommendation; moderate certainty evidence)</i>
Recommendation 35	Self-monitoring of blood coagulation and self-augmentation of dosage in patients receiving oral anticoagulation agents is recommended if affordable, and according to an agreed action plan with a health professional. <i>(Conditional recommendation; moderate certainty evidence)</i>
Recommendation 36	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. <i>(Conditional recommendation; moderate certainty evidence)</i>
Recommendation 37	People with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need. <i>(Conditional recommendation; low certainty evidence)</i>

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4.

Implementation and programmatic considerations for self-care interventions



At a Glance

This chapter presents the new and existing 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, as well as recommendations that should be considered during implementation of self-care interventions.

Human rights, gender equality
and equity considerations

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Financing and economic
considerations

p. 69

Training needs of health workers

p. 72

Population-specific
implementation considerations

p. 78

Digital health interventions

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Environmental considerations

p. 86

Recommendations and good practice statements are identified throughout the chapter by these icons:



New
recommendations



Existing
recommendations



Good practice
statements



This chapter presents all of the good practice statements developed for this guideline. For existing and adapted statements, any remarks on key implementation considerations are also provided; in most cases, the remarks are limited to the title, year of publication, and the weblink for the original source guideline. For each new good practice statement, more information is given, in the following order after the statement:

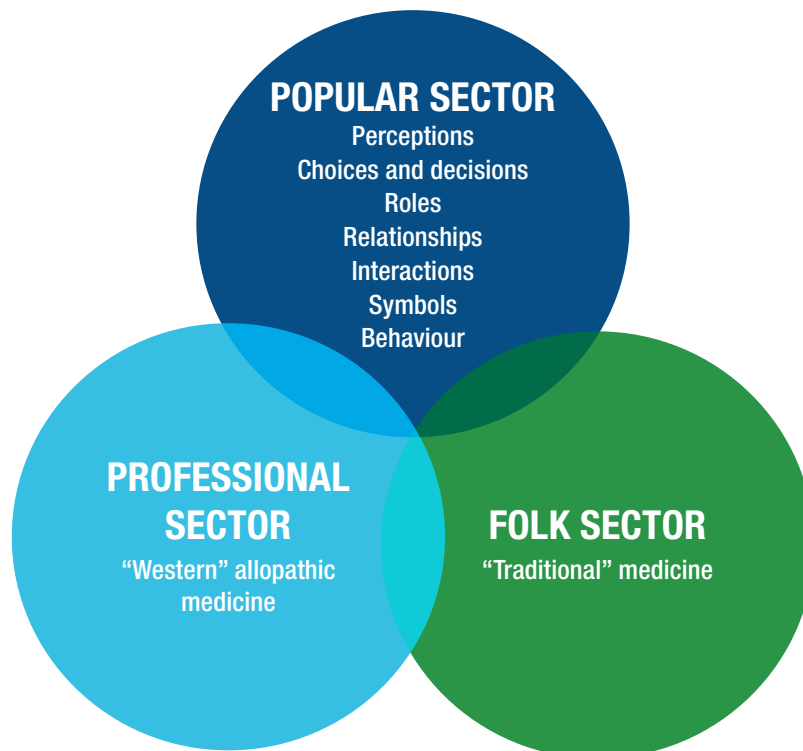
- Background information;
- The components of an enabling environment that will address the barriers and support health and well-being; and
- A summary of the evidence and of the Guideline Development Group's (GDG) considerations, including any additional implementation considerations, to support optimal understanding, implementation and outcomes.

This chapter also includes two new recommendations (38 and 39), presented in the same way as all the other recommendations, which are presented in Chapter 3.

4.1 BACKGROUND

Many everyday health problems are treated at home and in communities, increasingly with modern pharmaceuticals obtained from pharmacies, other shops and markets (1). Sometimes people combine remedies from traditional (folk) medicine and modern medicine, learning from friends, family, the internet, vendors and professionals, and apply the therapies themselves, especially if they are constrained by cost and/or distance to health services (2). As Kleinman defined it, this is the “popular” healthcare sector (see Fig. 4.1). 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 are promoted or used by the “professional” sector to promote self-care must be implemented in a manner that respects people’s needs and rights.

FIG. 4.1. KLEINMAN’S HEALTHCARE SECTORS



Source: adapted from Kleinman (4).



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 the correct and

accelerated implementation of interventions that have the potential to improve health and well-being by improving the coverage of effective and safe healthcare interventions (5).

This chapter is not intended to be an implementation guide. Key aspects of implementation – monitoring, evaluation, regulatory considerations and other efforts – will thus be developed in a separate implementation tool.



4.2 HUMAN RIGHTS, GENDER EQUALITY AND EQUITY CONSIDERATIONS

	Good practice statements
Good practice statement 1 (new)	All self-care interventions for health must be accompanied by accurate, understandable and actionable information, in accessible formats and languages, about the intervention itself and how to link to relevant community- or facility-based healthcare services, and the opportunity to interact with a health worker or a trained peer supporter to support decisions around, and the use of, the intervention.
Good practice statement 2 (new)	The provision of self-care interventions for health should increase clients' options about when and how they seek healthcare, including offering flexibility in the choice of interventions and in the degree and manner of the engagement with health services.
Good practice statement 3 (new)	Self-care interventions for health, and their delivery mechanisms, should be designed to accommodate the needs of all people across the gender spectrum, recognizing that there may be differences in the barriers that individuals and communities face accessing quality interventions, in their needs and priorities, in the nature of support they need, and in their preferred points of access.
Good practice statement 4 (new)	Countries should review and, where necessary, revise laws, policies and regulations to ensure that quality self-care interventions are made widely available in the community, that they are accessible to all without discrimination, through public, private and community-based health workers, and that they are acceptable to users.

Remarks

For good practice statement 1

- Opportunities to interact with health workers should be designed to support people's self-care decisions, use of interventions and ability to complete appropriate follow-up actions.

For good practice statement 2

- The design, delivery and monitoring of self-care interventions for health should be participatory and include the involvement of communities and community-led organizations.

For good practice statement 4

- Appropriate, accessible and functional mechanisms for oversight, accountability and redress should be integral parts of all self-care interventions for health.

Background information

The conceptual framework presented in Chapter 2, and the cross-cutting principles of human rights, equity and gender, provide useful guidance on the issues that need consideration in the introduction and scaling up of self-care interventions for sexual and reproductive health and rights (SRHR). Successful implementation of self-care interventions rests on providing adequate support to individual end users as well as on the health system.

With the increasing adoption of self-care interventions around the world, valuable lessons have been learnt since the 2019 guideline that might help to guide future implementation. Although there is little documentation of the experiences of implementing self-care interventions from an explicit human rights standpoint, many of the different elements of the human rights framework presented in Chapters 1 and 2 are covered in the literature, with useful lessons for the future implementation of self-care interventions, including for SRHR and noncommunicable diseases.

Examples of self-care interventions: human rights and gender considerations

There has been a lot of attention on the acceptability of different self-care interventions, with far less attention to availability, accessibility or quality. Offering self-care interventions for health in the community generally increases availability and acceptability while ensuring privacy has also been identified as a key element of the latter. Access to appropriately tailored information and support increases the acceptability and quality of self-care interventions for health. Other factors contributing to acceptability vary based on the self-care intervention and the population in which it is being introduced, highlighting the need to understand context- and intervention-specific acceptability prior to implementation.

Given the variability in the acceptability of self-care interventions (including where to access the intervention, where to use it, whether to do so alone or with assistance, and what kind of information and/or support is preferred), participation is key to ensuring that the implementation of self-care interventions is appropriately designed for the intended end users. Some formative research has sought to understand potential end users' attitudes, to inform interventions; however, community participation in the design and implementation of self-care interventions as part of routine health services is underexplored.



It is important to ensure that people can make informed decisions about whether or not to use self-care interventions for health. The amount of information provided for different interventions varies, as does their accessibility (concerning e.g. language, complexity of language, technology requirements). There may be a need to devise different ways of providing information to populations with diverse needs and different levels of literacy that connect them back to the health system as appropriate. Particularly where self-care interventions can be used without any contact with the health system, many people will seek information online to

guide their decision-making. There is a challenge with regard to the information available online, because its quality is highly variable. Countries and communities should be encouraged to build or adopt strategies for fighting misinformation. This is particularly relevant in crises, when inaccurate and potentially harmful information can spread widely and swiftly. Strategies may include having a misinformation reporting system or running awareness campaigns.

Many studies have disaggregated findings by sociodemographic characteristics, which can help with understanding non-discrimination, including by gender, and will require careful consideration in the context of linking information on self-care interventions with routine health management information systems. Also critical in considering non-discrimination and equity is identifying which groups might struggle to access the self-care intervention being implemented, and the additional efforts that could be made to improve their access.

Ensuring accountability in the context of self-care interventions for health is critical. Accountability is central to human rights and, in particular, to ensuring constructive, corrective change. Different types of accountability, including legal, social and programmatic, might all be relevant, so attention is needed to ensuring accessible mechanisms for accountability of all types. The most appropriate approach will be context-specific.

Summary of the evidence and considerations of the GDG

Just as self-care interventions are diverse in nature, their users are also heterogeneous. Flexible implementation can allow users choice in the interventions they access and in how and when they interact with health services. Within each self-care intervention for health, people will want different levels of support and connection with health services. Furthermore, while some people might choose self-care interventions for health, others will prefer to see a health provider. Self-care interventions for health thus have to be a complement to health services and sufficiently flexible to allow clients choice and to meet their range of needs. Links to the health system are critical so that clients can seek services whenever they need to – including when they are deciding whether or not to use a self-care intervention – for support to use it, and for follow-up care as needed.

The different service points through which self-care interventions can be provided (e.g. healthcare facility, pharmacy, community health worker, online) influence the availability, accessibility, acceptability, privacy and

confidentiality and, ultimately, uptake. The choice of service delivery point should also include attention to health worker capacity and the available mechanisms for accountability.



Attention to gender goes far beyond disaggregating data by gender. It should also encompass seeking to understand gender as a social construct and how this might affect different people's attitudes towards self-care interventions for health. A person's gender or gender identity influences their motivation for using self-care interventions for health and the potential access barriers they face. There are important equity implications in self-care that may negatively affect women. Women often have childcare responsibilities and may be unable to travel to a health facility, or they may lack the financial autonomy to do so. In some settings, women attending health facilities can access products (including contraception) delivered by health workers, but when they have to make health decisions by themselves, they may not have the autonomy to do so. This decision-making capacity for some self-care recommendations is an important element to take into consideration. In some places, men prefer not to access health services, as they fear this might be perceived as a sign of weakness. Transgender people often avoid health services entirely, because of the discrimination that they experience there. Self-care interventions have the potential to help to overcome some of these barriers, but, to do so, their implementation must be designed and carried out with these considerations in mind.

Ensuring an appropriate legal, policy and regulatory environment for self-care interventions for health is a prerequisite to their implementation. Laws, policies and regulations can create barriers to accessing self-care interventions for health or, when well designed, can help to promote access to human rights-based and gender-responsive self-care interventions for health. The 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. It should also be applicable to the diversity of locations where these interventions are purchased and used. Moving beyond the approvals



required for introducing new devices, it may also be important, for example, to review which cadres of health worker (including community health workers) are permitted to assist with specific tasks such as providing injections or diagnostic testing. At any level of the health workforce, the introduction of new tasks related to self-care interventions must be contextualized within existing workloads, capacities and mechanisms of oversight and accountability. In many places, the legal, political, economic and social contexts still create barriers to access to health and other services. In some such contexts, self-care may be the only option available to people; a harm-reduction approach to guide supportive public health approaches and minimize risks to users remains important in these settings.

These lessons from existing implementation efforts can help to inform future implementation to ensure that it is human rights-based and gender-responsive.



4.3 FINANCING AND ECONOMIC CONSIDERATIONS

	Good practice statements
Good practice statement 5	Good-quality health services and self-care interventions should be made available, accessible, affordable and acceptable to underserved and marginalized populations, based on the principles of medical ethics; the avoidance of stigma, coercion and violence; non-discrimination; and the right to health.

Background information

In addition to increasing 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 (see Fig. 4.2) (6, 7). Self-care interventions could enhance the efficiency of healthcare delivery by designating users as

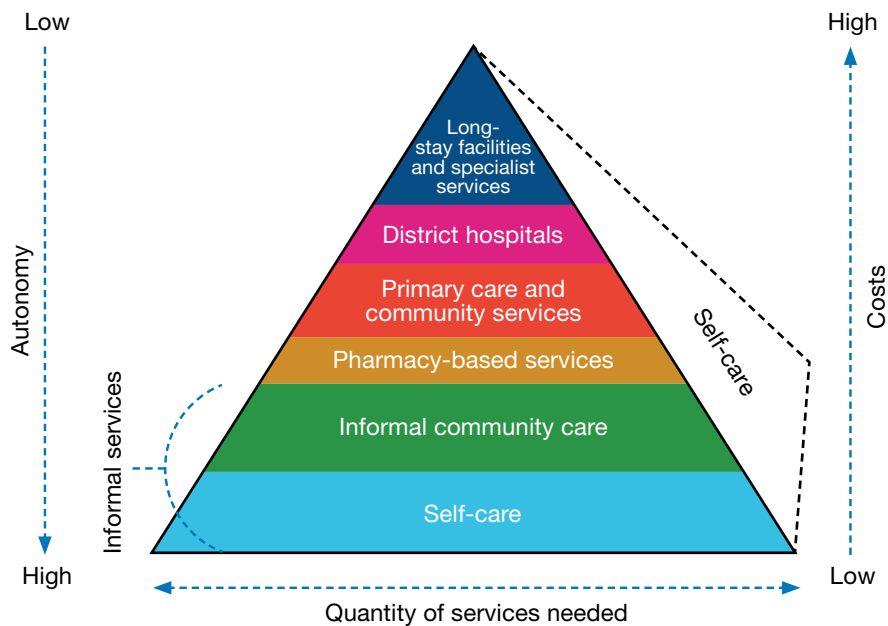
lay health workers, thereby increasing access to essential services. They could also increase the uptake of preventive services and improve adherence to treatment, thereby reducing downstream complications and healthcare use (8). Underserved and marginalized populations could be given new routes of access to sexual and reproductive health (SRH) services that they would otherwise not access through health workers due to stigma, discrimination, distance and/or cost.



However, there are also the 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. 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 that would otherwise be paid for by the health system when accessed through health services, these costs should, wherever possible, remain with the health system and not be transferred to the user.

FIG. 4.2. SELF-CARE WITHIN THE HEALTHCARE PYRAMID



Source: adapted from WHO (9).

BOX 4.1. UNIVERSAL HEALTH COVERAGE: WHAT IS IT?

- The United Nations resolution on universal health coverage (UHC) 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, underserved and marginalized and marginalized segments of the population” (10).
- “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” (11).
- “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” (12).

In 2020, WHO released the UHC Compendium, a database of health services and intersectoral interventions designed to assist countries with their progress towards UHC. This global repository provides a strategic way to organize and present information and creates a framework within which to think about health services and health interventions. Version 1 of the compendium focuses on clinical health services and includes a list of over 3500 health actions across different health areas.³ The database spans the full spectrum of promotive, preventive, resuscitative, curative, rehabilitative and palliative services, and a full complement of intersectoral interventions, including self-care interventions (13).

Access for all to essential health services of high quality is the cornerstone of UHC. However, since economic considerations are particularly important for underserved and marginalized 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 (14). Benefit packages and risk-pooling mechanisms may have to be designed to support people 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 4.1), 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.



Self-care interventions can also help to limit some health system costs, by co-opting users as members of the health team when accessing care

outside of healthcare 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 workers is needed 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 attenuate 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 needing 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 people who can manage their own healthcare 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 healthcare provider involvement and those that are integrated within healthcare provision. Self-care interventions must be promoted as part of a coherent health system, and reinforced with health system support where needed. The health system remains accountable for patient outcomes linked to the use of these interventions and should closely monitor the economic and financial implications for households and governments; otherwise, the wide use of self-care interventions may promote fragmented, consumerist approaches to healthcare and undermine integrated person-centred care.

BOX 4.2. CASE STUDY ON THE 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 healthcare 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\$ 9.46 in Senegal and US\$ 10.12 in Uganda). In all three countries, the direct non-medical costs were lowest for users who were self-injecting contraceptives, compared with community-based and facility-based delivery (15).

³ The UHC Compendium is available at <https://www.who.int/universal-health-coverage/compendium>

BOX 4.2. (Continued) CASE STUDY ON THE COSTS AND COST-EFFECTIVENESS OF SELF-INJECTING CONTRACEPTION

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 intramuscular 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 would cost more than provider-administered DMPA-IM, due to the training needed 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 (16).



4.4 TRAINING NEEDS OF HEALTH WORKERS

	Good practice statement
Good practice statement 6	Health workers should receive appropriate recurrent education to ensure that they have the competencies, underpinned by the required knowledge, skills and attitudes, to provide self-care interventions based on the right to health, confidentiality and non-discrimination.

There is an escalating mismatch between the supply and the need for health workers (17, 18). The WHO strategy for human resources for health (17) proposes the reorientation of health systems towards the needs and rights of individuals, communities and populations rather than around professional clinical specialties, and competency-based professional, technical and vocational education and training.

The term health workforce here refers to those health workers providing services targeted at 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 (CHWs). 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 in their own healthcare.

Health systems and the training needs of health workers have to be understood not only in relation to the individuals, communities and populations they are trying to serve, but also the wider sociocultural, economic, legal, political and historical context in which they are situated and shaped. For self-care interventions to be successfully accessed and

used, learning, communication and intersectoral collaboration are needed to facilitate respectful engagement between community members, users of self-care interventions, health workers and policy-makers.



Respectful, non-judgemental, non-discriminatory attitudes of the health workforce will be essential for the effective introduction of self-care interventions. These include, for instance, demonstrating active empathic listening and conveying complete and accurate information in a jargon-free and non-judgemental manner to all people.

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

4.4.1 TRAINING NEEDS AND THE ENGAGEMENT OF COMMUNITY HEALTH WORKERS

WHO recommendations support several key aspects of CHW engagement in promoting and supporting the introduction, use and uptake of self-care interventions, including (19):

- community engagement:
 - community participation in CHW selection;
 - selection and priority setting of CHW activities;
 - support to community-based structures; and
 - involvement of community representatives in decision-making, problem-solving, planning and budgeting processes.
- community resource mobilization:
 - identifying priority health and social problems and developing and implementing corresponding action plans with the communities;
 - mobilizing and helping to coordinate relevant local resources representing different stakeholders, sectors and civil society organizations to address priority health problems;
 - strengthening linkages between the community and health facilities.
- competencies required for CHW pre-service education:
 - competencies required to ensure high-quality service delivery;
 - pre-existing knowledge and skills (whether acquired through prior training or relevant experience); and
 - the social, economic and geographical circumstances of trainees.

Background information

A growing body of evidence supports the effectiveness of CHWs for a range of promotive, preventive and curative health services, including self-care interventions, contributing to reducing inequities in access to care.

Although CHW integration in health systems and communities varies – and is typically inadequate – and while evidence-based policy adoption regarding CHW engagement is uneven, the *WHO guideline on health policy and system support to optimize community health worker programmes* offers opportunities to harness the potential of CHWs to strengthen primary healthcare and expand equitable access to priority health services for all (19).

Examples of self-care interventions: engagement of community health workers

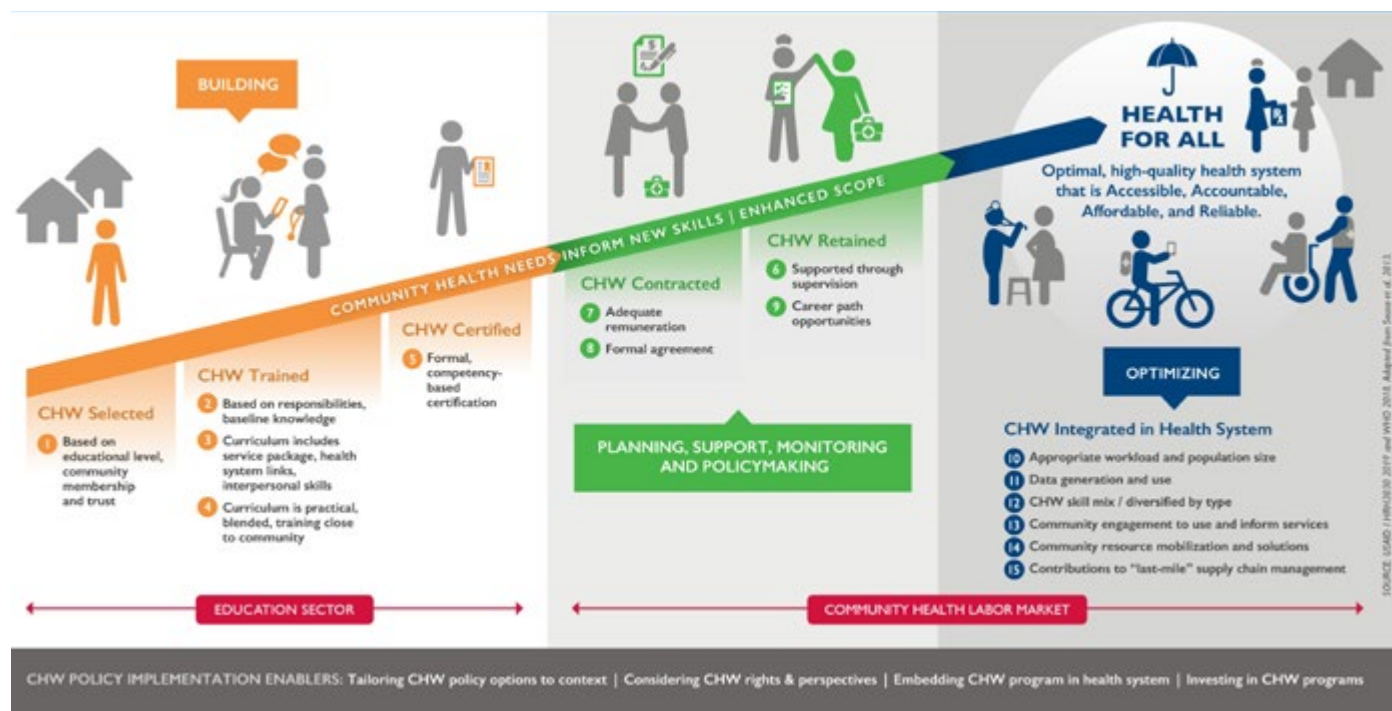


The reorientation of the health workforce will require health workers to “approach patients, clients and communities differently, be more open to working in teams (particularly inter-professional teams), use data more effectively in their work and be willing to innovate in their practice” (20). It is important that all health workers see CHWs as respected colleagues who can help share the workload and promote health system and community goals.

Summary of the evidence and considerations of the GDG

The *WHO guideline on health policy and system support to optimize community health worker programmes* reflects the growing body of evidence on CHWs in healthcare and the need for recommendations and policies to integrate them into the health workforce and health systems more broadly (19). The guideline aims to optimize the design, scale-up and sustainability of CHW programmes. In presenting the recommendations, this guideline takes a policy and health systems approach, spanning the education domain, community health labour market, and CHW integration into health systems (see Fig. 4.3). The application of this guideline should be tailored to countries: the global WHO guideline provides the broad principles, but then these need to be adapted to local context with country-specific policies for CHWs and for aligning with broader health system policies and community structures.

FIG. 4.3. WHO COMMUNITY HEALTH WORKER GUIDELINE RECOMMENDATIONS, USING A LIFE-COURSE APPROACH



Source: WHO (19).



4.4.2 RATIONAL DELEGATION OF TASKS AND TASK SHARING

	Good practice statements
Good practice statement 7	Countries, in collaboration with relevant stakeholders, including patient groups and the community, should consider implementing and/or extending and strengthening the rational delegation of tasks to individuals, carers and communities, as members of the health team, in effective ways that lead to equitable health outcomes.
Good practice statement 8	Self-carers and caregivers who are not trained health workers can be empowered to manage certain aspects of healthcare under the responsibility of a health worker, particularly in relation to self-care and the use of self-care interventions, where appropriate and within the context of safe, supportive health systems.

Background

WHO's definition of the rational delegation of tasks among health teams supports the redistribution of specific tasks, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications, such as CHWs – to make more efficient use of the available human resources for health (21).



The principles of people-centred care include that individuals, carers and communities are seen as active participants in managing their own health, and as members of the health team. Thus, dialogue around the rational delegation of tasks also includes discussing the roles and tasks provided by individuals, carers and communities in self-care and managing their own health.

The rational delegation of tasks can strengthen the existing health workforce provision of health services by increasing access to health services, and can therefore be a pragmatic response to health workforce shortages as well as to improving access and cost-effectiveness. However, the assignment of tasks and roles needs to be implemented in ways that lead to equitable outcomes, and alongside other investments in human resources for health.

Examples of self-care interventions: delegation of tasks for delivering health services

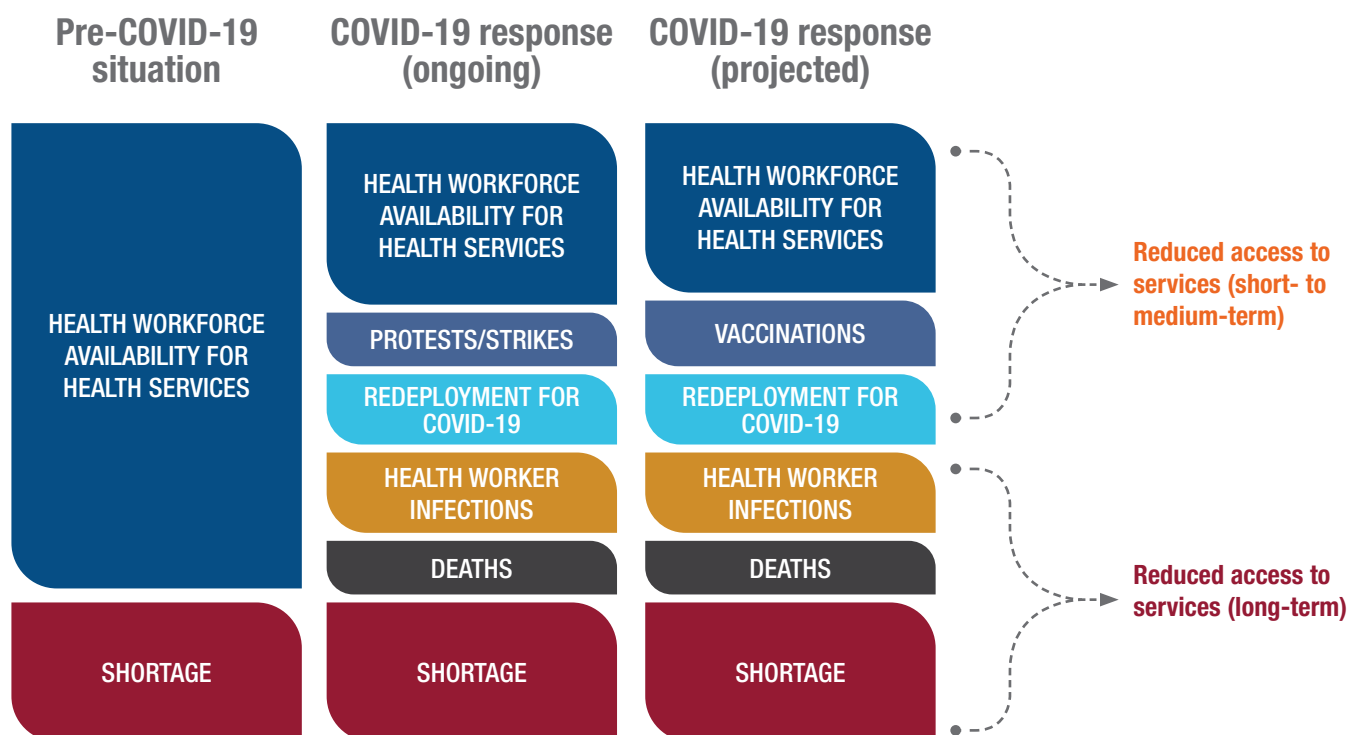
Many examples are covered by WHO guidance for a range of SRH issues such as HIV (21), family planning (22), safe abortion (23) and maternal health (24). Examples also include empowering people living with HIV to participate in the management of their own chronic condition and to support others as part of expert patient programmes (24–27). Such an approach need not be a permanent delegation of tasks from health workers to individuals, carers and communities, and is

not an abrogation of the responsibility or accountability of health workers. Rather, it is an opportunity where appropriate and needed. Further, the delegation of tasks offers an enhancement and acknowledgement of the important roles that individuals, families and communities play in managing their health as self-carers and as caregivers. This delegation is being implemented to various degrees in many countries and is acknowledged in several national guidance documents and strategies.



The delegation of tasks is also increasingly seen as relevant during humanitarian and pandemic situations, where many health workers have been redeployed in a crisis response that exacerbates the existing overall shortage of health workers for essential health services. The COVID-19 pandemic, for instance, has clearly shown that programmatic approaches that link to existing national responses are insufficient in estimating health workforce needs, given the overlapping social, financial and human costs (see Fig. 4.4) (28).

FIG. 4.4. FACTORS AFFECTING HEALTH WORKFORCE READINESS DURING COVID-19 IN 2020



Source: European Commission (28).

Summary of the evidence and considerations of the GDG

A general implementation of the delegation of tasks to individuals, carers and communities is shaped by context, sociocultural factors and political factors. It is relevant when (29):

- self-care interventions can be managed with little or no support from a health worker; and
- individuals can acquire and apply certain skills to help them to manage their health, including gathering information, managing medication, managing symptoms, managing psychological consequences, adjusting their lifestyle, using social support and communicating effectively.

National dialogue will be needed to determine whether:

- health worker availability at different levels contributes to the accessibility and use of self-care interventions;
- policy-makers, programme managers and health workers are willing to consider the rational delegation of tasks to laypeople;
- health workers are supported by other interrelated health-system components to promote self-care interventions;
- self-care interventions are considered in the context of improving overall healthcare delivery, to enable holistic integrated care.


Further research is needed for specific health topics, with the goals of (i) increasing the number of studies from the settings, health areas and populations that are inadequately represented in current research, and (ii) understanding the contextual factors that determine what works in what circumstances.



The delegation of tasks within the health team is more likely to succeed when the stakeholders involved are convinced that the consequences will be positive. Redistributing or delegating tasks requires stakeholder dialogue to understand and address the expectations and fears of the people who will be affected, including the individuals, their carers and communities, and health workers and managers. This means that delegation should not be seen as a cost-saving measure. When tasks are delegated to individuals and their carers, the goals, expectations and capacities of those adopting new roles regarding self-care should be recognized, ensuring they are empowered to engage fully with health workers to design their healthcare, and with the ongoing monitoring and evaluation needed to ensure improved health outcomes.

4.4.3 COMPETENCY-BASED TRAINING OF HEALTH WORKERS

Culturally sensitive, respectful and compassionate care in the provision of self-care interventions requires the following.

	Good practice statement
 <p>Good practice statement 9 (adapted)</p>	<p>Countries should adopt a systematic approach to harmonized, standardized and competency-based training that is needs-driven and accredited so that health workers are equipped with the appropriate competencies for:</p> <ul style="list-style-type: none"> • engaging in and supporting self-care practices that promote emotional resilience, health and well-being; • determining the extent to which an individual wishes to, and is able to, self-monitor and self-manage healthcare; • promoting access to and the correct use and uptake of self-care interventions; and • educating individuals for preparing and self-administering medications or therapeutics.

Background information

A transformative education agenda grounded in competency-based learning is important for the scale-up of competency-based professional, technical and vocational education and training, and to increase the quality of the workforce (17, 30). Furthermore, competency-based curricula have the potential of bringing about positive

educational effects that can lead to better health-service delivery, such as improving curricula that entail the revision of teaching modalities, focusing on prevailing health needs and trends, addressing individual student needs, generating a comprehensive approach to infrastructure development to include technology development, and improving the curricula (31).

BOX 4.3. CASE STUDY ON COMPETENCY-BASED LEARNING FOR HEALTH WORKERS TO IMPLEMENT SELF-CARE CONTRACEPTIVE INTERVENTIONS AND MAINTAIN CONTRACEPTION AS AN ESSENTIAL SEXUAL AND REPRODUCTIVE HEALTH SERVICE

The WHO Academy has launched a learning programme on the counselling and prescribing of contraception in pharmacies. It covers contraceptive counselling and the prescribing of self-administered contraceptive methods that can be taken at home and/or within safe environments such as shelters for women at risk of intimate-partner violence.

A 2020 survey by WHO identified that family planning services were disrupted in 68% of countries during the pandemic (32). In many countries, the number of health workers is not sufficient to address the need for contraceptive services (33). Pharmacies play an important role in meeting the increasing demand for contraception; small drug shops and pharmacies are often the first line of healthcare in resource-limited settings (34–36), and drug shops and pharmacies are an important source of contraceptive supply in many countries (37). Engaging pharmacy health workers to expand the provision of contraceptive methods can significantly improve access to contraception for all (33, 37).

The WHO Academy learning programme is targeted at health workers in community drug store and pharmacy settings who provide (or will be providing) over-the-counter contraception. Learners are guided at their own pace using a question-and-answer approach via simulated interactive clinical scenarios to provide self-administered, over-the-counter contraceptive methods, including emergency contraception, progestogen-only pills, combined oral contraceptives, self-injectables, and male and female condoms. Learners are provided with relevant guidelines and job aids to assist their progression through each scenario. The programme ends with a short assessment component, and a certificate is awarded for successful completion.

This learning programme is a first entry point to a wider programme covering further self-care interventions. The programme is available in the six official languages of the United Nations.



Summary of the evidence and considerations of the GDG


The WHO global competency and outcomes framework for UHC in 2021 (30) seeks to guide the development of education programmes that use the progressive sequencing of knowledge, skills and attitudes to support learners to achieve educational outcomes that translate knowledge into provision in healthcare. The focus is on the functions of health services – both individual-focused and population-focused health services – rather than the occupations that provide those services.

The competencies defined in the framework fall under six domains: people-centredness, decision-making, communication, collaboration, evidence-informed practice and personal conduct. There are 35 practice activities that have been identified for the whole health team in the health workforce. The practice activities are categorized into three domains: individual health, population health, and management and organization.

Should the use of a self-care intervention lead to the need for further support or counselling within the health

system (e.g. when a test result is positive), 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 them and potentially 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 that may impact their 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.
- 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 any alternative and conflicting views of family members, carers, friends and members of the multidisciplinary healthcare team where appropriate to maintain the 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.

4.5 POPULATION-SPECIFIC IMPLEMENTATION CONSIDERATIONS



4.5.1 IMPLEMENTATION CONSIDERATIONS DURING HUMANITARIAN CRISES INCLUDING PANDEMICS

	Recommendation
Recommendation 38 (new)	WHO recommends prioritizing digital health services, self-care interventions, task sharing and outreach to ensure access to medicines, diagnostics, devices, information and counselling when facility-based provision of sexual and reproductive health services is disrupted.
Recommendation 39 (new)	WHO recommends maximizing occupational health and staff safety measures, including providing mental healthcare and psychosocial support and promoting self-care strategies.

Background information

Public health and social measures imposed by governments and public health agencies during the COVID-19 pandemic have resulted in an unprecedented demand on individuals and communities to practise self-care measures and use self-care interventions. For instance, individuals, communities and entire societies have been asked to contribute to reducing the transmission of the coronavirus, to reduce mortality and morbidities and protect their own health, through a range of actions, including washing hands, physical distancing and self-managing health conditions that do not require going to a health facility.



Strategic adaptations in healthcare delivery during pandemic and humanitarian responses should be made in accordance with ethical principles, such as equity in the allocation of resources and access, self-determination, non-abandonment, and respect for dignity and human rights (38).

When facility-based provision of SRH services is disrupted, WHO recommends prioritizing digital health services, self-care interventions, rational delegation of tasks, and outreach to ensure access to medicines, diagnostics,

devices, information and counselling (38). This prioritization should include ensuring access to contraception, abortion to the full extent allowed by law, and prevention and treatment services for sexually transmitted infections (STIs), including HIV and human papillomavirus (HPV).



Existing gender and social inequalities are exacerbated by pandemic contexts, which impact girls and women in different ways than they affect men and boys. Women’s and girls’ exposure is likely to be affected by social norms and expectations for their caregiving role: they provide the overwhelming majority of care in the home and make up the majority of the health workforce. Overall, the failure to protect underserved and marginalized groups puts them at a higher risk of infection and undermines the broader response to COVID-19 and other pandemics and crises.

Examples of self-care interventions prioritized during pandemics

Table 4.1 highlights some examples of self-care interventions that have been prioritized by WHO during public health and social measures in response to the COVID-19 pandemic (38).

TABLE 4.1. ESSENTIAL SELF-CARE INTERVENTIONS DURING PANDEMICS

Programme activities	Modifications for safe delivery of sexual and reproductive health services
Access to contraception	<ul style="list-style-type: none"> • If a woman's regular contraceptive method is not available, other contraceptive options should be made more readily available (including barrier methods, fertility awareness-based methods and emergency contraceptives). • Relax requirements for a prescription for oral or self-injectable contraception and emergency contraception, and provide multi-month supplies with clear information about the method and how to access referral care for adverse reactions. • Enable pharmacies and drug stores to increase the range of contraceptive options they can provide and allow for multi-month prescriptions and the self-administration of subcutaneous injectable contraceptives if available.
Safe abortion to the full extent of the law, and post-abortion care	<ul style="list-style-type: none"> • Consider reducing barriers that could delay care and therefore increase risk for adolescents, rape survivors and others who are particularly underserved and marginalized in this context. • Consider the option of using non-invasive medical methods for managing safe abortion and incomplete abortion. • Minimize facility visits and provider–client contacts through the use of telemedicine and self-management approaches, when applicable, while ensuring access is maintained to a trained provider if needed. • Adjust forecasting for commodities and supplies to meet the anticipated increase in the need for medical methods of abortion. Consider expanding telemedicine mechanisms for medication delivery in contexts where it is proven effective.
Sexual health	<ul style="list-style-type: none"> • Increase access to condoms and lubricants for safer sexual practices by using different outlets. • Prioritize the need for menstrual products and ensure they are included in lists of priority health products, to mitigate supply disruption. • Communicate about alternative, reusable menstrual health products. • Where available, engage community groups to extend the availability of menstrual products. • Increase the availability of self-testing for HIV and self-collection of samples for sexually transmitted infections, including syphilis, and referrals to treatment if needed. • Prioritize appropriate messaging for safe and consensual sex during periods of self-isolation. • Ensure adequate access to essential commodities for people under long-term treatment (e.g. receiving HIV medications, menopause management or hormonal therapy as part of gender-affirming care).
Cervical cancer screening and prevention	<ul style="list-style-type: none"> • Promote self-sampling for HPV testing, facilitating the collection of specimens through pharmacies or drop-off at facilities. Promote online advice after a negative screening test, and adequate management after a positive screening test.
Noncommunicable diseases	<ul style="list-style-type: none"> • General management: create self-management plans and support self-monitoring of disease, if appropriate, that is backed up by healthcare workers using alternative delivery mechanisms if needed. Increase home supplies of medication and stocks of monitoring devices. • Management of chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease: if appropriate, ensure patients with asthma have rescue packs (i.e. a short course of steroids) to manage acute exacerbations at home with support, according to a self-management plan agreed with a clinician. • Management of diabetes: provide people with type 1 diabetes with urine ketone self-monitoring strips and ensure phone contact is established with a provider.

Programme activities	Modifications for safe delivery of sexual and reproductive health services
Communicable diseases	<ul style="list-style-type: none"> • HIV: promote HIV self-testing to partners, peers and contacts of key populations. • Scale up the provision of self-testing through the use of community distribution points, facility-based pick-up points (including in the private sector), the internet and through postal services; give HIV self-test kits to male partners. • Sexually transmitted infections: modify testing through the use of home-based self-sampling, ensuring the provision of information about proper self-sampling and where to send samples. Modify the provision of test results and treatment and prevention messaging to deliver them through digital platforms, including mobile phones. • Partner services and social network-based testing approaches for people living with HIV: prioritize the partners and social contacts of people living with HIV for testing, using internet and telephone follow-up, and self-testing (include a self-testing option for partners and peers to distribute).
Neglected tropical diseases	<ul style="list-style-type: none"> • For leprosy (Hansen’s disease) treatment, reduce patient contact by promoting self-care and instructing patient and family members about basic measures to avoid and manage sequelae (e.g. ulcers).

Summary of the evidence and considerations of the GDG

For maintaining and meeting the SRH needs of individuals, families and communities during a situation of self-isolation or in places with overstretched health systems, the following three methods of increasing access and coverage are essential.

1. Digital technologies and platforms, which are increasingly important mechanisms for sustaining and maintaining reproductive health interventions, services and treatment when other places of accessing healthcare and treatment are limited. Countries need to leverage digital technologies to deliver self-care interventions and information for reproductive health, to continue providing individuals with access to interventions, services and treatment. Examples include:
 - client-to-provider telemedicine to increased self-care where health services are provided and delivered at a distance, such as remote consultations or follow-up, including referrals for self-administering injectable contraceptives and/or self-testing for HIV;
 - targeted communication to certain client audiences to provide health education content about health-seeking behaviours, such as education on condom use, sexual health and safer sex messages; and
 - targeted client communication interventions to provide notifications and reminders for medication adherence and follow-up services, which can support the use of regulated medicines, such as for women managing post-abortion care.

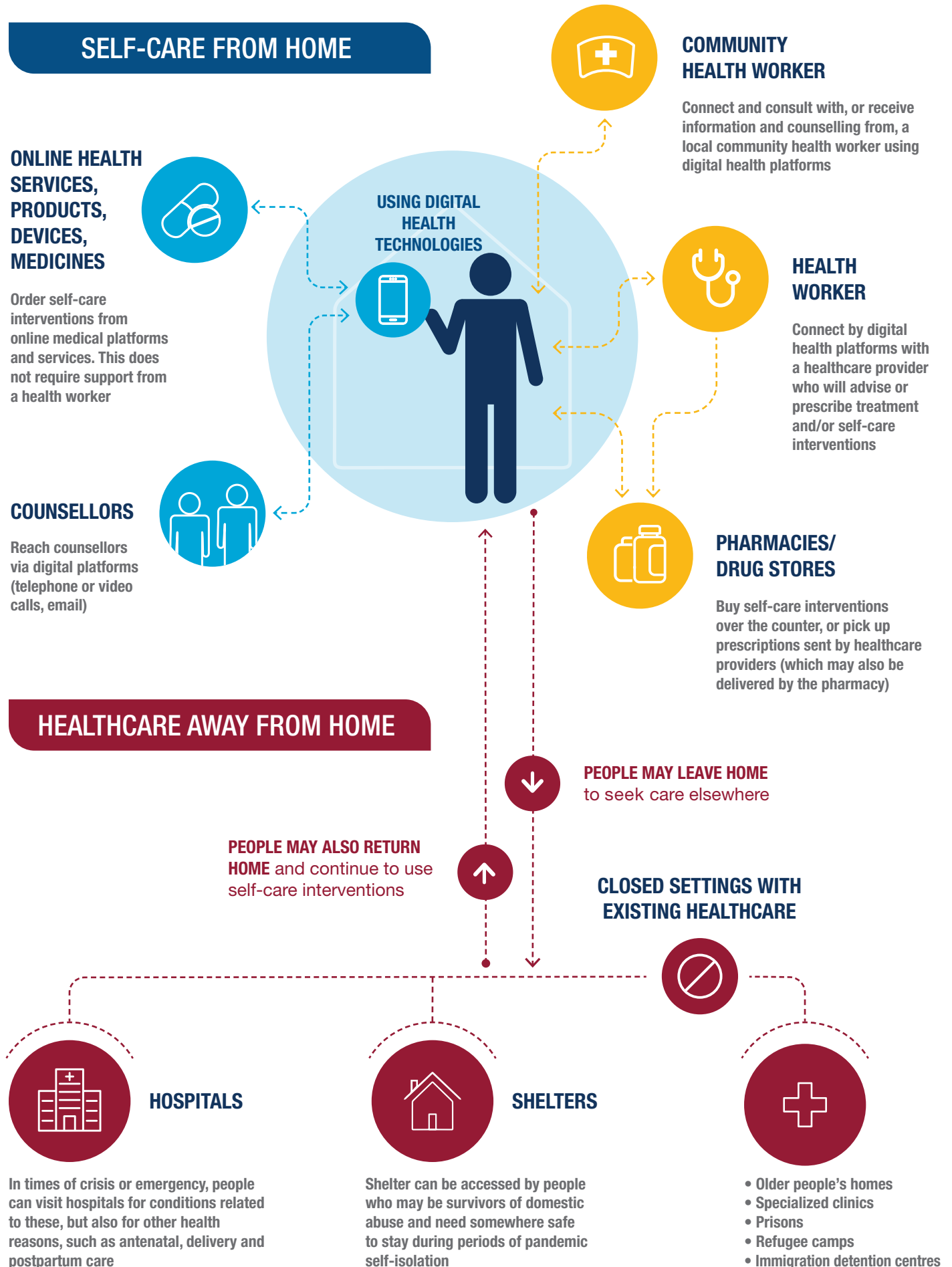
2. Over-the-counter availability of medical devices, medicines, information and diagnostics, which has been growing globally. Ensuring that these commodities are available through pharmacies and drug stores, whether mobile or fixed, improves coverage, access, uptake and health outcomes.

Examples include:

- over-the-counter oral contraception, which may increase access to this effective option and reduce unintended pregnancies;
- menstrual hygiene products, including in situations of water scarcity or lack of clean water; and
- Post-exposure prophylaxis for HIV for people at increased risk of sexual violence. While the data on this are primarily on women and girls, other underserved and marginalized populations, including transgender individuals, may also be at increased risk.

3. Method of increasing access and coverage during public health and social measures for non-pandemic-related SRH conditions. Examples include:
 - antenatal care visits, and delivery and postpartum care;
 - retesting and access to treatment if an HIV self-test is positive, and access to diagnostics and treatment for other sexually transmitted infections if needed; and
 - access to crisis centres, shelters, legal aid and protection services for people surviving violence.

FIG. 4.5. ROLE OF SELF-CARE INTERVENTIONS IN PUBLIC HEALTH AND SOCIAL MEASURES DURING PANDEMICS





4.5.2 LIFE-COURSE APPROACH

	Good practice statement
Good practice statement 10	Sensitization about self-care interventions 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.

Background information

Under a life-course approach, health and the risk of disease are understood as the result of people's life experiences and social and physical exposures, from gestation to late adulthood (39). 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, intergenerational, social, environmental and temporal factors in the health and well-being of individuals and communities (40).

The main outcome of the life-course approach is functional ability, which is determined by individuals' intrinsic capacity in their interactions with their physical and social environments, and is thus interdependent with the realization of human rights (41). 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 (42).

A lack of systematic knowledge about the way health at different stages of life 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. There are few studies on this issue, and most of them focus 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 to a better understanding of the health needs of populations at particular stages of life. Notions about the sexual lives, needs and health of older populations and adolescents are often clouded by stereotypes, for example. Discrimination against older people has received increased attention since the 1980s, when the term ageism was coined for this particular kind of age-based discrimination (43).

A 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 are critical to better tailor policy and actions.

Examples of life-course approaches for self-care interventions

Age-appropriate environments will enable the health 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 (44). Healthy ageing is recognized by the United Nations and the decade of action on healthy ageing, launched in 2020 (45), as a contributing factor to the attainment of the Sustainable Development Goals (46).

WHO case studies on the implementation of the life-course approach to health in the small European countries of Iceland and Malta have identified three factors enabling implementation (47). The first entails the strengthening of collaboration across different government areas, sectors and society – the studies showed that planning and action benefited from the perspectives and involvement of all the actors involved. The second is about making healthcare 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 the allocation of time and resources to monitoring and knowledge exchange; these two activities are key to ensuring the adoption and ongoing improvement and durability of the life-course approach and actions.

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. „Older adults” remains too broad a category, as

it is often shorthand for all adults in the second half of life (48). Yet older adulthood comprises different stages of life that should be differentiated and better understood before the health needs of specific stages can be met. WHO currently identifies three age categories in older adulthood: middle adulthood (age 50–64 years) and the two age groups in later adulthood (65–79 years and 80-plus years of age) (49). Sexual health, for instance, remains a key consideration among older adults (50). 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 (51).

A life-course approach that is sensitive, respectful and knowledgeable about the particular challenges and opportunities at all ages would also help to 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 poorly studied, 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. To support informed choices, improving the health literacy of older adults regarding accurate information, services and self-care for SRHR remains of great importance.



4.5.3 IMPLEMENTATION CONSIDERATIONS OF UNDERSERVED AND MARGINALIZED POPULATIONS

	Good practice statements
Good practice statement 11 (adapted)	People from underserved and marginalized populations should be able to experience full, pleasurable sex lives and have access to a range and choice of reproductive health options.
Good practice statement 12 (adapted)	Countries should work towards implementing and enforcing anti-discrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against underserved and marginalized populations.
Good practice statement 13 (adapted)	Transgender and gender-diverse individuals who self-administer gender-affirming hormones require access to evidence-based information, quality products and sterile injection equipment.

Remarks

- For good practice statement 13: Transgender and gender-diverse individuals should also be supported by the health system, with health workers trained to manage adverse events arising from the self-administration of gender-affirming hormones; and other gender-affirmative care should also be available.

Background information

People from underserved and marginalized populations should enjoy the same health and rights as all other individuals. It is important, for instance, that they have access to family planning and other SRH services. Efforts to reduce stigma and discrimination at the national level, such as by promoting anti-discrimination

and protective laws and policies for many underserved and marginalized populations, can foster a supportive environment, particularly within the healthcare and justice systems – and the same applies to other underserved and marginalized populations. Policies are most effective when they simultaneously address individual, organizational and public policy factors that drive or enable stigma and discrimination. Programmes, both within and outside the health sector, need to institute anti-stigma and anti-discrimination 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 any people who may experience stigma and/or discrimination when they try to obtain health services (52), with access to redress also being made available.

Laws and policies can help to protect the human rights of underserved and marginalized populations. Legal reforms such as decriminalizing consensual sexual behaviours and giving legal gender recognition to transgender people are critical enablers that can change a hostile environment into a safe and supportive, enabling one. Specific consideration



should be given to such legal reforms as part of any revision of policies and programmes for underserved and marginalized populations.

Supporting the health and well-being of underserved and marginalized populations may need legislation to be changed and new policies and protective laws to be adopted in accordance with international human rights standards. Without protective laws and policies, barriers to access, uptake and use of essential health services – including self-care interventions – will remain (52).

Examples of self-care interventions: harm reduction

In Indonesia, youths buy psychoactive prescription drugs for pleasure over the counter in pharmacies (despite government efforts to control such sales), while information on how to use them is exchanged in peer groups and online through social media. A harm-reduction campaign on the use of psychoactive prescription drugs was developed with two youth communication collectives in Jakarta known as Pamflet and Kok Bisa. These collectives proposed spreading “tales of caution” on social media (53).

Several quantitative studies of transgender and gender-diverse individuals globally have documented the reported rates of unprescribed hormone use ranging from 11% in Ontario, Canada (54), to 31% in London, United Kingdom

of Great Britain and Northern Ireland (55), to 49.1% in San Francisco, United States of America (56), and to 78.7% in Rio de Janeiro, Brazil (57). While some routes of administration may be fairly easily achieved by an individual without health system support, others may pose risks; at least one study has suggested that self-injection is associated with an increased prevalence of HIV, perhaps due to sharing needles (58). Harm-reduction programmes could prevent such harm, building on existing guidelines for gender-affirming care.

Summary of the evidence and considerations of the GDG

Harm-reduction efforts are critical for all populations, and particularly for underserved and marginalized people. While harm reduction is mainly associated with substance use, there is a wide range of programmes. While some target the use of substances such as amphetamines, cannabis, tobacco and alcohol, others are focused on safer means to administer them, such as clean needles, safer alternatives, and the creation of safe spaces (59). Harm-reduction efforts aimed at broader groups have called on smokers and drinkers to take responsibility for their own health, and successful programmes acknowledge factors such as the safe use of an intervention or the essential role of social relations (53). Harm reduction in the context of introduction and access to self-care interventions, such as the use of drugs for self-management of medical abortion, requires efforts to be in place to ensure clients do not experience added harm. Communities of substance users should be actively involved in the conceptualization, development, implementation and evaluation of harm-reduction activities.



4.6 DIGITAL HEALTH INTERVENTIONS

	Good practice statements
Good practice statement 14 (adapted)	Digital health interventions offer opportunities to promote, offer information about and provide discussion forums for self-care interventions.
Good practice statement 15 (adapted)	Client-to-provider telemedicine to support self-care interventions can be offered to complement face-to-face health services.
Good practice statement 16 (adapted)	Digital targeted client communication by health workers on the use of self-care interventions can help to implement, monitor and evaluate health outcomes.

Background information

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

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

Examples of self-care interventions: digital health interventions

Self-care interventions for health has perhaps the greatest potential to address unmet needs or demands in marginalized populations or in contexts of limited access to healthcare, 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 about them (60) and reticence to discuss an intervention because of the associated stigma (61). For example, when young people obtain emergency contraception from pharmacists but immediately discard the packaging and information sheet because of its potential to incriminate them.

Many studies of digital health interventions – including eHealth and mHealth (mobile health, a component of eHealth) – which often facilitate targeted client communication or provider–client telemedicine, recognize issues of access (particularly in relation to the availability of mobile phones and connectivity) and 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 designs (62).

Digital health technologies offer potential conduits for information beyond the 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 (63). In terms of on-demand information, the internet is popular, particularly because the information online is available and affordable and can be accessed anonymously and in private (64, 65). Online discussion forums – using social media or apps – can be sources of peer-to-peer information around self-care technologies. With regard to information provision via mobile phones (text messages or smartphone apps), recent reviews have demonstrated high feasibility and acceptability in the provision of health-related information, with studies also demonstrating knowledge and behaviour change (66).

Summary of the evidence and considerations of the GDG

A systematic review of studies of adolescents accessing SRHR information online highlighted a demand for information and education (and not just technical information) about sexual experiences, and reviewed the behaviour-change impact of accessing information in this way. The review also highlighted how demand for information varies across the adolescent age groups, showing that adolescents are generally good at evaluating information. On the role of social media in providing SRHR-related information, however, there is a lack of research. The relatively few studies undertaken highlight issues with measuring impact, the limitations of study designs and a lack of standard reporting (67).

Recent reviews highlight how the effectiveness of digital health interventions to provide appropriate information for safe and effective self-care interventions for SRHR is predicated on consideration of (i) potential users' access to technology/digital devices, including connectivity; (ii) diversity and changes in the types of delivery channel (e.g. text, voice, apps); (iii) the information priorities and needs specific to different population groups (e.g. age, gender, sexuality, disability); (iv) the need to tailor content and maintain the fidelity of messages; (v) concerns about confidentiality; and (vi) the current levels of overall literacy as well as digital and health literacy.



4.7 ENVIRONMENTAL CONSIDERATIONS

	Good practice statements
Good practice statement 17	Safe and secure disposal of waste from self-care products should be promoted at all levels.
Good practice statement 18	Countries, donors and relevant stakeholders should work towards environmentally preferable purchasing of self-care products by selecting supplies that are less wasteful, can be recycled or produce less-hazardous waste products, or by using smaller quantities.

Remarks

- Promote adequate arrangements for storage, including the safe storage of sharps at home.
- Provide mechanisms for the safe and secure disposal of equipment used for the 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 promoting awareness about or providing training on the 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.
- Additional support needs to be provided to underserved and marginalized individuals and populations who may not have the possibility of safely disposing of medical waste products.

These good practice statements were adapted from statements in the 2014 WHO publication *Safe management of wastes from health-care activities* (68), available at <https://www.who.int/publications/i/item/9789241548564>.

Background information

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, road accidents, poor land-use practices and poor natural resource management (69). More than one quarter of the 6.6 million annual deaths of children aged under 5 years are associated with environment-related causes and conditions (70). 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 (70).

As the dependence on hospital-based systems reduces and the reliance on self-care products such as diagnostic tests performed at home increases, there will be an inevitable increase in associated waste disposal.

The rising incidence of cardiovascular and respiratory diseases is the major driving factor for the growth of the market for self-care medical devices. The preference for the 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 healthcare has also triggered the demand for self-care medical devices, and this is expected to grow further. For self-care interventions to be sustainable, a change in the patterns of healthcare consumption, more sustainable production methods of healthcare 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.

Examples of self-care interventions: effect on the environment

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 losing opportunities for reuse (71). In 2010, unsafe injections using contaminated supplies were responsible for as many as 33 800 HIV infections, 1.7 million hepatitis B infections and 315 000 hepatitis C infections. There are additional hazards in scavenging at unsecured waste disposal sites and in handling and manually sorting hazardous waste from healthcare 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 assessment by WHO and the United Nations Children's Fund found that only 58% of the facilities sampled in 24 countries had adequate systems in place for the safe disposal of healthcare waste (72).

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 (so-called 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 (73).

To effect green procurement, WHO supports the 4R strategy to (73):

- rethink the requirements to reduce environmental impact;
- reduce material consumption;
- recycle materials/waste; and
- reduce energy consumption.

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 is buying the least-damaging products and services in terms of environmental impact. At its simplest, environmentally preferable purchasing may lead to the purchase of recycled paper; more-sophisticated measures include 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 (74).

WHO supports the safe and sustainable management of waste from healthcare activities (74, 75). To better understand the problem of healthcare waste management, WHO guidance recommends that countries conduct assessments before deciding which healthcare management methods to choose. Tools are available to assist with the assessment and decision-making process so that appropriate policies lead to the choice of adapted technologies (75).

As stated in a key policy paper in 2007, WHO core principles require that all financing and supporting healthcare activities should provide for the costs of managing healthcare waste. This is a duty of care. Manufacturers also share a responsibility to take waste management into account in the development and sale of their products and services (76). In keeping with these core principles, the 2007 policy paper made a series of specific recommendations aimed at governments, donors/partners, nongovernmental organizations, the private sector and all concerned institutions and organizations (see Box 4.4) (76). The case study in Box 4.5 gives some information on progress that has already been achieved in this area.

BOX 4.4. WHO RECOMMENDATIONS ON SYSTEMS FOR HEALTHCARE WASTE MANAGEMENT

Governments should:

- allocate a budget to cover the costs of establishing and maintaining sound healthcare 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; and
- implement and monitor sound healthcare waste management systems, support capacity-building, and ensure worker and community health.

Donors and partners should:

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

Nongovernmental organizations should:

- include the promotion of sound healthcare waste management in their advocacy; and
- undertake programmes and activities that contribute to sound healthcare waste management.

The private sector should:

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

All concerned institutions and organizations should:

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

Source: WHO (76).

BOX 4.5. CASE STUDY ON ENVIRONMENTAL CONSIDERATIONS RELATED TO SELF-CARE

The United Nations informal interagency task team on sustainable procurement in the health sector is hosted at the regional hub in Istanbul, Türkiye, of the United Nations Development Programme (UNDP). Its aim is to facilitate and coordinate the introduction of sustainable procurement 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 launched the 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 the implementation of health programmes (77).

Among many initiatives implemented under the UNDP's procurement strategy 2015–2017 was the sustainability assessment of long-term suppliers of antiretrovirals. The assessment was based on the responses and documentation provided by suppliers to a detailed questionnaire, which took into consideration international standards, recognized reporting systems and similar scorecards used by other international organizations and public procuring institutions. A set of requirements was then established to help to verify which suppliers were taking the necessary actions towards improving sustainability practices without compromising their delivery of goods (78).

Summary of the evidence and considerations of the GDG

In addition to the environmental considerations reviewed for the 2019 guideline, the public health and social measures against COVID-19 have since led to the use of many self-care products, including face masks, hand sanitizers and plastic gloves – and the volume of the resulting medical waste has increased steadily globally (79). During the peak of the outbreak in Wuhan, China, for instance, hospitals produced more than six times more waste than usual, most of which was plastic personal protective equipment (80).

The safe disposal of these waste products is not only relevant for reducing the further transmission of the virus; the products also have a negative impact on the environment, from constituents such as the high levels of microplastic fibres in the face masks (81). These emerging challenges in solid waste management during and after the pandemic require further research and changes in environmental policies and programmes. One example is noted in Box 4.6.

BOX 4.6. CASE STUDY ON THE SAFE DISPOSAL OF SELF-CARE PRODUCTS

In response to The World's Largest Lesson – the global educational initiative from the United Nations Children's Fund (UNICEF) – UNICEF Romania proposed a project for the responsible discarding of used face masks and other self-care products for personal protection in the COVID-19 pandemic.

Teachers and pupils worked together to promote the best way to discard used masks, gloves, antibacterial wipes and other pieces of equipment for personal protection. Tens of thousands of Romanian children now know that these items are to be collected only in closed containers to avoid the risks of viral contamination and environmental pollution. Based on the educational materials distributed by UNICEF Romania, teachers guide their teams to create collective action plans. The children aim to raise awareness about the impact of inappropriately discarded personal protective equipment on the environment and to persuade the members of their communities to collect them responsibly.

Source: UNICEF (82).

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5.

Developing the research agenda for self-care interventions



At a Glance

This chapter presents the strategies and approaches that should be leveraged when developing a research agenda for self-care interventions and stresses the importance of expanding research on self-care and self-care interventions to advance the field.

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Developing an appropriate approach to research

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5.1 RESEARCH ON SELF-CARE AND SELF-CARE INTERVENTIONS CONTRIBUTING TO THE WORLD HEALTH ORGANIZATION'S TRIPLE-BILLION GOALS

In the context of the World Health Organization (WHO) goal to ensure 1 billion more people benefit from universal health coverage (UHC), a strategy to increase access to essential self-care interventions for primary healthcare can increase UHC coverage. This will require a strong evidence base and targeted efforts to reach underserved people and communities. The empirical body of evidence for the needs of many underserved people, such as gender-diverse individuals, is inadequate. Developing evidence-based guidance from WHO that can help to reach UHC, including with self-care interventions, will need an added emphasis on these existing research gaps. The research and development agenda will be defined and coordinated in line with national and regional public health priorities.

Regarding the WHO goal to better protect 1 billion more people from health emergencies, the research agenda should 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 response to the COVID-19 pandemic, for instance, WHO support for research priorities that contribute to global research platforms aims to facilitate learning from the response to the current pandemic, to better prepare for the next one. Given the importance of the self-care and self-care interventions prioritized in response to the COVID-19 pandemic, increased research in humanitarian and emergency contexts is a priority.

With respect to the WHO goal for 1 billion more people to enjoy better health and well-being, research will be needed into the optimal delivery of self-care interventions to increase health literacy, reduce health risk factors and promote optimal health outcomes. Research is also needed on how self-care interventions can lead to improved health and well-being through the empowerment of individuals to understand their rights and support their ability to navigate through the healthcare system as consumers informed about the health benefits and risks of products and services. This can be achieved through multisectoral action, which must include the meaningful engagement of all stakeholders, especially civil society and underserved communities, and both the public and private sectors.

5.2 TOWARDS AN APPROPRIATE APPROACH TO RESEARCH ON SELF-CARE INTERVENTIONS

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 the meaningful engagement of users and health workers throughout the research process.

Future research on self-care can be conceptualized under two broad areas:



1. Development 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?



2. Delivery of self-care interventions: 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, safety, implementation and delivery will be the perspectives of individuals, collectives, communities and health workers as well as systems perspectives. As such, attention needs to be given to matching the selection of the processes and outcomes to be assessed with the relevant perspectives. The same is true for studies of costs and cost-effectiveness.

The increasing adoption of digital health technologies and digital therapeutics in self-care offers new opportunities to generate real-world evidence in real time. At the same time, though, 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 the people who participate in research and conduct it are paramount to creating a sustainable research environment.



The research endeavours specific to self-care interventions can be conceptualized as combining conventional healthcare epidemiological principles with social science, human rights, gender equality, ethics and law. Studies on self-care interventions 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.

5.3 SPECIFIC RESEARCH CONSIDERATIONS TO STRENGTHEN THE EVIDENCE BASE

During the guideline development process and Guideline Development Group (GDG) meetings for the 2019 guideline and this guideline, the GDG identified important knowledge gaps that needed to be addressed through further primary research. For several of the questions addressed by new recommendations in the 2019 guideline and this guideline, the evidence base was limited. The reasons for this included: (i) few or no rigorous studies related to the topics of interest being published in peer-reviewed journals, (ii) little representation of research from low- and middle-income countries, and (iii) few outcomes of interest (especially harms) being included in the studies. In addition, most results were not disaggregated to support an understanding of the potential differences in outcomes among different groups of (potential) users of self-care interventions.

The certainty of the evidence was rated as low or very low for several of the interventions evaluated according to the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology. For some interventions, there simply was not enough evidence to make a recommendation. This implies that further research on these interventions would be 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.

The measurement of social harms (such as stigma or intimate partner violence) as outcomes was consistently absent from the studies included in the reviews prepared for the 2019 guideline and this guideline (see Annex 7). The GDG noted that social harms were especially important to measure, as the use of the intervention was intended to take place outside the health system. Both the social benefits and the social harms needed 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 the person needs further healthcare assistance. For example, following the use of a self-care intervention for screening or sampling, the results might require further tests in health facilities. 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 to give information for informed decision-making and provide appropriate linkage to care. Similarly, the burden of care and costs should not be transferred to the individual under the guise of self-care without careful consideration of the individual benefits and potential harms.

Illustrative research questions are provided in Table 5.1 in relation to the enabling environment for self-care interventions, and then some intervention-specific questions are presented, following the structure of the GRADE framework, in Tables 5.1 and 5.2. Each research question should consider the range of self-care interventions, the diversity of potential users and the different locations in which self-care interventions are purchased and used, following the elements of the conceptual framework presented in Fig. 2.1 (Chapter 2). The classification of self-care interventions can further help to define research priorities (as noted in Chapter 1).

Table 5.1 lists questions to address the research gaps identified by the GDG, organized by topic for the self-care interventions addressed by new recommendations in the 2019 guideline and this guideline, and by GRADE domain. The research gaps identified in the 2019 guideline have been retained, as the gaps are still relevant at the time of writing this guideline (see Table 5.2). These lists are not intended to be exhaustive – many other topics may also merit further research. In addition, it is important to note that this process does not aim to prioritize research, but to shape the research questions in response to a guideline. Therefore, no hierarchy of importance is implied by the order of the research gaps in the tables.

5.4 CENTRING HUMAN RIGHTS AND EQUITY IN SELF-CARE INTERVENTIONS

Throughout the development process for this guideline and during the in-person GDG meeting, human rights and issues of equity were emphasized as integral components 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 should systematically consider how human rights and ethics can inform the appropriate implementation of self-care interventions, and how the intervention under study impacts human rights and equity. 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 5.3, along with illustrative research questions for each.

More work is needed to explore and identify the specific outcomes related to these domains and the optimal instruments for their accurate measurement. 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 (1). 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 the outcomes in a trial should be restricted to those in the relevant core outcome set. Rather, at least the core outcomes are expected to 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 and process measures as well.



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

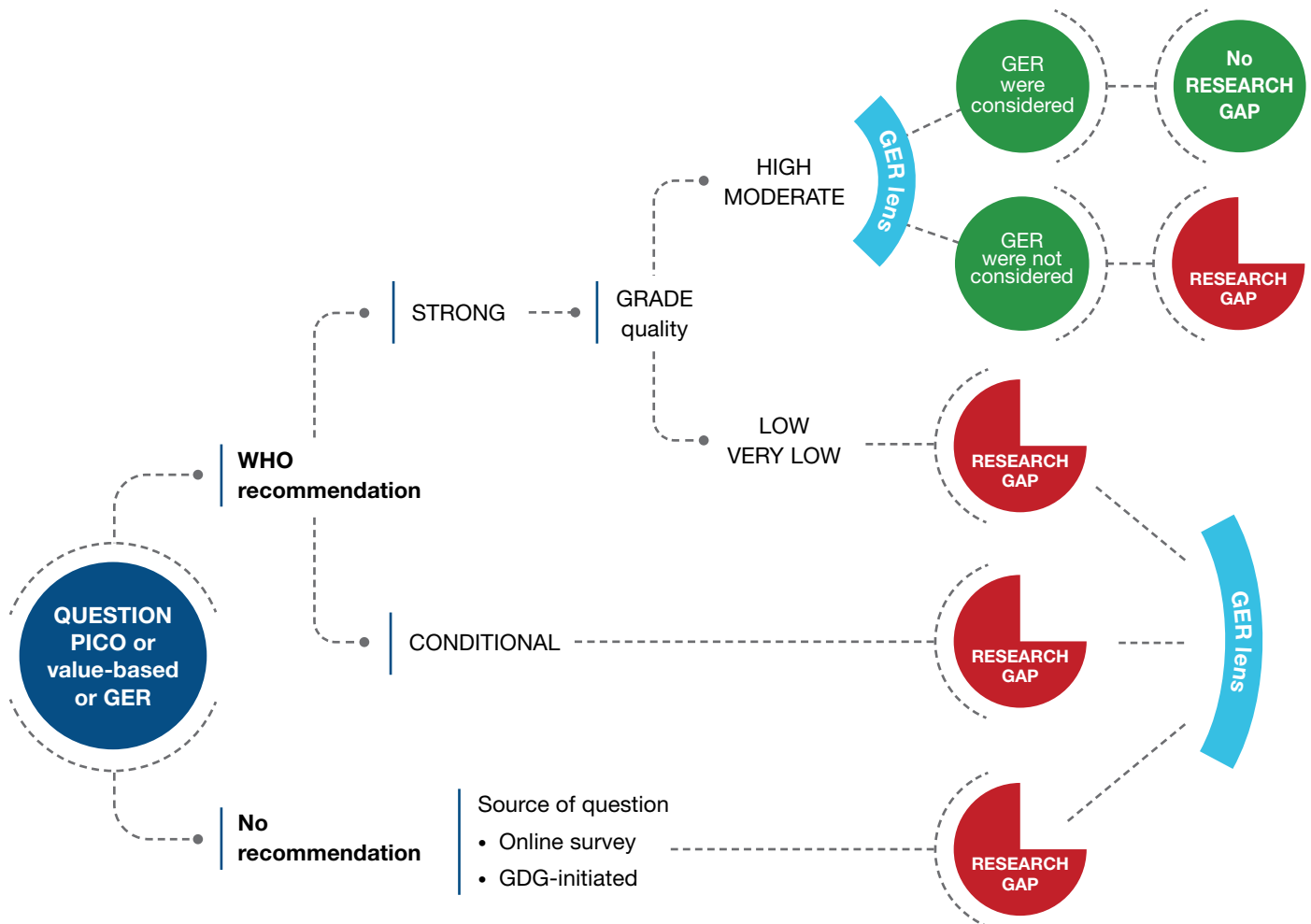
human rights-related questions on self-care interventions, both with regard to service-delivery processes and the intended and unintended outcomes of the use of self-care interventions.

Ethical considerations are also important. In research on self-care interventions, these include considering whether (i) the research has social value for the communities that take part or from which the participants are drawn; (ii) the end users of self-care interventions benefit from the research and are made aware of the research findings; and (iii) the rights and well-being of individual research participants are protected (3).

Engagement with users of self-care interventions before, during and after WHO GDG meetings has led to a constructive approach to the development of a guideline-informed and guideline-linked research agenda (4, 5). This approach adopts a GRADE-based framework, which permits the prioritization of gender, equity and human rights in the determination and design of future research studies of self-care interventions, as shown in Fig. 5.1. Key to this approach is the extensive, meaningful participation of rights holders, including those from marginalized groups, such as transgender people and people living with HIV.

There can be several sources of a research gap, including those (i) identified during the systematic review process; (ii) raised by stakeholders during external engagement, such as in surveys or interviews; or (iii) highlighted by the GDG during the guideline meeting. The identification of a research gap is followed by the determination of one or more future research questions. This is informed by combining four factors: (i) whether or not a recommendation was made during the meeting; (ii) the strength of that recommendation, where applicable; (iii) the certainty of the currently available evidence supporting the recommendation; and (iv) whether an impact on gender, equity and human rights was measured. This approach permits the formulation of a future research agenda in which optimal study designs are articulated along with the associated feasibility and methodological considerations.

FIG. 5.1. HIERARCHICAL DECISION-MAKING ALGORITHM TO FORMULATE RESEARCH QUESTIONS BASED ON THE PRESENCE AND STRENGTH OF A WHO RECOMMENDATION COMBINED WITH THE SOURCE OF THE QUESTION



GDG: Guideline Development Group; GER: gender, equity and human rights; PICO: population, intervention, comparator, outcome
 Source: reproduced with the permission of Siegfried et al. (5).

5.5 ENSURING THE MEANINGFUL ENGAGEMENT OF COMMUNITIES IN RESEARCH

The acceptability and perception of quality of care is shaped by relational and contextual factors, and not necessarily the efficacy or safety of clinical or technical interventions alone; factors such as compassion, empathy and trust are important attributes of quality care.



Important opportunities to improve the quality of care are missed by ignoring how culture and context shape not only the relationships

between people, but also how the outcomes of these relationships and human interactions influence the way that health services and healthcare are organized, delivered and experienced. In ignoring these factors, patient–provider interaction, particularly for underserved populations, continues to be suboptimal across high-income countries and low- and middle-income countries.

Thoughtful, innovative and creative approaches are needed for applying the principles of meaningful community engagement in research and research methodologies. Engaging a community to identify and assess its own priorities highlights the gaps or inequities important to the community itself, instead of imposing perceived needs. It can also point to needs previously unidentified or undervalued by the investigator that need to be researched further (6, 7). As a research agenda-setting organization, WHO has the responsibility to set research priorities that will make progress on filling the gaps in health services that are important to the population being served. Good practice in participatory research can also help to inform models and interventions for community engagement in the design, implementation and monitoring of service delivery.

5.6 KNOWLEDGE TRANSLATION FOR SELF-CARE INTERVENTIONS

Knowledge derived from research and experience may be of little value if it is not put into practice and its success or otherwise is monitored and regularly evaluated. Knowledge translation has emerged to address many of the challenges to facilitating the closure of the “know–do” gap (8). Knowledge transfer is the flow of evidence through the evidence ecosystem. For knowledge to inform and strengthen health systems, it needs to flow efficiently between people who produce evidence (primary researchers), those who synthesize it (systematic reviewers), those who process it (guidelines developers) and the people who disseminate, implement, monitor and evaluate evidence-based interventions. The purpose of the evidence ecosystem is to sustain continual evidence generation and synthesis and evidence-informed policy and practice. To achieve a flow of evidence and its translation into action, each stage needs to be connected, and at each stage there should be both the demand for and the supply of quality-assured evidence, together with a demand for evidence-informed decision products (evidence in usable forms) (9).

Fig. 5.2 illustrates the components needed for a well-functioning evidence ecosystem (10). The appropriate mix of evidence types is determined by the policy issue being addressed and the stage of the policy cycle. For example, qualitative evidence may be useful in better understanding a self-care opportunity such as the acceptability and feasibility to pharmacists of providing a previously prescription-only medication as an over-the-counter medication. Quantitative data derived from randomized trials or implementation-science studies provide evidence on the effectiveness of a self-care intervention, while economic evidence answers questions about what resources are needed to achieve these benefits, and how these resources should be prioritized. Qualitative evidence can also provide insights into stakeholders’ views of the acceptability and feasibility of these options (11). Ultimately, guideline-linked and guideline-informed research is necessary to inform future WHO guidelines in a dynamic and cyclical fashion, contributing to the evidence ecosystem.

FIG. 5.2. THE DYNAMIC NATURE OF KNOWLEDGE TRANSLATION FOR SELF-CARE INTERVENTIONS

PRODUCE EVIDENCE

Undertake primary research, including quantitative research into effectiveness and safety of self-care interventions and qualitative studies of uptake, applicability, feasibility and cost-effectiveness, and incorporate evidence produced by affected communities and through meaningful community engagement

SYNTHESIZE EVIDENCE

Combine evidence from primary research into systematic reviews of effectiveness; values and preferences; gender, equity and human rights; and resource use

EVALUATE AND IMPROVE POLICY AND PRACTICE

Consider population-based data from registries, quality indicators, consultation with end users and affected communities and programmatic data for use in the evaluation of policies and programmes



KNOWLEDGE TRANSLATION

Use evidence to inform decision-support products, including guidelines, guidance, policy briefs and evidence summaries, and identify gaps in primary research from these

IMPLEMENT EVIDENCE

Policies and programmes informed and developed based on evidence of self-care interventions

DISSEMINATE EVIDENCE TO STAKEHOLDERS

Ensure evidence of beneficial and harmful self-care interventions is widely disseminated to decision-makers, health workers, affected communities and end users, and the public. Consider accessibility and user-friendliness

Source: adapted from MAGIC (10).

TABLE 5.1. QUESTIONS TO GUIDE FUTURE RESEARCH ON SELF-CARE INTERVENTIONS FOR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS – concerning the interventions addressed in this guideline

GRADE domain	Research questions to address gaps
Should self-monitoring of blood pressure among individuals with hypertensive disorders of pregnancy be made available in addition to clinic check-ups?	
Benefits versus harms	<ul style="list-style-type: none"> What are the benefits and harms of the self-monitoring of blood pressure in individuals with different hypertensive disorders living in low- and middle-income countries?
Feasibility	<ul style="list-style-type: none"> What health literacy is needed to successfully implement this practice?
Should self-testing for proteinuria during pregnancy be available as an additional option?	
Benefits versus harms	<ul style="list-style-type: none"> Is self-testing for proteinuria as effective and accurate for detecting pre-eclampsia as provider testing?
Should self-monitoring of blood glucose levels among pregnant individuals with gestational diabetes be made available in addition to clinic check-ups?	
Benefits versus harms	<ul style="list-style-type: none"> What are the long-term maternal and child health outcomes of the self-monitoring of blood glucose by pregnant individuals? What is the evidence base, specifically among adolescents and young women?
Acceptability	<ul style="list-style-type: none"> How acceptable to health workers is the self-monitoring of glucose by pregnant individuals? Is there evidence that health workers may ration the use of self-monitors?
Values and preferences	<ul style="list-style-type: none"> What do adolescent girls and young women think about self-monitoring of glucose during pregnancy?
Resource use	<ul style="list-style-type: none"> Who will carry the cost of the device – the health system or the individual? What are the cost-effectiveness considerations, and how is it best to define these to be inclusive of economic and social costs?
Feasibility	<ul style="list-style-type: none"> What are the optimal ways to implement self-monitoring in areas where the universal screening of gestational diabetes is not available?
Equity and human rights	<ul style="list-style-type: none"> What is the evidence base for the use of self-monitoring in low-resource settings? How accessible and available are monitors, and what are the implications for equity?
Should emergency contraceptive pills be made available without a clinician's prescription?	
Benefits versus harms	<ul style="list-style-type: none"> Are there harms from providing emergency contraception (EC) without a prescription? Are longitudinal data available to indicate whether EC is correctly used and within the appropriate timeframe when provided without a prescription?
Resource use	<ul style="list-style-type: none"> How large are the resource requirements (costs) to the end user when accessing EC without a prescription in a pharmacy compared with accessing it from a health worker or clinic?

GRADE domain	Research questions to address gaps
Equity and human rights	<ul style="list-style-type: none"> • Is there evidence of social harms (e.g. intimate partner violence, stigma) following the use of EC without a prescription? • What are the challenges and constraints to the provision of EC without a prescription in low- and middle-income settings? • What are the barriers to access to EC without a prescription, particularly for marginalized populations?
<p>Should self-testing for pregnancy be available as an additional option to clinic-based testing?</p>	
Benefits versus harms	<ul style="list-style-type: none"> • What is the appropriate measurement to determine the benefits and harms of self-testing for pregnancy? • Are there social harms, such as intimate partner violence, related to self-testing for pregnancy compared with testing in the health facility? • What are the effects of limited access to pregnancy self-testing in rural areas? • What forms of evidence can be collated to provide appropriate support for interventions where few comparative data exist?
Resource use	<ul style="list-style-type: none"> • What are the best (i.e. most private) disposal mechanisms for pregnancy self-testing, especially in humanitarian contexts (e.g. refugee camps)?
Equity and human rights	<ul style="list-style-type: none"> • What is the accessibility and availability of self-testing for pregnancy in rural areas? • What is the accessibility and availability of self-testing for pregnancy in humanitarian settings (e.g. refugee camps)?
<p>Should pre-exposure prophylaxis (PrEP) initiation be available following screening by a pharmacist, without a prescription?</p>	
Benefits versus harms	<ul style="list-style-type: none"> • What are the benefits and harms of PrEP initiation without a prescription following screening by a pharmacist, compared with initiation by a doctor with a prescription? • What indirect evidence is available from the pharmacy initiation of other medications or interventions to inform pharmacy-based PrEP initiation?
Resource use	<ul style="list-style-type: none"> • How much are people willing to pay for PrEP compared with (i) their monthly income and (ii) the expected price/cost? • What is the cost-effectiveness of PrEP initiation by a pharmacist without a prescription compared with initiation with a prescription? • How might pharmacies be linked to laboratories to facilitate PrEP initiation by a pharmacist without a prescription? • How sustainable is it to initiate PrEP by a pharmacist without a prescription?
Values and preferences	<ul style="list-style-type: none"> • What do adolescents think about initiating PrEP? Where would they want to initiate it?
<p>Should PrEP continuation be available from a pharmacist, without a prescription?</p>	
Benefits versus harms	<ul style="list-style-type: none"> • What are the benefits and harms of PrEP continuation by a pharmacist without a prescription, compared with continuation by a doctor with a prescription? • What indirect evidence is available from the pharmacy initiation of other medications or interventions to inform pharmacy-based PrEP continuation?

GRADE domain	Research questions to address gaps
Resource use	<ul style="list-style-type: none"> • What is the cost-effectiveness of the task-sharing of PrEP services down the cascade of health workers? • What are the costs of PrEP continuation by a pharmacist, and what are the long-term out-of-pocket costs to the user?
Equity and human rights	<ul style="list-style-type: none"> • How does access to PrEP continuation in a pharmacy affect equity?
Does use of lubricants during or prior to sex result in improved sexual health and well-being?	
Benefits versus harms	<ul style="list-style-type: none"> • Are there safety issues with the use of lubricants, especially if they are of poorer quality or used incorrectly?
Resource use	<ul style="list-style-type: none"> • What is the affordability of lubricants?
Equity and human rights	<ul style="list-style-type: none"> • What is the availability of lubricants? • Do some populations struggle to access them?
Should self-administration of gender-affirming hormones (GAHs) be made available in addition to health worker administration?	
Benefits versus harms	<ul style="list-style-type: none"> • What are the benefits and harms of the self-administration of GAHs compared with provider administration? • How can the benefits of GAHs be best supported when they are self-administered?
Acceptability	<ul style="list-style-type: none"> • How can health workers support a more patient-centred and harm-reducing approach for the self-administration of GAHs?
Values and preferences	<ul style="list-style-type: none"> • What GAHs are used and for what purposes? • Which transgender populations are using GAHs (including analyses of sub-populations such as youth) and in what settings?
Equity and human rights	<ul style="list-style-type: none"> • How do laws, policies, regulations and practices impact on the use of GAHs in general? • How do cultural norms impact on attitudes to gender diversity and/or the acceptance of GAHs? • What is the availability, accessibility (including affordability), acceptability and quality of GAHs? • How does the self-administration of GAHs impact on the right to health (i.e. regarding availability, accessibility, affordability, acceptability and quality)?

GRADE: Grading of Recommendations Assessment, Development and Evaluation.

TABLE 5.2. QUESTIONS TO GUIDE FUTURE RESEARCH ON SELF-CARE INTERVENTIONS FOR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS – concerning the recommendations addressed in this guideline

GRADE domain	Research questions to address gaps
Self-administration of injectable contraception	
Values and preferences	<ul style="list-style-type: none"> • Are there differences between groups of end users (e.g. grouped by age, socioeconomic indicators, occupation and/or education level) in terms of their values and preferences? • What happens after the 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 the characteristics of health workers (e.g. age, country income status, private/public sector) have an impact on whether they view users' self-injection of contraception as acceptable? • What are the scale and consequences of the incorrect use of self-injection?
Resource use	<ul style="list-style-type: none"> • What are the associated costs – for the health system and user – of the self-administration of injectable contraception? • What are the costs and benefits of the self-injection of contraception, and is it cost-effective? • What is the environmental impact of the 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 the self-administration of injectable contraception?
Self-management of contraceptive use with over-the-counter oral contraceptive pills	
Benefits versus harms	<ul style="list-style-type: none"> • What adverse events arise from the use of over-the-counter oral contraceptive pills? • Are there differences in the quality of oral contraceptive pills available over the counter compared with those 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 over the counter?
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 the over-the-counter availability of oral contraceptive pills? • Do adults and adolescents have different values and preferences with regard to the availability of over-the-counter oral contraceptive pills? • How does willingness to pay affect the uptake of over-the-counter oral contraceptive pills?
Acceptability	<ul style="list-style-type: none"> • What do health workers know and think about the provision of over-the-counter oral contraceptive pills, especially in low- and middle-income settings? • What are the optimal approaches to promoting the availability of over-the-counter oral contraceptive pills? • Does the implementation of over-the-counter oral contraceptive pills change the extent to which stigma and discrimination are barriers to oral contraceptive pill use?

GRADE domain	Research questions to address gaps
Resource use	<ul style="list-style-type: none"> Who bears the cost of over-the-counter oral contraceptive pills – 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 over-the-counter oral contraceptive pills? What barriers will remain? How can information best be provided to ensure informed decision-making around over-the-counter oral contraceptive pills, including about uptake, continuation and care-seeking in the case of side-effects?
Self-screening with ovulation predictor kits for fertility regulation	
Benefits versus harms	<ul style="list-style-type: none"> Does fertility management with ovulation predictor kits lead to better outcomes than fertility management without such kits in low- and middle-income settings?
Resource use	<ul style="list-style-type: none"> What are the costs and benefits of home-based ovulation predictor kits, 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 the willingness to pay affect the uptake of ovulation predictor kits? What impact does using a home-based ovulation predictor kit have on communication between partners?
Equity and human rights	<ul style="list-style-type: none"> How does the uptake of home-based ovulation predictor kits affect intra-household gender dynamics?
Human papillomavirus self-sampling for cervical cancer screening	
Resource use	<ul style="list-style-type: none"> What are the costs and benefits of human papillomavirus (HPV) self-sampling, 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?
Values and preferences	<ul style="list-style-type: none"> What are the optimal ways to engage potential users (e.g. via text or via community-based means)? Is HPV self-sampling an acceptable strategy for increasing access to screening and treatment for transgender men?
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 for testing for sexually transmitted infections	
Benefits versus harms	<ul style="list-style-type: none"> What is the impact on partner screening of the self-collection of samples for testing sexually transmitted infections (STIs)? What proportion of people who receive a positive result after the self-collection of samples for STI testing seek appropriate care and treatment services? What is the impact of the self-collection of samples for STI testing on the linkage to care and case finding? Does the self-collection of samples for STI testing offer a benefit in low-income settings? What are the benefits and harms of the self-collection of samples for testing for viral infections? Does the self-collection of samples for STI testing increase STI self-treatment (both appropriate and inappropriate)?

GRADE domain	Research questions to address gaps
Resource use	<ul style="list-style-type: none"> What are the costs and benefits of the self-collection of samples for STI testing, for the health system and for the user, and is this self-collection cost-effective?
Values and preferences	<ul style="list-style-type: none"> What are the values and preferences of marginalized populations (e.g. people of diverse sexual orientation and gender identity and expression, sex workers) regarding the self-collection of samples for STI testing?
Equity and human rights	<ul style="list-style-type: none"> Is there potential for coercion in the self-collection of samples for STI testing? If so, how can this be avoided?

GRADE: Grading of Recommendations Assessment, Development and Evaluation.

TABLE 5.3. OUTCOME DOMAINS FOR MEASURING HUMAN RIGHTS AND EQUITY IN SELF-CARE RESEARCH, AND ILLUSTRATIVE RESEARCH QUESTIONS

Human rights standard	Illustrative research questions
The right to health, including the 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 to 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 to ensure linkage to care following the use of self-care interventions? Is the quality of self-care interventions/technologies accessed outside the health system the same as that of 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, implementation, monitoring and evaluation of different self-care interventions, including products, and in how they are made available?
Equality and non-discrimination	<ul style="list-style-type: none"> How will underserved 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 the uptake of self-care interventions and the potential negative impacts of their use? Do self-care interventions improve health equity along the dimensions of gender, socioeconomic status and 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? What factors affect the extent to which different populations are comfortable accessing information on self-care interventions using shared mobile phones or public-access internet services? 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/intervention might be needed for different self-care interventions and for different populations?
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 healthcare setting? • What regulation might be needed to ensure that digital apps provide appropriate data protections to ensure the confidentiality of data?
Accountability	<ul style="list-style-type: none"> • What mechanisms for accountability and redress are effective in the context of self-care interventions?

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6.

Dissemination, applicability and updating of the guideline and recommendations



At a Glance

This chapter provides an overview of how the guideline will be disseminated, the anticipated impact of the guideline and monitoring and evaluation plans, as well as how and when the guideline is expected to be updated.

Dissemination

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Applicability

p. 115

Updating the guideline

p. 116



6.1 DISSEMINATION

This guideline will be available online at the World Health Organization (WHO) website.⁴ Technical meetings will be held with the WHO Department of Sexual and Reproductive Health and Research and regional offices to share the recommendations and forthcoming derivative products. These products will include implementation tools for policy-makers, programme managers and health workers to highlight the new recommendations and implementation-related contextual issues.

The dissemination plans also include workshops and briefings with different stakeholders at global, regional and national levels. WHO expects detailed plans for the dissemination and implementation of the guideline, and for the development of implementation tools to be formulated in collaboration with implementing partners, national stakeholders and civil society, allowing derivative products to be tailored to the needs in different national contexts.

This publication's executive summary and recommendations 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.

As well as being launched on the WHO webpages on self-care interventions and other relevant health topics, this guideline will be publicized in *HRP News*, the monthly electronic newsletter. *HRP News* has over 3000 subscribers, including clinicians, programme managers, policy-makers and health-service users worldwide. Also, to reach key partners working in the field, the guideline will be disseminated through several knowledge-sharing platforms, including the Implementing Best Practices (IBP) initiative.⁵ Finally, in line with the open access and copyright policies of WHO, the systematic reviews and literature reviews conducted for this guideline have been published in peer-reviewed journals (or have been submitted for publication and are in press or are awaiting editorial decisions; see Annex 7).

To further increase the dissemination of this guideline, a search function for the database of WHO guidelines and recommendations was created by the WHO Department of Sexual and Reproductive Health and Research.⁶ Furthermore, communication tools will continue to be developed. The short film on self-care interventions,⁷ launched for the first WHO month on self-care (24 June to 24 July 2019) and other communication materials such as social media tiles and other films have been included in a communications toolkit.⁸ In response to the COVID-19 pandemic, a series of films on self-care were also developed in collaboration with the Partnership for Maternal, Newborn and Child Health.⁹

6.1.1 COMMUNITY OF PRACTICE

In September 2020, WHO launched the community of practice on self-care interventions for health, hosted by the WHO Knowledge Action Portal.¹⁰ This community of practice is a platform for increased stakeholder engagement and collaboration, and a space for WHO and United Nations partners' to share research, evidence and tools to support the dissemination and implementation of this guideline. The platform aims to gather and share ongoing implementation work, research evidence and case studies on self-care interventions. The goal of the community of practice is to equip its members with the knowledge and tools to raise awareness about self-care interventions and implement best practices and evidence-based self-care interventions.

The community of practice is open to anyone interested in or working on self-care interventions, or related topics such as noncommunicable diseases, health promotion and digital health. WHO would encourage an interdisciplinary group of participants to participate, from both within and beyond the health sector, including researchers, civil society groups, representatives of underserved communities, health workers, policy-makers, donors and advocates.

⁴ Available at <https://www.who.int/health-topics/self-care>

⁵ For further information, see: <http://www.ibpinitiative.org>

⁶ To use the search function for this and other guidance, go to <https://www.srhr.org>

⁷ Available to watch at YouTube: <https://youtu.be/hwGPDQNYoo>

⁸ The toolkit is available at <https://www.who.int/health-topics/self-care>

⁹ The videos are available at https://www.who.int/health-topics/self-care#tab=tab_1

¹⁰ Go to the Knowledge Action Portal at <https://www.knowledge-action-portal.com>; an account can be created to join the community of practice on self-care at <https://www.knowledge-action-portal.com/en/cop-categories/self-care-interventions-health>

6.2 APPLICABILITY

6.2.1 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 healthcare resources, particularly in low- and middle-income countries. 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 need additional care;
- lack of understanding among health workers and health system managers of the value of newly recommended interventions;
- 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; and
- need for refinancing and re-budgeting to address the above shortcomings.

Given these potential barriers, a phased approach to adoption, adaptation and implementation of the guideline recommendations may be needed. WHO will be ready to support various strategies to operationalize the people-centred approach and key principles that underpin this guideline, and to support countries to address these barriers and facilitate implementation.

6.2.2 SMART GUIDELINES

In February 2021, WHO launched the first SMART guideline. The SMART (standards-based, machine-readable, adaptive, requirements-based and testable) approach to guidelines is a new way of systematizing and accelerating the consistent application of recommendations for the

digital age. A comprehensive set of reusable digital health components (e.g. interoperability standards, code libraries, algorithms, and technical and operational specifications) transform the guideline adaptation and implementation process, to preserve fidelity and accelerate uptake. SMART guidelines provide a five-step pathway to advance the adoption of best clinical and data practices, even if a country is not yet fully digital (1).

The present document is the narrative guideline component of the SMART guidelines package. Further components, including a digital adaptation kit, are in production.

The recommendations and good practice statements in the 2019 guideline have been included in the WHO Digital Adaptation Kit for Antenatal Care (2) and other forthcoming digital adaptation kits (e.g. for family planning). A SMART guideline approach is also being taken for a forthcoming client-facing self-care intervention based on this guideline.

6.2.3 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 the recommendations in this guideline will be monitored at health service, regional and country levels, based on existing indicators. Given the private space in which much of self-care is practised, however, alternative ways to assess the impact of the interventions need to be developed. The emphasis on uptake and use by underserved populations calls for a meaningful engagement of the affected communities.

In collaboration with the WHO Department of Health Metrics and Measurement (which leads data collection and analysis for the WHO Global Health Observatory), the Department of Sexual and Reproductive Health and Research will monitor and evaluate country- and regional-level data on health-seeking behaviours and the 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 the national policies of individual WHO Member States.

The WHO Thirteenth General Programme of Work Impact Framework will also be used to monitor self-care interventions (3).

6.3 UPDATING THE GUIDELINE

This guideline uses a living guideline approach and will be placed on the interactive MAGICapp platform¹¹ linked to the WHO self-care interventions health topic website. All research evidence and references are available on the web platform and will be available to download, and relevant implementation guidance will be linked to the recommendations. When recommendations are updated, they will be labelled as such and will always display the date of the most recent update. Each time there is an update, an updated PDF version of the guideline will be available on the WHO website to facilitate access where the internet is not reliably available. Furthermore, there will be a feedback option for users, to help WHO to identify recommendations that may need an update or further clarification.

The living guideline approach will allow the review of new research evidence, to ensure that it can be brought to the Guideline Development Group for review (see Chapter 1, section 1.3). Future updates to this guideline will include topics, recommendations, good practice statements and possibly key considerations relevant to SRHR such as menstrual hygiene, pain control for dysmenorrhoea, hormone therapy – oral and transdermal – for menopausal disorders, and vaginal pessary for pelvic organ prolapse and noncommunicable diseases; noncommunicable diseases (such as concern breast self-examination and improving mental health); communicable diseases (such as concern the self-use of dapivirine vaginal ring for HIV prevention, and malaria bed nets) as well as other areas of health.

This guideline will be updated as new evidence becomes available, in accordance with the GREAT Network (guideline-driven, research priorities, evidence synthesis, application of evidence and transfer of knowledge) concept,¹² which employs a systematic and continuous process of identifying and bridging evidence gaps following guideline implementation.

The rapidly evolving nature of self-care interventions calls for a continual review of the literature. An update to this guideline will likely be needed within 18–24 months of the dissemination of this version, to accommodate either new

evidence on existing recommendations or to develop new recommendations based on emerging evidence, including on new 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 interventions for health, and colleagues from other relevant departments will be brought in to expand the scope to other health topics. For example, 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 were supported by low-quality evidence, and in these cases, respectively, new recommendations or a change in the published recommendations may be warranted. Any concern about the validity of a recommendation will be communicated promptly following approval by the WHO Guidelines Review Committee of rapid guidance, and plans will be made to update the recommendation as needed in future versions of the guideline.

All technical products developed during the process of developing this guideline – including full reports of systematic reviews, corresponding search strategies and dates – 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 (Grading of Recommendations Assessment, Development and Evaluation) approach, in line with the standards in the *WHO handbook for guideline development (4)*.

The guideline development process identified a number of knowledge gaps, which are highlighted in Chapter 5 (Tables 5.1 and 5.2). WHO aims to develop further guidance that is 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.

¹¹ See <https://app.magicapp.org/#/guidelines>

¹² More information is available at <https://greatnetworkglobal.org>

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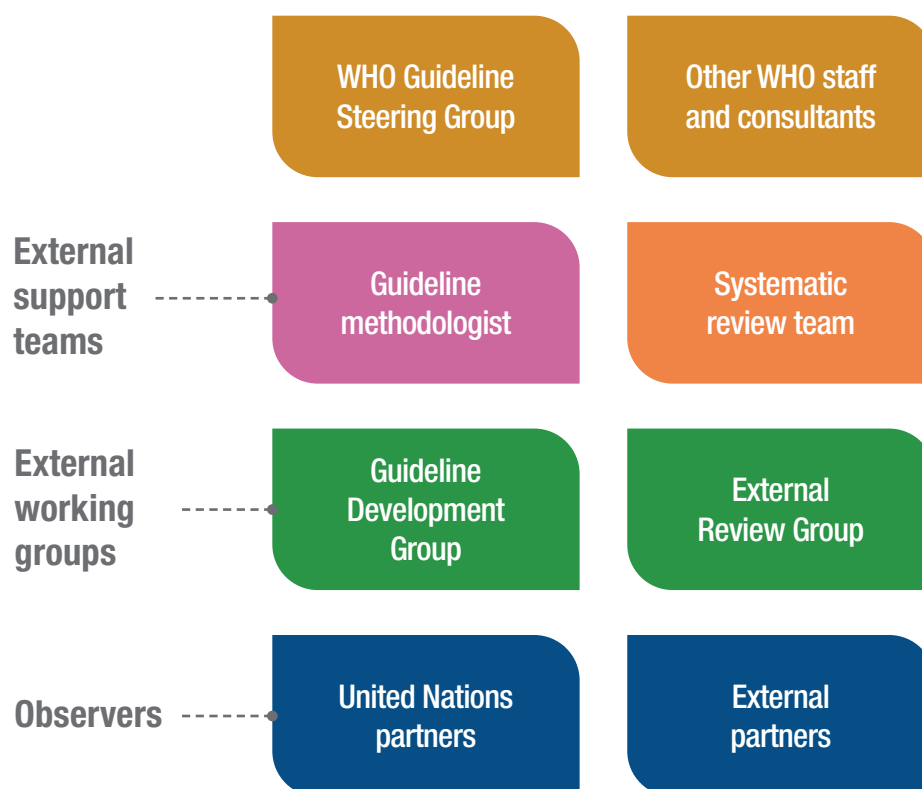
ANNEX 2. METHODOLOGY: GUIDELINE DEVELOPMENT PROCESS

The WHO guideline on self-care interventions for health and well-being was prepared in accordance with World Health Organization (WHO) standards and methods for guideline development, and originally published as the *WHO consolidated guideline on self-care interventions for health: sexual and reproductive health and rights* (2019). Details of the approach can be found in the *WHO handbook for guideline development* (1). The WHO Department of Sexual and Reproductive Health and Research led the development of this guideline. This annex gives an overview of the standards, methods and processes applied across the topics covered in this guideline.

A2.1 GUIDELINE DEVELOPMENT WORKING GROUPS

The department set up three working groups to perform specific guideline development functions (see Fig. A2.1): the WHO Guideline Steering Group, the Guideline Development Group (GDG) and the External Review Group. The members of the groups were selected to ensure a range of expertise and experience, including appropriate representation in terms of geography and gender. The following sections describe the three groups, and the names and institutional affiliations of the participants of each are listed in Annex 1.

FIG. A2.1: GUIDELINE DEVELOPMENT EXPERT WORKING GROUPS AND OBSERVERS



A2.1.1 THE WHO GUIDELINE STEERING GROUP

Due to the nature of the guideline, the Guideline Steering Group included representation and expertise in sexual and reproductive health – including the main fields of family planning, sexually transmitted infections (STIs), including HIV, maternal and infant health, sexual health and abortion – in noncommunicable diseases (NCDs), and in the relevant aspects of health systems. In addition, gender and human rights expertise ensured that key principles for building a strong enabling environment, particularly for underserved populations, were adequately reflected. Finally, regional

WHO representation provided expert perspectives, from the start of the normative guideline development process, on the practicalities of the implementation and uptake of the recommendations and good practice statements in the various regions.

The Guideline Steering Group, chaired by the Department of Sexual and 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 (population, intervention,

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comparator, outcome) format, and identified individuals to participate as a guideline methodologist and members of the systematic review teams, the GDG and the External Review Group. The Guideline Steering Group did not determine or agree on the final recommendations, as this was the role of the GDG. The Guideline Steering Group also finalized and published the guideline document, will oversee the dissemination of the guideline and will be involved in the development of implementation tools.

A2.1.2 THE GUIDELINE DEVELOPMENT GROUP

The Guideline Steering Group identified and invited external (non-WHO) experts to be part of the GDG, with expertise covering the same technical areas of work as the Guideline Steering Group, including researchers, policy-makers and programme managers, young health professionals, civil society, community members and patient group representatives. All WHO regions were represented, with gender balance.

The specific tasks of the GDG for the 2019 guideline and this guideline included:

- Building on the work of the Guidelines Steering Group to finalize the key questions in PICO format;
- Choosing and ranking the priority outcomes to guide the evidence reviews and focus the recommendations;
- Examining the GRADE (Grading of Recommendations Assessment, Development and Evaluation) evidence profiles or other assessments of the certainty of evidence used to inform the recommendations;
- Interpreting the evidence, with explicit consideration of the overall balance of benefits and harms;
- Formulating recommendations, good practice statements and key considerations, taking into account benefits, harms, values and preferences, feasibility, equity, acceptability, resource requirements and other factors, as appropriate;
- Identifying methodological issues and evidence gaps, and providing guidance on how to address these;
- Reviewing and approving the final recommendations prior to submission to the Guidelines Review Committee.

The GDG meeting was held online using video conferencing software, from 15–29 January 2021.

A2.1.3 THE EXTERNAL REVIEW GROUP

The External Review Group members, who were identified and invited to participate by the Guideline Steering Group, included peer reviewers with a broad range of expertise in issues related to the topics covered in the guideline, including clinicians, researchers, policy-makers and programme managers, and representatives of civil society (including patient representatives, transgender people, youth, and people living with HIV), and young health professionals. The External Review Group 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 Guideline Steering Group 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 the considerations related to implementation, adaptation and contextual issues. It was not within the External Review Group's remit to change the recommendations formulated by the GDG.

A2.2 ADDITIONAL KEY CONTRIBUTORS – EXTERNAL PARTNERS

Representatives of United Nations agencies were invited to attend the GDG meeting as observers with no role in determining the recommendations.

The United Nations partners included:

- The Defeat-NCD Partnership (hosted at the United Nations Institute for Training and Research)
- International Agency for Research on Cancer
- Joint United Nations Programme on HIV/AIDS
- Office of the United Nations High Commissioner for Human Rights
- Partnership for Maternal, Newborn and Child Health (hosted at WHO)
- United Nations Children's Fund
- United Nations Development Programme
- United Nations Population Fund
- World Bank.

The external partners, who also had no role in determining the recommendations as observers, included:

- International Pharmaceutical Federation
- PATH
- Population Council
- White Ribbon Alliance.

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A2.3 DECLARATIONS OF INTERESTS BY EXTERNAL CONTRIBUTORS

All proposed GDG and External Review Group members were requested to submit a one-page curriculum vitae and a signed WHO declaration-of-interests form. Two members of the Guideline Steering Group independently reviewed the declaration-of-interests forms. The reviewers considered all possible conflicts of interest based on the latest guidance from the WHO Guidelines Review Committee, including placing a particular focus on possible financial or personal non-financial conflicts (e.g. academic contributions), and relationships with institutions producing self-care interventions.

Subsequently, the biographical information for all GDG members deemed to have no significant conflicts of interest (i.e. no conflicts precluding their participation in the GDG) was posted on the WHO website for public comment from 1–16 November 2020. The GDG members were confirmed once this process was completed.

On confirmation of their eligibility to participate, all GDG and External Review Group experts were instructed to notify the responsible technical officer of any change in relevant interests during the guideline development process, directly before the meeting for GDG members and again before submitting comments on a draft version of the guideline. There were no cases of a conflict of interests that warranted any management or assessment by the WHO Office of Compliance, Risk Management and Ethics.

No member had a financial conflict of interest, and the GDG co-chairs did not present any conflicts of interest. A summary of the declaration-of-interests statements and information on how conflicts of interest were managed are included in Annex 5.

The GDG co-chairs had equal responsibilities and complementary expertise and perspectives, came from two different WHO regions, represented a gender balance, and had expertise in areas that were relevant to this guideline. Both also had experience in consensus-based processes. At the start of the meeting, the nomination of the co-chairs was presented to the GDG and accepted.

A2.4 DEFINING THE SCOPE AND TOPIC AREAS FOR NEW RECOMMENDATIONS, GOOD PRACTICE STATEMENTS AND KEY CONSIDERATIONS

Working within the general scope of the guideline, as presented in Chapter 1, section 1.5, 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 Guideline Steering Group first mapped all existing WHO guidance with relevance to self-care. The Guideline Steering Group then reviewed these and other materials to identify gaps, overlaps and inconsistencies and to determine the relevance of existing recommendations for inclusion in this guideline. The Guideline Steering Group identified topic areas where new recommendations and key considerations needed to be developed for sexual and reproductive health and rights. In addition, the Guideline Steering Group identified priority areas for implementation considerations, including good practice statements on gender and human rights, the training of health workers, the use of digital health interventions to support the use of self-care interventions, and priority self-care interventions in humanitarian and pandemic responses.

A2.5 REVIEW OF THE EVIDENCE AND FORMULATION OF THE RECOMMENDATIONS

A2.5.1 DEFINING AND REVIEWING PRIORITY QUESTIONS

The development of the new recommendations on health interventions (see Table 1 in the executive summary, and Chapter 3) began with formulating the PICO questions and subsequently conducting relevant systematic reviews of the evidence. The following were the eight PICO questions for the new recommendations.

1. Should individuals who are planning pregnancy self-manage with folic acid supplements or be offered only provider-led management of such supplements? (*Recommendation 10a*)

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2. Should pregnant individuals self-manage the use of iron and folic acid supplementation as per international guidance (currently either a daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid, or an intermittent [e.g. weekly] dose of 120 mg of elemental iron and 2.8 mg of folic acid) or be offered only provider-led management of such supplements? (*Recommendation 10b*)
3. Should postnatal individuals self-manage the use of iron (with or without folic acid) supplementation for at least three months after delivery as per international guidance (currently either a daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid, or an intermittent [e.g. weekly] dose of 120 mg of elemental iron and 2.8 mg of folic acid) or be offered only provider-led management of such supplements? (*Recommendation 10c*)
4. Should self-monitoring of blood pressure among individuals with hypertensive disorders of pregnancy be made available in addition to clinic check-ups? (*Recommendation 11*)
5. Should self-monitoring of blood glucose among pregnant individuals with gestational diabetes be made available in addition to clinic check-ups? (*Recommendation 12*)
6. Should emergency contraceptive pills be made available without a clinician's prescription? (*Recommendation 15*)
7. Should self-testing for pregnancy be available as an additional option to clinic-based testing? (*Recommendation 20*)
8. Does use of lubricants during or prior to sex result in improved sexual health and well-being? (*Recommendation 32*)

Full details of the population, intervention, comparator and outcomes for each of the PICO questions are presented in Annex 6.

A2.5.2 ASSESSMENT OF THE CERTAINTY 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 certainty of the available evidence. WHO has adopted the GRADE approach to developing recommendations (1). This approach specifies four levels of certainty of evidence, which are interpreted as detailed in Table A2.1.

TABLE A2.1. DESCRIPTION OF THE FOUR 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.

Based on the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (2).

Source: WHO (1); Balshem et al. (2).

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The GRADE approach to appraising the certainty of quantitative evidence was used for all outcomes identified as critical for each 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 guideline. The rating of the outcomes was identified a priori by the GDG via an online survey in which GDG members ranked outcomes from 1 (not important) to 9 (critical), with outcomes ranked 7–9 being considered critical and included in the GRADE tables to guide decision-making. Following the completion of each systematic review, a GRADE evidence-to-decision table was prepared for each PICO question. These tables convey the judgements made by the GDG with respect to several factors in addition to the benefits and harms and the certainty thereof, and includes the values and preferences of end users, resource use, including costs and cost-effectiveness, the potential impact on human rights and equity, and acceptability and feasibility. The GRADE tables and the evidence-to-decision tables are presented in Web Annex B available at <https://apps.who.int/iris/bitstream/handle/10665/342654/9789240031326-eng.pdf>.

A2.5.3 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 – described as either “strong” or “conditional” – reflects the degree of confidence that the GDG has in the desirable effects of the recommendation outweighing the undesirable effects (or the reverse in the case of the GDG recommending against the intervention – where the undesirable effects outweighing the desirable effects).

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 end users, health workers or programmes would have to bear), and the potential legal ramifications where certain practices are criminalized.

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

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

The values and preferences of end users (or potential end users), in relation to the intervention and to the acceptability to health workers of implementing it, contribute, along with a consideration of the relevant resource use, feasibility and equity issues, to determining the strength of a recommendation (see Table A2.2). For this guideline, specific attention was focused on the need for an enabling environment for the implementation of the interventions (see Chapter 2, section 2.5), and the GDG was asked to consider the human rights, gender equality and equity implications (both positive and negative) of each recommendation.

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TABLE A2.2. GRADE DOMAINS CONSIDERED WHEN ASSESSING THE STRENGTH OF RECOMMENDATIONS

Domain	Rationale
Benefits and harms	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	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 and human rights	If an intervention will reduce inequities, improve equity or contribute to the realization of human rights, the greater the likelihood of a strong recommendation.
Acceptability	If a recommendation is widely supported by health workers and programme managers and there is widespread acceptance for implementation within the health service, the greater the likelihood of a strong recommendation.

Source: Schünemann et al. (3).

A2.5.4 DECISION-MAKING BY THE GDG DURING GUIDELINE DEVELOPMENT

The GDG members were guided by the clear process articulated in the *WHO handbook for guideline development* (1). All decisions were, ideally, made by consensus. However, at the beginning of the meeting 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 in the systematic reviews and in the GRADE evidence-to-decision 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 A2.2) and formulate recommendations through a process of group discussion, engagement and revision. In the online environment, close attention was paid

to eliciting responses from all members of the GDG through regular straw-polling and use of the chat function 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, and every member of the GDG was asked to express their decision verbally. The judgements made by the GDG related to each recommendation are noted in Annex 8.

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A2.6 COMPILATION AND PRESENTATION OF GUIDELINE CONTENT

Following the GDG meeting, members of the WHO Guideline Steering Group prepared a draft of the full guideline document to accurately reflect the deliberations and decisions of 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 External Review Group members electronically for their input. The Guideline Steering Group then carefully evaluated the input of the External Review Group members for inclusion in the guideline document, and the revised version was again shared electronically with GDG members for information. Any further modifications that the Guideline Steering Group made to the guideline were limited to the correction of factual errors and improvement in language to address any lack of clarity. The revised version was then submitted to the Guidelines Review Committee for approval; minor requested revisions were made before final copy-editing and publication.

A list of all reviews conducted for the development of this guideline – starting with the systematic reviews on the PICO questions – is presented in Annex 6. Please refer to the published protocols for systematic reviews at PROSPERO for information about the methods used, including search strategies (the PROSPERO details are noted under each respective section in Chapter 3).

Among these reviews were qualitative and costing reviews for each topic, including the values and preferences of end users or potential end users and health workers relating to the self-care interventions addressed by each of the PICO questions. See also Chapter 1, section 1.7, about the Global Values and Preferences Survey (GVPS) on self-care interventions for sexual and reproductive health and rights.

REFERENCES FOR ANNEX 2

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Evidence derived from the nine systematic reviews in support of the six new recommendations and the three key considerations (see Annex 7) is 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 Web Annex B available at <https://apps.who.int/iris/bitstream/handle/10665/342654/9789240031326-eng.pdf>.

Key considerations were formulated for those PICO questions for which the GDG judged there to be insufficient evidence to make a recommendation. For these issues, the GDG instead provided critical considerations that will need to be addressed prior to future decisions regarding whether or not to develop recommendations with respect to these PICO questions.

The four PICO questions that resulted in key considerations were as follows:

1. Should self-testing for proteinuria during pregnancy be available in addition to clinic check-ups?
2. Should pre-exposure prophylaxis (PrEP) initiation be available following screening by a pharmacist, without a prescription?
3. Should PrEP continuation be available from a pharmacist, without a prescription?
4. Should self-administration of gender affirming hormones be made available in addition to health worker administration?

The discussions related to PICO questions 2 and 3, on PrEP initiation and continuation, were grouped into one key set of key considerations.

ANNEX 3. SCOPING REVIEW: WHO SELF-CARE DEFINITIONS

A3.1 METHODS

The World Health Organization (WHO) Department of Sexual and Reproductive Health and Research conducted a scoping review of the definitions of self-care available in WHO tools and guidance. An initial database search in the WHO Institutional Repository for Information Sharing (IRIS) for “self-care” retrieved 1700 documents. After narrowing down to the specific mentions of self-care, 922 WHO documents remained. These were entered into Microsoft Excel and categorized by year and topic. After removing documents that provided neither a clear definition nor an 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 the definitions and select their top five definitions. They then discussed their findings to reach a consensus on a working definition for this guideline.

A3.2 FINDINGS

A3.2.1 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 worker” (1).

Self-care is a broad concept that 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 the following.

- Non-professional care, “unorganized health activities and health-related decision-making by individuals, families, neighbours, friends, colleagues at work” (3).
- The “utilization of all non-health professional resources, i.e. the individual himself or herself, members of the family, neighbours and other laypersons, for any health-related activity, be it promotive, preventive, curative or rehabilitative” (4).

- “Self-care ... is the primary health resource in the health 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 laypeople to one another in both natural and organized settings” (5).

A3.2.2 KEY ASPECTS OF SELF-CARE DEFINITIONS

Relationship with the health system

One of the primary characteristics 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. Some definitions considered self-care part of primary health care, for example, or the first level of care, 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 of the definitions of self-care mentioned specific agents for self-care, usually referring to people who were not 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 – that is, care that could be practised at home, or a household process. Some definitions placed self-care in a “natural setting” – that is, in 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. Others emphasized the need for linkage to or support from the health system, especially when describing self-care as part of a continuum.

Scope

The definitions of self-care could generally be categorized through two dichotomies. First, self-care could be defined in terms of habits or activities of daily living or lifestyle, or in

ANNEX 3. (continued)

terms of the management of illness, medication(s) or disease episodes. Some definitions related self-care to coping, social support or the 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

The fundamental principles for self-care include aspects of the individual (e.g. self-reliance, empowerment, autonomy, personal responsibility, self-efficacy) and of the greater community (e.g. community participation, community involvement, community empowerment).

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A3.3 CONCLUSION

The working definition of self-care for this living guideline is, as set out above:

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 worker.

The scope of self-care in this definition includes health promotion, disease prevention and control, self-medication, providing care to dependent people, seeking hospital/specialist care if needed, 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 4. GLOSSARY

Acceptability	<p>All provision of health-care facilities, commodities and services must be acceptable to the people who are their intended beneficiaries. The provision must be in a manner that is respectful of medical ethics and of the culture of individuals, minorities, peoples and communities; sensitive to gender and to life-cycle requirements; and designed to respect confidentiality and improve health status. Countries should place a gender perspective at the centre of all policies, programmes and services affecting sexual and reproductive health, and should involve people in the planning, implementation and monitoring of such policies, programmes and services (1).</p>
Accessibility	<p>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, and 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 a spouse, parent/guardian or hospital authorities, distance from health-care facilities, and the absence of convenient and affordable public transport (1).</p>
Accountability	<p>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 people from marginalized populations, are made aware of their rights, including with regard to sexual and reproductive health, and are empowered to claim their rights (1).</p>
Adolescent	<p>For the purposes of this guideline, adolescents are defined as individuals between the ages of 10 and 19 years. 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 (2).</p>
Adult	<p>A person aged 18 years or older (3).</p>
Autonomy	<p>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).</p>
Availability	<p>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 the provision of safe drinking water, adequate sanitation facilities, health-related education, hospitals, clinics and other health-related buildings, and should 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 WHO model list of essential medicines, which guides the procurement and supply of medicines in the public sector (1).</p>
Children	<p>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” (3).</p>

ANNEX 4. (continued)

Comprehensive sexuality education	Comprehensive sexuality education 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 the 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 a sexually transmitted infection (e.g. HIV, human papillomavirus), pregnancy or other health condition. Initially reactive test results, including reactive self-test results, need to be confirmed by a health worker 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 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 table	A framework to assist people making and using evidence-informed recommendations and decisions. Their main purpose is to help decision-makers to use evidence in a systematic and transparent way. When used in a WHO guidelines context, evidence-to-decision 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 judgements, 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 the 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 the individual risk factors (e.g. advanced age, sexual health factors such as sexually transmitted infections, and lifestyle factors such as smoking and obesity) and non-individual risk factors (e.g. environmental and workplace factors); including the awareness of societal and cultural factors affecting options for reproductive family planning (11).

ANNEX 4. (continued)

Fertility care	Interventions that include fertility awareness, support and fertility management with the aim of helping individuals and couples to realize their desires associated with reproduction (11).
Gender equality	Equal opportunities for the diversity of 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). Also known as equality of opportunity – or formal equality. Often used interchangeably with gender equity, but the two refer to different, complementary strategies that are needed to reduce gender-based health inequities. Under gender equality, different people 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).
Gender equity	Refers to the different needs, preferences and interests of people of different genders. This may mean that different treatment is needed to ensure the equality of opportunity. This is often referred to as substantive equality (or equality of results) and requires considering the realities of people's lives. Often used interchangeably with gender equality, but the two refer to different, complementary strategies that are needed to reduce gender-based health inequalities.
Gender-responsive	A policy or programme that considers gender norms, roles and inequality and has measures to actively reduce their harmful effects.
Harm or social harm	Any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt by one person to another, by a person to themselves or by 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 to assess, improve, maintain, promote or modify health, functioning or health conditions. Health interventions can be carried out by a broad range of health workers, including laypeople, ^a across the full scope of health systems, and includes diagnosis, medical, surgical, mental health, primary care, allied health, functioning support, rehabilitation, traditional medicine and public health (13).
HIV self-testing	A process in which a person collects their 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 they trust (6).
HIV status	The final report given to a patient; the final interpretation of the disease state based on the 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	A process where a person who wants to know whether they have 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 HPV self-sampling cannot provide a diagnosis of cervical (pre-)cancer, it identifies people who are at higher risk (14).

^a This item is added here – it did not appear as part of the definition provided in the cited source; this is thus an adapted definition.

ANNEX 4. (continued)

Human rights	Human rights are legal guarantees that are equally applicable to everyone everywhere in the world and 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 (15–17).
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 their partner. Fertility interventions may be initiated before a year passes 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 or all options (1).
Intersectionality	The concept of intersectionality builds on, and extends, the understanding of how gender and interacts with other factors including race, ethnicity, age, class, geographic locations, gender identity and sexual orientation, among others. It is understood that unequal gender power relations do not operate in isolation but intersect with other social and economic inequalities to produce health inequities (18).
Intimate partner violence	Behaviour within an intimate relationship that causes physical, psychological or sexual harm, 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 relevant tertiary education degree (6).
Medically assisted reproduction	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 technology procedures, uterine transplantation, and intra-uterine, intracervical and intravaginal insemination with semen (11).

ANNEX 4. (continued)

mHealth	Part of eHealth , this is 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 or 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 (1).
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 the 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 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 to be represented in the formulation of public policy in all sectors and at all levels (1).
Patient engagement	To promote and support active patient and public involvement in health and health care and to strengthen 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 (19).
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 workers (20).
Patient safety	Patient safety is the absence of preventable harm to patients during the process of health care and the reduction of risks of unnecessary harms associated with health care, to an acceptable minimum. An acceptable minimum is the collective notion when the current knowledge, resources available and the context in which care is delivered are weighed against the risk of non-treatment or other treatment (21).
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 (22).

ANNEX 4. (continued)

Point-of-care test	The key elements of point-of-care tests are that they allow (i) testing to be done with or near the person being tested, (ii) results to be returned to the person being tested during the same visit, and (iii) results of a point-of-care test to be used immediately for patient care and referral (23).
Pregnancy	A state of reproduction beginning with the implantation of an embryo in a uterus 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 subjected to interference with their privacy, and that they should enjoy legal protection in this respect. Sexual and reproductive health involves many sensitive issues that are often 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 health workers 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 (1).
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 (24).
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 (1).
Quality assurance	Part of quality management to give confidence to stakeholders that the requirements for quality will be fulfilled (6).
Self-administration	The process of people administering pharmacological substances or biomedical interventions to themselves.
Self-care	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 worker” (25). The scope of self-care within this definition includes health promotion, disease prevention and control, self-medication, providing care to dependent people, seeking hospital/specialist care when needed, and rehabilitation, including palliative care (26). Self-care is a broad concept that also encompasses hygiene (general and personal), nutrition (choices about the type and quality of food eaten), lifestyle (choices of sporting activities, leisure, etc.), environmental factors (living conditions, social habits, etc.), socioeconomic factors (income level, cultural beliefs, etc.), and self-medication (27).
Self-management	Management of or by oneself; the taking of responsibility for one’s own behaviour, health and well-being (28).
Self-medication	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 (29).

ANNEX 4. (continued)

Self-monitoring	Self-monitoring is a key aspect of self-management and includes the monitoring of clinical parameters, symptom measures and daily activities (30).
Serodiscordant couple	A couple in which one partner is HIV-positive and the other is HIV-negative (6).
Social accountability	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 (31).
Stigma	Originally derived from a Greek word meaning a mark or stain, stigma is beliefs, attitudes, practices and social processes that label difference, enable discrimination, reduce opportunities and reproduce social inequalities. Stigma manifests in community norms (felt or normative stigma), mistreatment and acts of discrimination (enacted stigma), and can be internalized (self- or internalized stigma) (32).
Task sharing	The rational redistribution of tasks and the increased scope of work among different cadres of health worker, including trained laypeople (6).
Telemedicine	Within the WHO/International Telecommunication Union national eHealth strategy toolkit, telemedicine is defined as supporting “the provision of health care services at a distance” (33).
Transgender	An umbrella term for people whose gender identity and expression is not matched by the norms and expectations traditionally associated with the sex assigned to them at birth, including 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 hijra (India), waria (Indonesia), kathoey (Thailand) 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 may differ among different subgroups within the transgender community. For example, sexual risk may be higher among transgender women (assigned male at birth) or transgender men (assigned female at birth) who have receptive anal intercourse with men than among transgender men or transgender women who have sex only with women (34). Transgender people are often highly vulnerable to stigma, discrimination and violence, and have specific health needs that necessitate a distinct public health response.
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/or unequal power dynamics. WHO defines vulnerability as the degree to which a population, individual or organization is unable to anticipate, cope with, resist or recover from the impacts of disasters. Vulnerable populations can include children, pregnant individuals, elderly people, malnourished people and those who are ill or immunocompromised (35).
Waste management	The collection, transportation, disposal or recycling and monitoring of waste.
Young people	People between the ages of 10 and 24 years (36).
Youth	People between the ages of 15 and 24 years (32).

ANNEX 4. (continued)

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ANNEX 5. SUMMARY OF DECLARATIONS OF INTEREST AND THE MANAGEMENT OF CONFLICTS OF INTEREST

Name	Expertise	Declaration of interests	Conflicts of interest and their management
Dr Kaosar Afsana	Research, sexual and reproductive health and rights	None declared	Not applicable
Ms Hera Ali	Youth, pharmacist	None declared	Not applicable
Dr Elham Atalla	Sexual health, policy	None declared	Not applicable
Martha Brady	Self-care interventions	None declared	Not applicable
Professor Elizabeth Bukusi	Research, ethics, sexual and reproductive health and rights	None declared	Not applicable
Dr Laura Ferguson	Human rights, law	None declared	Not applicable
Anita Hardon	Sexual and reproductive health and rights, social science and implementation research	None declared	Not applicable
Jonathan Hopkins	Integrated health services for sexual and reproductive health and rights and human immunodeficiency virus, homeless populations	None declared	Not applicable
Hussain Jafri	Patient safety/user perspective	None declared	Not applicable
Mukesh Kapila	Policy, noncommunicable diseases	None declared	Not applicable
Po-Chin Li	Youth, clinician	None declared	Not applicable
Carmen Logie	Key populations, social science, human immunodeficiency virus, sexually transmitted infections	None declared	Not applicable
Kevin Moody	Pharmacy, education, key populations, patient groups, human immunodeficiency virus	None declared	Not applicable
Daniella K. Munene	Pharmacy, programme manager	None declared	Not applicable
Lisa Noguchi	Maternal health, innovations	None declared	Not applicable
Gina Ogilvie	Sexually transmitted infections, human immunodeficiency virus, human papillomavirus, research	None declared	Not applicable

ANNEX 5. (continued)

Name	Expertise	Declaration of interests	Conflicts of interest and their management
Ash Pachauri	Climate change, environmental and planetary health, abortion, women's health, vulnerable populations, youth	None declared	Not applicable
Michelle Remme	Health financing, sexual and reproductive health and rights, gender-based violence	None declared	Not applicable
Jaya Lakshmi Shreedhar	Advocacy, communications, journalism, tuberculosis and communicable diseases, noncommunicable diseases	None declared	Not applicable
Leigh Ann van der Merwe	Community perspective/human rights	None declared	Not applicable
Sheryl van der Poel	Infertility, research, normative guidance	None declared	Not applicable
Allen Zhiwei Wu	Sexually transmitted infections, human papillomavirus, education, research, policy	None declared	Not applicable

ANNEX 6. PRIORITY QUESTIONS AND OUTCOMES

PICO: population (P), intervention (I), comparator (C), outcome (O)

PICO questions (P–I–C)	Outcomes (O)
<p>Should individuals who are planning pregnancy self-manage the use of folic acid supplements or be offered only provider-led management of such supplements?</p> <p>P: Individuals who are planning pregnancy within the next three months</p> <p>I: Self-management of folic acid supplements</p> <p>C: Health worker-led provision of folic acid supplements</p>	<p>Maternal outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Autonomy (e.g. self-efficacy, self-determination, empowerment) 2. Correct use of product <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Folate concentration (serum or red blood cell) 2. Mental health and well-being (e.g. anxiety, stress, self-harm) 3. Adverse events (e.g. stock-outs, product diversion, counterfeit product) 4. Social harms (e.g. discrimination, intimate partner violence, stigma) <p>Fetal/newborn outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Neural tube defect 2. Stillbirth or perinatal death
<p>Should pregnant individuals self-manage the use of iron and folic acid supplementation as per international guidance (currently either a daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid, or an intermittent [e.g. weekly] dose of 120 mg of elemental iron and 2.8 mg of folic acid) or be offered only provider-led management of such supplements?</p> <p>P: Pregnant individuals of any gestational age and parity</p> <p>I: Self-management of iron and folic acid supplements (either daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid or intermittent dose of 120 mg of elemental iron and 2.8 mg of folic acid)</p> <p>C: Health worker-led provision of folic acid supplements</p>	<p>Maternal outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Counterfeit product 2. Anaemia/iron deficiency 3. Autonomy (e.g. self-efficacy, self-determination, empowerment) <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Correct use of product 2. Folate concentration (serum or red blood cell) 3. Puerperal sepsis 4. Mental health and well-being (anxiety, stress, self-harm) 5. Stock-outs, product diversion 6. Social harms (e.g. discrimination, intimate partner violence, stigma) <p>Fetal/newborn outcomes</p> <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Birth weight/size for gestational age 2. Preterm birth 3. Stillbirth or perinatal death

ANNEX 6. (continued)

PICO questions (P–I–C)	Outcomes (O)
<p>Should postnatal individuals self-manage the use of iron (with or without folic acid) supplementation for at least three months after delivery as per international guidance (currently either a daily dose of 30–60 mg of elemental iron and 400 µg [0.4 mg] of folic acid, or an intermittent [e.g. weekly] dose of 120 mg of elemental iron and 2.8 mg of folic acid) or be offered only provider-led management of such supplements?</p> <p>P: Low-risk, non-anaemic individuals after vaginal delivery</p> <p>I: Self-management of iron and folic acid supplements</p> <p>C: Health worker-led provision of iron and folic acid supplements</p>	<p>Maternal outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Counterfeit product 2. Anaemia/iron deficiency 3. Autonomy (e.g. self-efficacy, self-determination, empowerment) 4. Correct use of product 5. Folate concentration (serum or red blood cell) <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Stock-outs, product diversion 2. Mental health and well-being (anxiety, stress, self-harm) 3. Social harms (e.g. discrimination, intimate partner violence, stigma)
<p>Should self-monitoring of blood pressure among individuals with hypertensive disorders of pregnancy be made available in addition to clinic check-ups?</p> <p>P: Pregnant individuals with hypertension (gestational hypertension, chronic hypertension or pre-eclampsia)</p> <p>I: Self-monitoring of blood pressure (either by the pregnant individual or by another layperson, such as a family member)</p> <p>C: Clinic blood pressure monitoring by health workers during antenatal contacts only</p>	<p>Maternal outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Eclampsia or pre-eclampsia 2. Antenatal hospital admission 3. Follow-up care with appropriate management 4. Mental health and well-being (e.g. anxiety, stress, self-harm) 5. Adverse pregnancy outcomes: spontaneous abortion, premature rupture of membranes, placental abruption 6. Maternal mortality or near-miss <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Caesarean section 2. Autonomy (e.g. self-efficacy, self-determination, empowerment) 3. Long-term risk complications: stroke, cardiovascular outcomes, chronic kidney disease or chronic hypertension 4. HELLP syndrome 5. Device-related issues (e.g. test failure, problems with manufacturing, packaging, labelling or instructions for use) 6. Social harms (e.g. stigma, discrimination, intimate partner violence) <p>Newborn outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Stillbirth or perinatal death 2. Birthweight and size for gestational age 3. Apgar score

ANNEX 6. (continued)

PICO questions (P–I–C)	Outcomes (O)
<p>Should self-testing for proteinuria during pregnancy be available in addition to clinic check-ups?</p> <p>P: Pregnant individuals</p> <p>I: Self-testing for proteinuria (either by the pregnant individual or by another layperson, such as a family member)</p> <p>C: Clinic proteinuria testing by health workers during antenatal care contacts only</p>	<p>Maternal outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Maternal mortality or near-miss 2. Eclampsia or pre-eclampsia 3. Follow-up care and appropriate management 4. Autonomy (e.g. self-efficacy, self-determination, empowerment) <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Adverse pregnancy outcomes (e.g. spontaneous abortion, premature rupture of membrane, placental abruption) 2. Long-term cardiovascular risk, chronic hypertension, diabetes, stroke 3. Mental health and well-being (anxiety, stress, self-harm) 4. Adverse events and social harms (including discrimination, intimate partner violence, stigma) and whether these harms were corrected/redress was available 5. Device-related issues (e.g. test failure, problems with manufacturing, packaging, labelling or instructions for use) <p>Newborn outcomes</p> <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Stillbirth or perinatal death 2. Intrauterine growth restriction 3. Preterm birth
<p>Should self-monitoring of blood glucose among pregnant individuals with gestational diabetes be made available in addition to clinic check-ups?</p> <p>P: Pregnant individuals diagnosed with gestational diabetes</p> <p>I: Self-monitoring of blood glucose (either by the pregnant individual or by another layperson, such as a family member)</p> <p>C: Clinic blood glucose monitoring by health workers during antenatal contacts only</p>	<p>Maternal outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Autonomy (e.g. self-efficacy, self-determination, empowerment) 2. Follow-up care with appropriate management 3. Preterm labour <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Caesarean section (including emergency caesarean section) 2. Hypertensive disorders of pregnancy (pre-eclampsia) or eclampsia 3. Mental health and well-being (anxiety, stress, self-harm) 4. Long-term complications: type 2 diabetes or other metabolic disorders 5. Device-related issues (e.g. test failure, problems with manufacturing, packaging, labelling or instructions for use) 6. Social harms (including stigma, discrimination and intimate partner violence) and whether these harms were corrected/redress was available 7. Placenta previa <p>Newborn outcomes</p> <p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Stillbirth or perinatal death 2. Respiratory distress syndrome <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Birthweight/size for gestational age (including macrosomia) 2. Shoulder dystocia

ANNEX 6. (continued)

PICO questions (P–I–C)	Outcomes (O)
<p>Should emergency contraceptive pills be made available without a clinician's prescription?</p> <p>P: Individuals using emergency contraceptive pills</p> <p>I: Availability of emergency contraceptive pills over the counter (without a prescription or screening) or from a pharmacist (behind-the-counter or pharmacy access)</p> <p>C: Availability by prescription only (by a clinician other than a pharmacist)</p>	<p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Uptake of emergency contraception 2. Unintended pregnancy 3. Side-effects, adverse events or social harms 4. Correct use of product 5. Autonomy (e.g. self-efficacy, self-determination, empowerment) <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Changes in sexual health-related practices or behaviour (e.g. unprotected intercourse, consistent condom use, condom use at last sex, sexual partners, contraception) 2. Abortion
<p>Should self-testing for pregnancy be available as an additional option to clinic-based testing?</p> <p>P: Individuals seeking pregnancy testing</p> <p>I: Urine self-testing for pregnancy</p> <p>C: Health worker-led testing for pregnancy (health facility or community clinic with urine and/or serum test for pregnancy)</p>	<p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Appropriate clinical follow-up (counselling, antenatal care visits, contraceptive services, abortion services, etc.) 2. Gestational age at pregnancy awareness (knowledge of pregnancy) and at presentation for antenatal care or abortion 3. Autonomy (e.g. self-efficacy, self-determination, empowerment) 4. Device-related issues (e.g. test failure, problems with manufacturing, packaging, labelling or instructions for use) 5. Mental health and well-being (anxiety, stress, self-harm) 6. Adverse events and social harms (including stigma, discrimination, coercion, violence [including intimate-partner violence, violence from family members or community members, etc.] and breaches of confidentiality) and whether these harms were corrected/redress was available <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Missed ongoing pregnancy
<p>Should PrEP initiation be available following screening by a pharmacist, without a prescription?</p> <p>P: Individuals interested in PrEP</p> <p>I: PrEP access through a pharmacy without a prescription from a health worker</p> <p>C: PrEP access by prescription from a health worker</p>	<p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Correct use of product 2. HIV acquisition/incidence and linkage to care <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Adverse events (chronic kidney disease, sexually transmitted infection [STI] acquisition/incidence and linkage to care) 2. Autonomy (self-efficacy, self-determination, empowerment) 3. Mental health and well-being (e.g. anxiety, stress, self-harm) 4. Social harms (e.g. discrimination, intimate partner violence, stigma) 5. Uptake of PrEP 6. Continuation of PrEP (continued use or an intermittent pattern of use related to risk exposure) 7. Uptake of regular HIV testing (measures include one month after initiation and three-monthly thereafter while taking PrEP or if taking PrEP intermittently [seasons of risk], prior to starting another period of PrEP)

ANNEX 6. (continued)

PICO questions (P–I–C)	Outcomes (O)
<p>Should PrEP continuation be available from a pharmacist, without a prescription?</p> <p>P: Individuals taking PrEP</p> <p>I: PrEP access through a pharmacy without a prescription from a health worker</p> <p>C: PrEP access by prescription from a health worker</p>	<p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Chronic kidney disease 2. Autonomy (e.g. self-efficacy, self-determination, empowerment) 3. HIV acquisition/incidence and linkage to care <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. STI acquisition/incidence and linkage to care 2. Continuation of PrEP (continued use or an intermittent pattern of use related to risk exposure) 3. Correct use of product 4. Mental health and well-being (e.g. anxiety, stress, self-harm) 5. Social harms (e.g. discrimination, intimate partner violence, stigma) 6. Uptake of regular HIV testing (one month after initiation and three-monthly thereafter while taking PrEP or if taking PrEP intermittently [seasons of risk], prior to starting another period of PrEP)
<p>Does the use of lubricants during or prior to sex result in improved sexual health and well-being?</p> <p>P: Sexually active individuals</p> <p>I: Use of lubricant during sexual activity (defined as any penetration, including vaginal/anal, with/without a partner, and with any object)</p> <p>C: Sexual activity without lubricant</p>	<p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Vaginal dryness, pain during vaginal/anal penetration 2. Self-efficacy, self-determination, autonomy and empowerment around sexual health and sexuality (confidence, communication with partners, self-esteem) <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. STIs/HIV 2. Sexual desire, arousal, lubrication, orgasm, satisfaction and pleasure 3. Sexual arousal dysfunctions 4. Vaginal discharge and bacterial vaginosis 5. Side-effects (irritation, infections [yeast, reproductive tract infection, STI, urinary tract infection]) 6. Other side-effects, adverse effects, or social harms
<p>Should self-administration of gender-affirming hormones be made available in addition to health worker administration?</p> <p>P: Individuals seeking to use gender-affirming hormones</p> <p>I: Self-administration of gender-affirming hormones</p> <p>C: Health worker-administration of gender-affirming hormones</p>	<p>Critical outcomes:</p> <ol style="list-style-type: none"> 1. Adverse events (pituitary adenoma [prolactinoma], galactorrhoea, venous thromboembolism, low libido, autoimmunity, migraine, cancer, cardiovascular health, HIV infection, hepatitis C infection, etc.), including knowledge of potential interactions with other medications and/or experience of such interactions 2. Correct use of product 3. Mental health and well-being (e.g. anxiety, stress, self-harm) 4. Social harms (e.g. discrimination, intimate partner violence, stigma) 5. Trust and engagement with the health system for issues other than hormone use, or for following up with side-effects, etc. <p>Important outcomes:</p> <ol style="list-style-type: none"> 1. Autonomy (self-efficacy, self-determination, empowerment) 2. Peer/community support 3. Satisfaction with and appropriateness of clinical services (e.g. services that do not consider being transgender as a pathology or mental health issue, but as one form of gender diversity)

ANNEX 7. PUBLISHED REVIEWS

Title of manuscript	Authors
Systematic reviews on effectiveness relating to the six new recommendations (published or in review 2021)	
Self-management of iron and folic acid supplementation during pre-pregnancy, pregnancy, and postnatal periods: a systematic review (Recommendations 10a, 10b, 10c)	King SE, Yeh PT, Rhee DK, Tunçalp Ö, Rogers LM, Narasimhan M.
Self-monitoring of blood pressure among women with hypertensive disorders of pregnancy: a systematic review (Recommendation 11)	Yeh PT, Rhee DK, Kennedy CE, Zera CA, Lucido B, Tunçalp Ö, Gomez Ponce de Leon R, Narasimhan M
Self-monitoring of blood glucose levels among women with gestational diabetes: a systematic review (Recommendation 12)	Yeh PT, Kennedy CE, Rhee DK., Zera CA, Tunçalp Ö, Gomez Ponce de Leon R, Lucido B, Narasimhan M
Over-the-counter provision of emergency contraceptive pills: a systematic review (Recommendation 16)	Atkins K, Kennedy CE, Yeh PT, Narasimhan M
Self-testing for pregnancy: a systematic review (Recommendation 21)	Kennedy CE, Yeh PT, Gholbzouri K, Narasimhan M
Lubricants for promotion of sexual health and wellbeing: a systematic review (Recommendation 32)	Kennedy CE, Yeh PT, Li J, Gonsalves L, Narasimhan M
Additional reviews (in review 2021)	
Self-administration of gender-affirming hormones: a systematic review (Key consideration and good practice statement 13)	Kennedy CE, Yeh PT, Byrne J, van der Merwe L, Ferguson L, Poteat T, Narasimhan M,
PrEP distribution in pharmacies: a systematic review (Key consideration)	Kennedy CE, Yeh PT, Atkins K, Ferguson L, Baggaley R, Narasimhan M
Self-testing for proteinuria in pregnancy: a systematic review (Key consideration)	Yeh PT, Rhee DK, Kennedy CE, Zera CA, Tunçalp Ö, Kuzmenko O, Lucido B, Narasimhan M
Human rights, gender and law in practice: Lessons from implementation of self-care interventions for sexual and reproductive health and rights (Good practice statements 1–4)	Ferguson L, Narasimhan M

ANNEX 8. GUIDELINE DEVELOPMENT GROUP JUDGEMENTS ON NEW RECOMMENDATIONS

Recommendation	Recommendations 10a, 10b, 10c	Recommendation 11	Recommendation 12
Intervention	Self-management of iron and folic acid supplementation	Self-monitoring of blood pressure	Self-monitoring of glucose
Problem a priority?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain <input type="checkbox"/> Varies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain <input type="checkbox"/> Varies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain <input type="checkbox"/> Varies
Certainty of the evidence	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very low <input checked="" type="checkbox"/> NIL	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Low <input checked="" type="checkbox"/> Very low	<input checked="" type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very low
Balance of benefits and harms	<input type="checkbox"/> Favours intervention <input checked="" type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input type="checkbox"/> Favours intervention <input checked="" type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Values and preferences	<input type="checkbox"/> Important uncertainty or variability <input type="checkbox"/> Probably no important uncertainty or variability <input checked="" type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes	<input type="checkbox"/> Important uncertainty or variability <input type="checkbox"/> Probably no important uncertainty or variability <input checked="" type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes	<input type="checkbox"/> Important uncertainty or variability <input type="checkbox"/> Probably no important uncertainty or variability <input checked="" type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes
Resource requirements (costs)	<input type="checkbox"/> Large costs <input type="checkbox"/> Moderate costs <input checked="" type="checkbox"/> Negligible costs and savings <input type="checkbox"/> Moderate savings <input checked="" type="checkbox"/> Large savings <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input type="checkbox"/> Large costs <input type="checkbox"/> Moderate costs <input type="checkbox"/> Negligible costs and savings <input checked="" type="checkbox"/> Moderate savings <input type="checkbox"/> Large savings <input checked="" type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input type="checkbox"/> Large costs <input checked="" type="checkbox"/> Moderate costs <input type="checkbox"/> Negligible costs and savings <input checked="" type="checkbox"/> Moderate savings <input type="checkbox"/> Large savings <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Cost-effectiveness	<input checked="" type="checkbox"/> Favours intervention <input checked="" type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input type="checkbox"/> Favours intervention <input checked="" type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input checked="" type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain

ANNEX 8. (continued)

Recommendation	Recommendations 10a, 10b, 10c	Recommendation 11	Recommendation 12
Equity	<input checked="" type="checkbox"/> Increased <input type="checkbox"/> Probably increased <input type="checkbox"/> Reduced <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Increased <input checked="" type="checkbox"/> Probably increased <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Increased <input checked="" type="checkbox"/> Probably increased <input type="checkbox"/> Reduced <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Acceptability	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain
Feasibility	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Enough evidence to make a recommendation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Recommendation in favour or against the intervention	<input checked="" type="checkbox"/> In favour <input type="checkbox"/> Against	<input checked="" type="checkbox"/> In favour <input type="checkbox"/> Against	<input checked="" type="checkbox"/> In favour <input type="checkbox"/> Against
Strong or conditional recommendation	<input checked="" type="checkbox"/> Strong <input type="checkbox"/> Conditional	<input type="checkbox"/> Strong <input checked="" type="checkbox"/> Conditional	<input checked="" type="checkbox"/> Strong <input type="checkbox"/> Conditional

ANNEX 8. (continued)

Recommendation	Recommendations 16	Recommendation 21	Recommendation 32
Intervention	Over-the-counter emergency oral contraception	Self-testing for pregnancy	Lubricants for sexual health
Problem a priority?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain <input type="checkbox"/> Varies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain <input type="checkbox"/> Varies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain <input type="checkbox"/> Varies
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 checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very low	<input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input checked="" type="checkbox"/> Very low
Balance of benefits and harms	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Values and preferences	<input type="checkbox"/> Important uncertainty or variability <input checked="" type="checkbox"/> Probably no important uncertainty or variability <input checked="" type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes	<input type="checkbox"/> Important uncertainty or variability <input type="checkbox"/> Probably no important uncertainty or variability <input checked="" type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes	<input type="checkbox"/> Important uncertainty or variability <input type="checkbox"/> Probably no important uncertainty or variability <input checked="" type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes
Resource requirements (costs)	<input type="checkbox"/> Large costs <input checked="" type="checkbox"/> Moderate costs <input type="checkbox"/> Negligible costs and savings <input type="checkbox"/> Moderate savings <input type="checkbox"/> Large savings <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input type="checkbox"/> Large costs <input type="checkbox"/> Moderate costs <input type="checkbox"/> Negligible costs and savings <input type="checkbox"/> Moderate savings <input checked="" type="checkbox"/> Large savings <input checked="" type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain	<input type="checkbox"/> Large costs <input type="checkbox"/> Moderate costs <input type="checkbox"/> Negligible costs and savings <input type="checkbox"/> Moderate savings <input type="checkbox"/> Large savings <input checked="" type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain
Cost-effectiveness	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Favours intervention <input type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input type="checkbox"/> Favours intervention <input checked="" type="checkbox"/> Probably favours intervention <input type="checkbox"/> Against intervention <input checked="" type="checkbox"/> Varies <input checked="" type="checkbox"/> Uncertain

ANNEX 8. (continued)

Recommendation	Recommendations 16	Recommendation 21	Recommendation 32
Equity	<input checked="" type="checkbox"/> Increased <input type="checkbox"/> Probably increased <input type="checkbox"/> Reduced <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Increased <input type="checkbox"/> Probably increased <input type="checkbox"/> Reduced <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Increased <input type="checkbox"/> Probably increased <input type="checkbox"/> Reduced <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Acceptability	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Probably yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Feasibility	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input type="checkbox"/> Varies <input type="checkbox"/> Uncertain	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Uncertain
Enough evidence to make a recommendation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Recommendation in favour or against the intervention	<input checked="" type="checkbox"/> In favour <input type="checkbox"/> Against	<input checked="" type="checkbox"/> In favour <input type="checkbox"/> Against	<input checked="" type="checkbox"/> In favour <input type="checkbox"/> Against
Strong or conditional recommendation	<input checked="" type="checkbox"/> Strong <input type="checkbox"/> Conditional	<input checked="" type="checkbox"/> Strong <input type="checkbox"/> Conditional	<input checked="" type="checkbox"/> Strong <input type="checkbox"/> Conditional

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