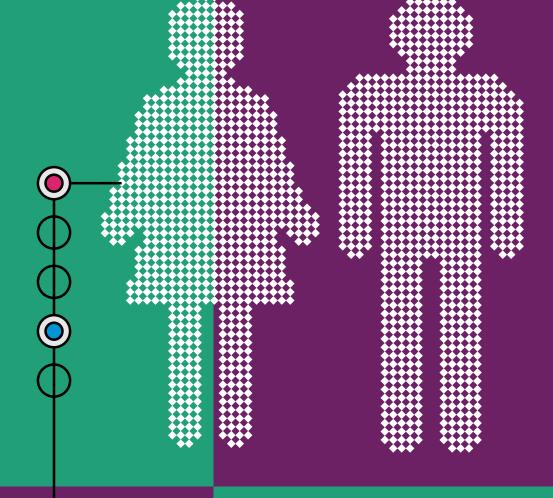
Digital Adaptation Kit for Family Planning

Operational requirements for implementing WHO recommendations in digital systems









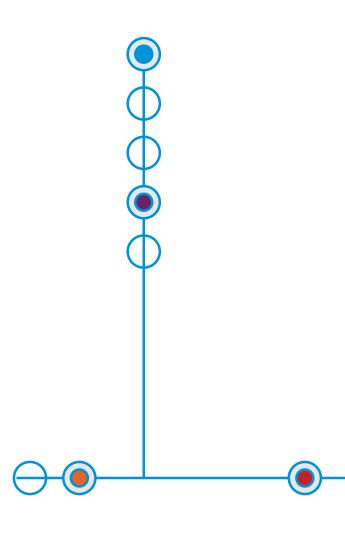
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Abbreviations

3ТС	lamivudine	ETG	etonogestrel
ABC	abacavir	ETR	etravirine
ART	antiretroviral therapy	FAB	fertility awareness-based method
AZT	zidovudine	FTC	emtricitabine
BBT	basal body temperature	HEADSS	home, education, activities/employment,
BMD	bone marrow density	110)/	drugs, suicidality and sex
ВМІ	body mass index	HPV	human papillomavirus
CHC	combined hormonal contraceptive	ICD	International Classification of Diseases
CIC	combined injectable contraceptive	ICT	information and communication technology
CIN	cervical intraepithelial neoplasia	ID	identification
сос	combined oral contraceptive	IM	intramuscular
Cu-IUD	copper-bearing intrauterine device	IUD	intrauterine device
CVR	combined contraceptive vaginal ring	LAM	lactation amenorrhoea method
D4T	stavudine	LNG	levonorgestrel
DAK	digital adaptation kit	LOINC	Logical Observation Identifiers Names and
DDI	didanosine	MEG	Codes
DHIS2	District Health Information Systems (version 2)	MEC	medical eligibility criteria
DMN	Decision Model and Notation	MI	myocardial infarction
DMPA	depot medroxyprogesterone acetate	МОН	ministry of health
DTDS	digital tracking and decision support	NET-EN	norethisterone enanthate
DVT	deep vein thrombosis	NNRTI	non-nucleoside reverse transcriptase inhibitor
ECP	emergency contraceptive pill	NRTI	nucleoside reverse transcriptase inhibitor
EE	ethinyl estradiol	NSAID	non-steroidal anti-inflammatory drug
EFV	efavirenz	NVP	nevirapine
		PE	pulmonary embolism
EMR	electronic medical record	PI	protease inhibitor

Abbreviations

PID pelvic inflammatory disease

POC progestogen-only contraceptive

POP progestogen-only pill

PVR progesterone-releasing vaginal ring

Quick Response (i.e. QR code)

RAL raltegravir
RPV rilpivirine

subcutaneous

SMS short message service (text message)

SNOMED Systematized Nomenclature of Medicine

STI sexually transmitted infection

SVT superficial venous thrombosis

TDF tenofovir

UHC universal health coverage

UNAIDS Joint United Nations Programme on HIV/AIDS

UPA ulipristal acetate

VTE venous thromboembolismWHO World Health Organization



Part

Background

Digital health – defined broadly as the systematic application of information and communications technologies (ICT), computer science and data to support informed decision-making by individuals, the health workforce and health systems, to strengthen resilience to disease and improve health and wellness (1) – is increasingly being applied as an essential enabler for health service delivery and accountability. Ministries of health (MOHs) have recognized the value of digital health as articulated within the World Health Assembly resolution (2) and the Global strategy on digital health (3). Likewise, donors have advocated for the rational use of digital tools as part of efforts to expand coverage and quality of services, as well as promote data use and monitoring efforts (4–6). Despite the investments into and abundance of digital systems, there is often limited transparency in the health data and logic contained in these digital tools, or relationship with evidence-based clinical or public health recommendations, which not only undermines the credibility of such systems, but also impedes opportunities for interoperability and threatens potential for continuity of care.

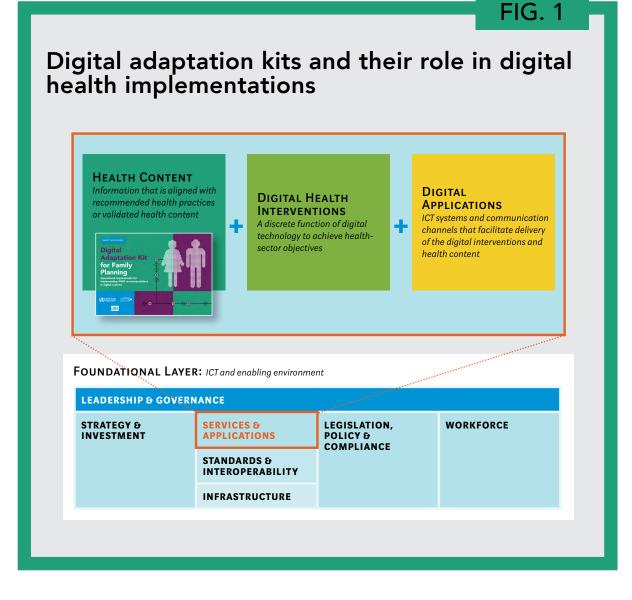
Evidence-based recommendations, such as those featured in WHO guidelines, establish standards of care and offer a reference point for informing the content of digital systems that countries adopt. However, guidelines are often only available in a narrative format that requires a resource-intensive process to be elaborated into the specifications needed for digital systems. This translation of guidelines for digital systems often results in subjective interpretation for implementers and software vendors, which can lead to inconsistencies or an inability to verify the content within these systems, potentially leading to adverse health outcomes and other unintended effects. Where digital systems exist, the documentation of the underlying data and content may be unavailable or proprietary, requiring governments to start from scratch and expend additional resources each time they intend to deploy such a system. This lack of documentation of the health content can lead to dependence on one vendor and haphazard deployments that are unscalable or difficult to replicate across different settings.

To ensure countries can effectively benefit from digital health investments, digital adaptation kits (DAKs) are designed to facilitate the accurate reflection of WHO's clinical, public health and data use guidelines within the digital systems countries are adopting. DAKs are operational, software-neutral, standardized documentation that distil clinical, public health and data use guidance into a format that can be transparently incorporated into digital systems. Although digital implementations comprise multiple factors – including the (i) health domain data and content, (ii) digital intervention or functionality, and (iii) digital application or communication channel for delivering the digital intervention – DAKs focus primarily on ensuring the validity of the health content (see <u>Fig. 1</u>) (1,7). Accordingly, DAKs provide the generic content requirements that should be housed within digital systems, independently of a specific software application and with the intention that countries can customize them to local needs.



For this particular DAK, the requirements are based on systems that provide the functionalities of digital tracking and decision support (see <u>Box 1</u>) and include components such as personas, workflows, core data elements, decision-support algorithms, scheduling logic and reporting indicators. Operational outputs, such as spreadsheets of the data dictionary and the detailed decision-support algorithms, are included as part of the DAK as practical resources that implementers can use as starting points when developing digital systems. Furthermore, data components within the DAK are mapped to standards-based terminology, such as the International Classification of Diseases (ICD), to facilitate interoperability.

The DAKs follow a modular approach in detailing the data and content requirements for a specific health programme area – such as antenatal care, family planning, sexually transmitted infections (STIs) – among the different health areas for which DAKs have been developed. This DAK focuses on providing the content requirements for a digital tracking and decision-support system used in primary health care settings by health workers for family planning/contraception services. It also includes cross-cutting elements focused on the client, such as self-care interventions, although these interventions are described from the perspective of the health worker, not from that of the clients.



What is digital tracking and decision support?

Digital tracking is the use of digitized records to capture and store clients' health information to enable follow-up of their health status and services received (8). This may include digital forms of paper-based registers and case management logs within specific target populations, as well as electronic patient records linked to uniquely identified individuals (7,8).

Digital tracking makes it possible to register and follow up patient services, and may be done through an electronic medical record (EMR) or other digital forms of health records. Digital tracking aims to reduce lapses in continuity of care by stimulating timely follow-up contacts, and may incorporate decision-support tools to guide health workers in: executing clinical protocols to deliver appropriate care, scheduling upcoming services, and following checklists for appropriate case management at point of care. Some other descriptors include: "digital versions of paper-based registers for specific health domains; digitized registers for longitudinal health programmes including tracking of migrant populations' benefits and health status; case management logs within specific target populations, including migrant populations" (8).

Health worker decision support is defined as: "digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions" (8). Thus, a person-centred digital tracking and decision-support (DTDS) system is one used by health workers at the point of care; it includes a persistent record of health events and encounters that links to clinical decision-support systems to reinforce good practice. It also links to reporting and management tools to reinforce accountability. A DTDS record includes all the information required for detailing an individual's health status and the health interventions provided to them.

DTDS end-users are all cadres of health-care providers operating at all care levels, including those operating outside of formal health-care facilities (e.g. community health workers, health volunteers). DTDS systems emphasize the use of "collect once, use for many purposes" (9), in which data collected for service delivery can also be used for accountability (i.e. they can be used to calculate aggregate indicators required for reporting, including monitoring provider, stock and system performance).

WHO has provided the following context-specific recommendation for the use of an integrated system that provides both a digital track of client's health status and decision support (7).



Effective coverage
Accountability
coverage

Digital tracking of clients' health status and services (digital tracking) combined with decision support

RECOMMENDATION 8: WHO recommends digital tracking of clients' health status and services, combined with decision support under these conditions:

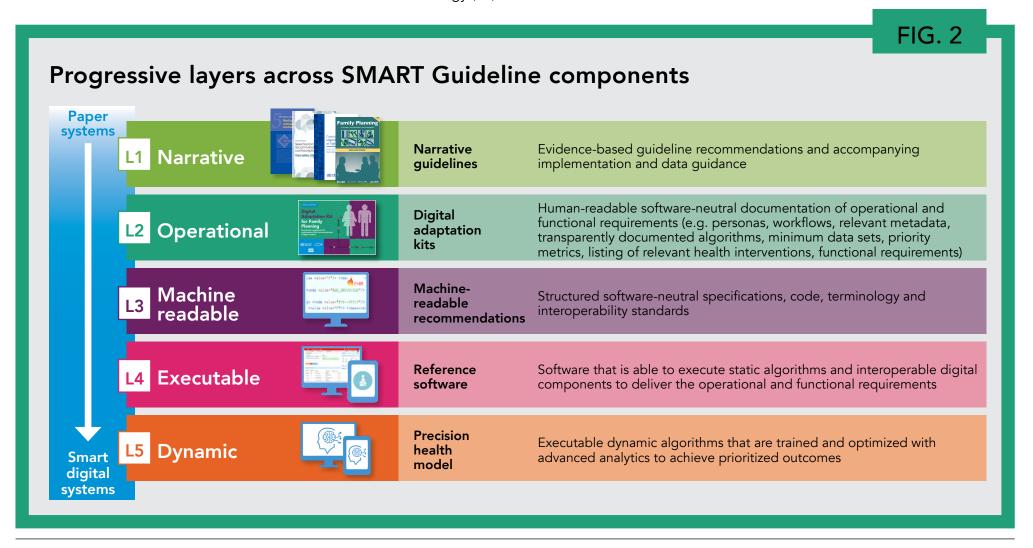
- in settings where the health system can support the implementation of these intervention components in an integrated manner; and
- for tasks that are already defined as within the scope of practice for the health worker.

(Recommended only in specific contexts or conditions)



Digital adaptation kits within a strategic vision for SMART Guidelines

The operational and standardized documentation reflected within the DAKs represents one of the steps within a broader vision of **S**tandards-based, **M**achine-readable, **A**daptive, **R**equirements-based and **T**estable (SMART) Guidelines. SMART Guidelines aim to maximize health impact through improved fidelity and uptake of recommendations within standards-based digital systems through a *systematic process for* transforming guideline development, delivery and application (10,11). Within this vision, DAKs serve as a prerequisite for developing computable, or machine-readable, guidelines, as well as executable reference software and advanced analytics for precision health. Fig. 2 provides an overview of the different layers of the SMART Guidelines continuum and where DAKs fit within this strategy (10).



Objectives

This DAK focuses on family planning and aims to provide a common language across various audiences – family planning and other programme managers, software developers, and implementers of digital systems – to ensure a common understanding of the appropriate health information content within a defined health programme area, as a mechanism to catalyse the effective use of these digital systems. The key objectives of the DAK are:

- » to ensure adherence to WHO clinical, public health and data use guidelines, and facilitate consistency of the health content that is used to inform the development of a person-centred digital tracking and decision-support (DTDS) system;
- » to enable both health programme leads and digital health teams (including software developers) to have a joint understanding of the health content within the digital system, with a transparent mechanism to review the validity and accuracy of the health content; and
- » to provide a starting point of the core data elements and decision-support logic that should be included within DTDS systems for family planning.

Information detailed in this DAK reflects generic workflow processes, data and decision-support algorithms, as derived from *Medical eligibility criteria for contraceptive use (12), Selected practice recommendations for contraceptive use (13), Family planning: a global handbook for providers (14)* and other related WHO documents described below. This DAK also includes technical considerations for self-care interventions from the perspective of the health worker who promotes these interventions to a client. It also describes linkages to related services for sexually transmitted infections (STIs) and intimate partner violence, and considerations for adolescents. **Note that the outputs of the DAKs are intentionally generic and will need to be contextualized to local policies and requirements.**

DAKs have also been developed for antenatal care (ANC), HIV and STIs, and this approach is being expanded to additional health domains, such as immunizations, postnatal care (PNC) and child health. To complement these there is a forthcoming DAK for self-care interventions from the perspective of a client; taken together, all of these DAKs work towards a comprehensive approach for standardized software requirements for primary health care settings.



Components of a digital adaptation kit

The DAK comprises eight interlinked components: (1) health interventions and associated recommendations; (2) generic personas; (3) user scenarios; (4) business processes and workflows; (5) core data elements; (6) decision-support logic; (7) indicators and performance metrics; and (8) high-level functional and non-functional requirements. Table 1 provides an overview of each of the contributing components of the DAK, which this document elaborates. All information within the adaptation kit represents a generic starting point, which can then be adapted according to the specific context.

Table 1. Components of a digital adaptation kit

Component	Description	Purpose	Outputs	Adaptation needed
1. Health interventions and recommendations	Overview of the health interventions and WHO recommendations included within this digital adaptation kit (DAK). DAKs are meant to be a repackaging and integration of WHO guidelines and guidance documents in a particular health domain. The list of health interventions is drawn from the universal health coverage (UHC) menu of interventions compiled by WHO (15).	Setting the stage – To understand how this DAK would be applied to a digital tracking and decision-support system in the context of specific health programmes and interventions	 » List of related health interventions based on WHO's UHC essential interventions » List of related WHO recommendations based on guidelines and guidance documents 	 » Contextualization to reflect current or planned national policies
2. Generic personas	Depiction of the end-users, supervisors and related stakeholders who would be interacting with the digital system or involved in the care pathway.	Contextualization – To understand the wants, needs and constraints of the end-users	» Description, competencies and essential interventions performed by targeted personas	» Greater specification and details of the end-users, based on real people (i.e. health workers) in a given context » High-level information to describe the provider of the health service (e.g. the general background, roles and responsibilities, motivations, challenges, and environmental factors)

Component	Description	Purpose	Outputs	Adaptation needed
3. User scenarios	Narratives that describe how the different personas may interact with each other. The user scenarios are only illustrative and are intended to give an idea of a typical workflow.	Contextualization – To understand how the system would be used, and how it would fit into existing workflows	» Example narrative of how the targeted personas may interact with each other during a workflow	» Greater specification and details of the real needs of end- users in a given context
4. Business processes and workflows	A business process is a set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling, referrals (1,16). Workflows are a visual representation of the progression of activities (tasks, decision points, interactions) that are performed within the business process (1,16).	Contextualization and system design – To understand how the digital system would fit into existing workflows and how best to design the system for that purpose	 Overview matrix presenting the key processes in family planning Workflows for identified business processes, with annotations 	» Customization of the workflows, which can include additional forks, alternative pathways or entirely new workflows
5. Core data elements	Data elements required throughout the different points of the workflow. These data elements are mapped to the International Classification of Diseases version 11 (ICD-11) codes and other established concept mapping standards to ensure the data dictionary is compatible with other digital systems.	System design and interoperability – To know which data elements need to be logged and how they map to other standard terminologies (e.g. ICD, Systematized Nomenclature of Medicine [SNOMED]) for interoperability with other standards-based systems	» List of data elements » Link to data dictionary with detailed data specifications in spreadsheet format (Web Annex A).	» Translation of data labels into the local language, and additional data elements created depending on the context



Component	Description	Purpose	Outputs	Adaptation needed
6. Decision-support logic	Decision-support logic and algorithms to support appropriate service delivery in accordance with WHO clinical, public health and data use guidelines.	System design and adherence to recommended clinical practice – To know what underlying logic needs to be coded into the system	 » List of decisions that need to be made throughout the encounter » Link to decisionsupport tables in a spreadsheet format with inputs, outputs and triggers for the decision-support logic (Web Annex B) » Scheduling logic for services (Web Annex B) 	 Change of specific thresholds or triggers in a logic (IF/THEN) statement, e.g. body mass index (BMI) cut-off, age trigger for youth-friendly services Additional decision-support logic formulas depending on the context
7. Indicators and performance metrics	Core set of indicators that need to be aggregated for decision-making, performance metrics, and subnational and national reporting. These indicators and metrics are based on data that can feasibly be captured from a routine digital system rather than survey-based tools.	System design and adherence to recommended health monitoring practices – To know what calculations and secondary data use is needed for the system, based on the principle of "collect once, use for many purposes" (9)	» Indicators table with numerator and denominator of data elements for calculation, along with appropriate disaggregation (Web Annex C)	 » Changing calculation formulas of indicators » Adding indicators » Changing the definition of the primary data elements used to calculate the indicator based on data available
8. Functional and non-functional requirements	List of core functions and capabilities the system must have to meet the end-users' needs and achieve tasks within the business process.	System design – To know what the system should be able to do	» Table of functional and non-functional requirements with the intended end-user of each requirement, as well as why that user needs that functionality in the system (Web Annex D)	 Adding or reducing functions and system capabilities based on budget and end-user needs and preferences

Notation guidance

Throughout the DAK, there are identification (ID) numbers to simplify tracking and referencing of each of the components. Note that the DAK represents an overview across the different components, while the comprehensive and complete outputs of each component (e.g. data dictionary, decision-support tables) are included in appended spreadsheets. The notation guidance is as follows.

Component 1: Health interventions and recommendations No notations used.

Component 2: Generic personas

No notations used.

Component 3: User scenarios

No notations used.

Component 4: Business processes and workflows

Each workflow should have a "Process name" and a corresponding letter.

- » Each workflow should also have a "Process ID" that should be structured "Abbreviated health domain" (e.g. FP). "Corresponding letter for the process" (e.g. A).
- » Each activity in the workflow should be numbered with an "Activity ID" that should be structured "Process ID" from above "Activity Number" (e.g. FP.B7).

Component 5: Core data elements (data dictionary)

Each data element should have a running number and a "Data Element (DE) ID" that should be structured "Abbreviated health domain" (e.g. FP)."DE". "Sequential number of the data element" (e.g. FP.B7.DE.1, FP.B7.DE.2).

Component 6: Decision-support logic

Each decision-support logic table should have a running number and a "Decision-support table (DT) ID" that should be structured "Abbreviated health domain" (e.g. FP). "DT". "Sequential number of the decision-support table" (e.g. FP.DT.1, FP.DT.2).

Component 7: Indicators and performance metrics

Each indicator should have an "Indicator ID" that should be structured "Abbreviated health domain" (e.g. FP). "IND". "Sequential number of the indicator" (e.g. FP.IND.1, FP.IND.2).

Component 8: High-level system requirements

- » Each functional requirement should have a "Functional requirement ID" that should be structured "Abbreviated health domain" (e.g. FP). "REQ". "Sequential number of the functional requirement" (e.g. FP.REQ.1, FP.REQ.1).
- » Each non-functional requirement should have a "Non-functional requirement ID" that should be structured "Abbreviated health domain" (e.g. FP). "NFXNREQ". "Sequential number of non-functional requirements" (e.g. FP.NFXNREQ.1, FP. NFXNREQ.2).



How to use this digital adaptation kit

Target audience

The primary target audience for this DAK is health programme managers within the MOH, who will be working with their digital or health information systems counterparts in determining the health content requirements for a family planning DTDS system. The health programme manager is responsible for overseeing and monitoring the implementation of the clinical practices and policies for the health programme area, in this case family planning. Other stakeholders, including software development teams and implementers in the private sector, will can also benefit from the content in the DAK for evidence based decision making to enhance quality of care and strengthen data quality.

The DAK also equips individuals responsible for translating health-system processes and guidance documents for use within digital systems with the necessary components to kick-start the process of developing a DTDS system in a standards-compliant manner. These individuals are also known as business analysts who interface between health content experts and software development teams. Specifically, the adaptation kit contains key outputs, such as the data dictionary and decision-support algorithms, to ensure the validity and consistency of the health content with the DTDS system.

Additionally, using this DAK requires a collaboration between health programme managers responsible for family planning, and counterparts in digital health and health information systems. Although each DAK focuses on a particular health programme area (in this case family planning), the DAKs are envisioned to be used in a modular format and link to other health programme areas within primary health care settings, in an effort to support integration across services.

Scenarios for using this DAK

The DAK may be used across various scenarios, some of which are listed below.

Scenario 1:

Incorporating WHO guideline content into existing DTDS systems

Countries that already have digital systems in place, such as electronic medical records (EMRs) and decision-support tools, may use the information in the DAK to cross-check whether the underlying content and data for specific health programme areas are aligned to WHO guidelines. Users of the DAK can identify and extract specific decision algorithms that would need to be incorporated into their existing digital systems. By reviewing this systematic documentation, health programme managers and implementers can more readily identify differences in workflows, data inputs and decision-support logic to examine the rationale for deviations and understand local adaptions of guideline content.

Scenario 2:

Transitioning from paper to DTDS systems

Some countries may currently have paper-based systems that they would like to digitize. The process of optimizing paper-based client-level systems into digital records and decision-support systems may be overwhelming. Users in this scenario may review the DAK as a starting point for streamlining the necessary data elements and decision support that should be in the optimized client-level digital system. Users may also then refer to the paper-based tools to determine whether there are missing fields or content that should also be included within the digital system.

Users should also review the WHO *Handbook for digitizing primary health care (17)*, which provides stepwise guidance on how to map data on paper-based forms into a digital system, including ways of accounting for data elements that are redundant or may not add value to the health system.

Scenario 3:

Linking aggregate health management information system (HMIS; e.g. DHIS2) to DTDS systems used at point of care In some instances, countries may already have a digital system for aggregate reporting and HMIS, but may not yet have implemented digital systems that function at the service-delivery level. The DAK can guide the development of a digital client record system that operates at point of care, and ensure that there are linkages between the aggregate and service-delivery levels (e.g. community or facility level).

As such, a component of the DAK provides aggregate indicators derived from individual-level data to provide the linkage between these different levels. Complementary guidance dedicated specifically to aggregate-level data, such as Analysis and use of health facility data: guidance for RMNCAH programme managers (18) and WHO Survey Count Optimize Review Enable (SCORE) tools (https://www.who.int/data/data-collection-tools/score), should also be consulted for supporting the use of routine data at the facility management and district levels.

Scenario 4:

Leveraging data standards to promote interoperability and integrated systems This DAK includes data elements mapped to ICD codes, and other standards, to support the design of interoperable systems. The data dictionary in <u>Web Annex A</u> provides the necessary codes for different data elements, thus reducing the time for implementers to incorporate these global standards into the design of their digital systems.

In addition, a critical part of service delivery in any health domain is engaging with clients. Digital interventions aimed at clients themselves – such as on-demand information services, targeted client communication (e.g. transmitting health information and reminders), reporting of health-system feedback by clients on the quality of care, accessing their own medical records/home-based records, and self-monitoring of their health and diagnostic data (8) – are all emerging approaches for complementing the services provided by health workers. The content requirements for some of these client-facing digital tools will be included in a forthcoming self-care interventions DAK.



FIG. 3

Source: Adapted from WHO (1).

Linkages to the broader digital health ecosystem

DAKs represent one piece of the resources in the broader digital health ecosystem and should be used once there is a strategic vision by the MOH to use a DTDS system. In contexts where such vision may not exist, users should first consult the WHO-ITU National eHealth strategy toolkit (19), WHO guidelines on digital interventions for health system strengthening (7), and the WHO digital investments and implementation guide (1), to establish a better understanding of how to select and apply appropriate digital health interventions. Fig. 3 situates DAKs within the broader set of resources for planning and implementing digital health systems.

Digital adaptation kits within the broader digital health ecosystem **ASSESSING THE** Global digital health Digital health Conduct an inventory of existing or previously used WHO HIS stages of **CURRENT STATE** software applications, ICT systems and other tools to better digital continuous AND ENABLING investment health atlas understand the requirements for reuse and interoperability review tool ESTABLISHING A SHARED Develop a national digital health strategy outlining WHO WHO-ITU WHO guideline: overarching needs, desired activities and outcomes national Principles UNDERSTANDING AND STRATEGIC PLANNING eHealth of digital for donor diģital on Digital Define a vision for how the health system will be strategy toolkit health alignment development Health System nterventions strengthened through the use of digital technology Strengthening Formulate a digital health investment roadmap to support the national digital health strategy UNICEF human-Digital Square Global WHO digital DEFINING THE FUTURE STATE centred Plan and identify appropriate digital interventions, alongside the health and data content, to improve health system goods guidebook ITU SDG processes and address programmatic needs ITU digital health digital nvestment platform investment Review the current state and develop an architecture framework blueprint for the design of the digital health The Open Guidance World Bank **PLANNING THE** Group Architectur implementations Health or investing ENTERPRISE ARCHITECTURE formation + Identify validated open standards to ensure data exchange, Exchange (Open HIE) Framework (TOGAF) systems integration and future-proofing of digital health WHO handbook for Identify validated health content appropriate for the Be He@lthy, Be Mobile WHO SMART GUIDELINES **DETERMINING** WHO core implementation context handbooks for non-communicable diseases Digital adaptation kits Machine-**HEALTH CONTENT** indicator digitalizing Ensure use of content aligned with identified standards for readable REQUIREMENTS primary health care recommen the future state dations D Monitor implementation to ensure digital implementations M&E OF DIGITAL PATH MEASURE are functioning as intended and having WHO M&E Defining data the desired effect **IMPLEMENTATIONS** nd huildi demand ligital healtl a data use and use of AND FOSTERING Foster data-driven adaptive change management within the overall health system WHO MAPS Asian IMPLEMENTING. Maintain and sustain digital health implementations toolkit Bank total mHealth cost of + Identify risks and appropriate mitigations assessmen PDF for print and planning ☐ Online environment ICT: information and communications technology; M&E: monitoring and evaluation.



Digital adaptation kit content for family planning

Component

Health interventions and recommendations



This DAK focuses on the following health interventions and recommendations related to contraception and family planning.

1.1 Interventions referenced in this DAK are based on the WHO universal health coverage (UHC) list of essential interventions

The key interventions for contraception and family planning are the following, as defined in the WHO UHC compendium of interventions (15).

- » Screening, testing and counselling for choosing contraceptive methods
 - HIV testing services
 - Screening for pregnancy and medical eligibility
 - Performing medication review.
- » Management of family planning and contraception
 - Assessing patient's values and barriers, and advising patient on contraception methods
 - Counselling on family planning, with all available barrier and contraceptive methods, including nonhormonal, short-acting hormonal, long-acting hormonal, and sterilization
 - Counselling on self-care contraceptive methods
 - Obtaining consent for procedure
 - Provision of male and female condoms, hormonal contraceptive method, nonhormonal contraceptive method, intrauterine devices (IUDs), subdermal contraceptive implant, sterilization, vasectomy
 - Provision of oral antiretrovirals for pre-exposure prophylaxis (PrEP)
 - Provision of post-abortion contraceptives



- Provision of postpartum contraceptives
- Removal of implant
- Removal of IUD
- Monitoring follow-up visits.
- » Care and support for survivors of intimate partner and sexual violence, including rape
 - Provision of oral hormonal medications for emergency contraception.

1.2 WHO guidelines, recommendations and guidance

The DAKs are intended to reflect health recommendations and content that has already been published in WHO guidelines and guidance documents. The health content and interventions for this DAK are based on the following WHO documents.



Medical eligibility criteria for contraceptive use (5th edition, 2015)



Selected practice recommendations for contraceptive use (3rd edition, 2016)



Contraceptive eligibility for women at high risk of HIV (2019)

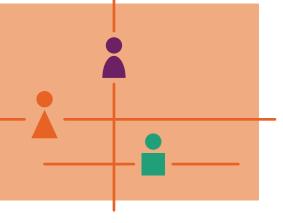


Family planning: a global handbook for providers (3rd edition, 2018)

Other WHO guidance represented in the DAK includes:

- » Adolescent job aid: a handy desk reference tool for primary level health workers (2010)
- » Decision-making tool for family planning clients and providers (2006)
- » Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines (2013)
- » WHO consolidated guideline on self-care interventions for health: sexual and reproductive health and rights (2019)
- » WHO recommendations on adolescent sexual and reproductive health and rights (2018)
- » WHO recommendations: optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting (2012).

Generic personas



A persona is a depiction of a relevant stakeholder, or end-user, of the system. Although the specific roles and demographic profiles of the personas will vary depending on the setting, the generic personas are based on the WHO core competencies and credentials of different health worker personas. Please note that these are developed based on synthesis across multiple contexts as a starting point, and further contextualization will be required according to the needs, motivations and challenges of the targeted personas in each setting.

2.1 Targeted generic personas

In the case of family planning, auxiliary nurse midwives and midwives are the primary personas for the digital tracking and decision-support system. In the health systems surveyed for this DAK, the common combination of service providers was a lay health worker along with a nurse who was also trained as a midwife. The key competences of nurse midwives compared with those of lay health workers are defined by WHO (*Table 2*) (20).



Table 2. Descriptions of key generic personas

Occupational title	Description	Different names	ISCO code (21)
Auxiliary nurse midwife	Auxiliary nurse midwives assist in the provision of maternal and newborn health care, particularly during childbirth but also in the prenatal and postpartum periods. ANMs have some training in secondary school and a period of on-the-job training may be included, sometimes formalized in apprenticeships. Like an auxiliary nurse, an auxiliary nurse midwife has basic nursing skills but no training in nursing decision-making. They possess some competencies in midwifery but are not fully qualified as midwives (22).	Auxiliary midwife (e.g. <i>Bidan</i> in Indonesia)	3221 (Nursing associate professional) 3222 (Midwifery associate professional)
Midwife	A person who has been assessed and registered by a state midwifery regulatory authority or similar regulatory authority. They offer care to childbearing women during pregnancy, labour and birth, and during the postpartum period. They also care for the newborn and assist the mother with breastfeeding. Their education lasts three, four or more years in nursing school, and it leads to a university or postgraduate university degree, or the equivalent. A registered midwife has the full range of midwifery skills (22).	Registered midwife, midwife, community midwife, nurse-midwife	2222 (Midwifery professional)
Nurse	A graduate who has been legally authorized (registered) to practise after examination by a state board of nurse examiners or similar regulatory authority. Education includes three, four or more years in nursing school, and it leads to a university or postgraduate university degree, or the equivalent. A registered nurse has the full range of nursing skills (20).	Registered nurse, nurse practitioner, clinical nurse specialist, advance practice nurse, practice nurse, licensed nurse, diploma nurse, BS nurse, nurse clinician	2221 (Nursing professional)

ISCO: International Standard Classification of Occupations.

As defined in Family planning: a global handbook for providers (14), many countries and programmes are allowing more provider types to offer contraceptive methods, and changing policies and regulations are allowing for more types. To encourage and guide task sharing, WHO has developed recommendations on which types of health workers can safely and effectively provide specific family planning methods. The WHO recommendations are shown in Fig. 4.

FIG. 4

Task sharing among health staff, as defined in the WHO's Family planning: a global handbook for providers (2018 update)

Family Planning Methods and Services Typically Offered by Various Types of Service Providers

National policies and service delivery guidelines specify which cadres of providers can offer specific family planning services. The chart below shows the family planning methods that are typically offered by these cadres of providers based on recommendations from WHO.

CONTRACEPTIVE SERVICE	Lay Health Workers (Such as CHWs)	Pharmacy Workers	Pharmacists	Auxiliary Nurses	Auxiliary Nurse- Midwives	Nurses	Midwives	Associate/ Advanced Associate Clinicians	Non- specialist Doctor	Specialist Doctor
Informed choice counselling Combined oral contraceptives (COCs) Progestin-only oral contraceptives POPs) Emergency contraceptive pills (ECPs) Standard Days Method and TwoDay Method Lactational amenorrhea method (LAM) Condoms (male & female), diaphragms, caps, spermicides	Ø *	Ø *	Ø _*	Ø *	Ø *	•	Ø *	Ø *	Ø *	Ø _*
• Injectable contraceptives (DMPA, NET-EN, combined monthly injectables)	Ø	Ø	Ø	Ø	Ø	Ø *	⊘ ∗	Ø *	Ø *	Ø *
• Implant insertion and removal	&	×	×	⊘	⊘	Ø	Ø	Ø *	Ø *	Ø *
• Intrauterine devices (IUD)	×	×	×	®	Ø	Ø	Ø	Ø *	Ø *	Ø *
Vasectomy (male sterilization)	€,	€3,	⊗ *	&	&	&	&	⊘ ∗	⊘ ∗	Ø *
• Tubal ligation (female sterilization)	€,	€,	8 *	*	€,	>	②	Ø *	Ø *	Ø *

All of the recommendations assume that the assigned health workers will receive task-specific training prior to offering services. Adopting task-sharing also requires functioning mechanisms for monitoring, supervision, and referral.

The recommendations are applicable in both high- and low-resource settings. They provide for a range of types of health workers who can perform the task safely and effectively. The options are intended to be inclusive and do not imply either a preference for or an exclusion of any particular type of provider. The choice of the type of health worker for a specific task will depend upon local needs and conditions.

LEGEND

Recommende

📿 Considered within typical scope of practice; evidence not assessed

Recommended in specific circumstances

Recommended in the context of rigorous research

★ Recommended against

Considered outside the typical scope of practice; evidence not assessed.

Source: WHO (14).



2.2 Related personas

In addition to the targeted personas detailed in <u>Table 2</u>, there may be value in exploring other cadres and personas within the context of family planning services, such as physicians and lay health workers. However, these were not identified as the central personas for the data and decision-support content detailed in this DAK. Additional personas related to the role of the targeted auxiliary nurse midwife are listed in Table 3.

Table 3. Descriptions of related personas

Name	Description	Different names (if relevant)	ISCO code (if relevant) (21)
Client	A man or woman who intends to receive family planning services from the targeted health worker personas. A client who is under 19 years of age is considered to be an adolescent.	Family planning client	N/A
Lay health worker	Any health worker who performs functions related to health-care delivery, was trained in some way in the context of the intervention, but has received no formal professional or paraprofessional certificate or tertiary education degree (22).	Community health volunteer, village health worker, treatment supporter, promotors, etc.	3259 (Health associate professionals not elsewhere classified)
Community health worker	Community health workers provide: health education, referral and follow-up; case management and basic preventive health care; and home visiting services to specific communities. They provide support and assistance to clients seeking family planning and to their families in navigating the health and social services system (20).	Health extension worker	3253 (Community health workers)
Pharmacist	Often encountered at a retail outlet (e.g. a pharmacy, chemist or drug store), a pharmacist stores, preserves, compounds and dispenses medicinal products, including contraception. They counsel on the proper use and adverse effects of contraception following prescriptions issued by medical doctors and other health-care professionals. Depending on the country policy, prescriptions for contraceptives might not be required and pharmacists are able to dispense contraceptives directly to the client.	Chemist, clinical pharmacist, community pharmacist, hospital pharmacist, retail pharmacist, dispensing chemist	2262 (Pharmacists)
Physician	A legally qualified and licensed practitioner of medicine, concerned with maintaining or restoring human health through the study, diagnosis and treatment of disease and injury, through the science of medicine and the applied practice of that science. A medical doctor requires training in a medical school. Depending on the jurisdiction and on the university providing the training, these may be either undergraduate-entry or graduate-entry courses. Gaining a basic medical degree may take from five to nine years, depending on the jurisdiction and the university providing the training.	Family doctor, general practitioner, medical doctor, specialist doctor (e.g. gynaecologist, obstetrician), non-specialist doctor	2211 (Generalist medical practitioners) 2212 (Specialist medical practitioner)

ISCO: International Standard Classification of Occupations.

2.3 Additional considerations for contextualizing personas

Although this section provides an overview of the generic roles of the targeted personas, it will be important to contextualize these personas to the specific setting. The generic personas described above can be supplemented by reflecting on these additional considerations.

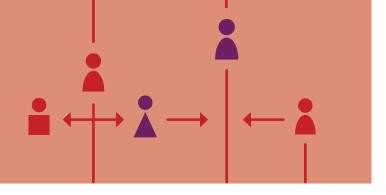
- » **Background and demographics** (e.g. gender, age, whether they are from the community, familiarity with digital devices, do they own a mobile phone/smartphone?).
- **Local environment** and any relevant contextual information about their surroundings (e.g. work-site characteristics; rural or urban; availability of electricity, water, Internet; distance from nearest referral facility).
- » **Expected roles and responsibilities:** What are the expected roles and responsibilities, based on country context? How do these differ from the roles and responsibilities defined by WHO?
- » Actual roles and responsibilities: What are their actual roles and responsibilities, if there is any difference from what is expected?
- » **Context:** What is the level of Internet connectivity? How are they compensated? How far away is the nearest referral facility? What other personas/ health workers do they interact with?
- » Challenges: What are the day-to-day challenges the end-user might face?
- » Motivations: What does success look like to them? Are there targets they need to achieve?

See <u>Annex 1</u> for examples of contextualized personas. For more details on persona development, please refer to the WHO <u>Handbook</u> for digitalizing primary health care (17).



Component

User scenarios



3.1 User scenario for nurse

Key personas

Nurse: Aisha Client: Hope

Hope is a 26-year-old woman who has brought her 6-week-old baby, Mosi, into a primary health care facility for routine immunizations.

While nurse Aisha is providing the immunizations for the child, they begin discussing Hope's future and desire for more children. As she is looking to space out the next birth by more than a year, Aisha suggests they talk more about family planning.

Hope has not yet been registered in the electronic system. So, Aisha sets her up as a new client, gathers her contact and address information, and then provides her with a unique ID number. As Hope has yet to discuss the use of contraception with her husband, she is hesitant to provide her phone number as they sometimes share the phone. Aisha reassures her that the information is kept confidential, and she would only be contacted if she so wishes and can change her preferences at any time. Aisha instructs Hope to have a seat in the waiting area, and Aisha will be over shortly after finishing with a few more child immunizations.

Aisha calls in Hope as she heads into the family planning consultation room. They both sit down at the desk and Aisha gathers a few more details from their earlier conversation. Hope is breastfeeding her firstborn and does not have any other health concerns of note. She is excited about having a larger family, but just is a bit overwhelmed with being a new mother at this point. While they are having the conversation, Aisha checks Hope's blood pressure and finds that it is within the normal range. When asked if she has a method in mind, Hope mentions she has heard about the new injectable contraceptives available and wonders if that would be right for her. Aisha discusses injectables (DMPA), progestogen-only pills (POPs) and intrauterine devices (IUDs). As she is currently breastfeeding Mosi, Hope decides to start with POP and monitor its effects, but she may switch to an injectable in the future.

As Hope is new to the method, Aisha informs her that she can start the pills at any time, and prescribes and provides her with one month's supply of POP and promotes the use of dual protection, asking if she would also like a supply of condoms. Aisha suggests they schedule a follow-up around the time of the next immunization for Mosi in one month, to both review her selection of the POP and provide a full year's supply if needed. Aisha asks if she would like a follow-up reminder to her mobile phone and reassures Hope that no confidential information would be shared, just that she has an appointment scheduled. Aisha asks if Hope has any other concerns or questions.

A few days prior to the scheduled follow-up visit, the system automatically sends out a series of SMS reminders to the clients with appointments who scheduled for the week and have consented to be contacted.

Corresponding business processes (see Component 4)

This scenario refers to the following business processes:

- » Registration
- » Family planning counselling
- » Family planning service provision.

User scenarios

3.2 User scenario for an adolescent

Key personas Nurse/Midwife: Maria

Client: Anna

Registration Clerk: Zeinab

An adolescent girl has come to the clinic with an accompanying person. Zeinab, the female registration clerk who has received training in provision of adolescent-friendly health services, moves her away from the crowd. Once away from the long line of clients, Zeinab asks her the reason for her visit. The young girl opens up to her and says, "I have come to discuss about birth control." She gets to know this girl is a new client. Her name is Anna, and she is 16 years old and unmarried. Zeinab makes sure that the emergency contact number Anna gives the clinic does not belong to her parents or someone who may be judgemental of her. She tells Anna, who looks worried, "Don't worry. All your information in the digital system is password protected, so no one else can access it."

During counselling, the health worker, Maria, interviews Anna using the home, education, activities/employment, drugs, suicidality and sex (HEADSS) assessment. This sheds light on the fact that Anna lives alone, has a boyfriend, and that she is sexually active. She also explains that she has had other boyfriends. Anna makes Maria promise that she will not discuss any of this with her parents. On further probing, Anna tells Maria that she has come for advice as the condom slipped while having sex the previous night. Maria enquires whether she has any history of abnormal vaginal discharge. With Anna's consent, Maria conducts a physical examination. Maria checks Anna's body mass index (BMI), blood pressure, and abdomen for tenderness.

Maria tells Anna about the emergency contraceptive pill and that she should take it as soon as possible, preferably within 72 hours of the incident. However, she also explains that sometimes this may not work, so she would have to check for pregnancy if she misses her period. She discusses other contraceptive methods for long-term use. Anna wants to know whether the three-monthly hormone injection could be a good choice or the copper IUD. Maria explain to Anna that due to her age and the higher dose of hormone (progestogen) released in the intramuscular injectable, using the injectable for a longer period of time (e.g. two years or more) may lower her bone density. Again, as she has had many partners before (which Maria learnt during the HEADSS assessment), she is also prone to sexually transmitted infections (STIs).

Maria explains that combined oral contraceptive pills (COCs) along with condoms – dual protection – is a good choice for protecting her from both pregnancy and STIs. She provides Anna with three months' worth of COCs, and then Maria schedules a follow-up visit after three months to check whether Anna remains comfortable using COCs or whether she would prefer a different method. Anna receives an SMS reminding her of her next visit.

Corresponding business processes (see Component 4)

This scenario refers to the following business processes:

- » Registration
- » Family planning counselling
- » Family planning service provision.



3.3 How to interpret user scenarios for functional requirements

User scenarios are helpful tools not only to better understand the context in which a digital tool would operate, but also for some insights into what key data elements would need to be recorded and accounted for in the database. Additionally, the context in which the tool would operate, illuminated by the user scenarios, provides insight into some functional and non-functional requirements that the system would also need. For example, highlighted in yellow are some key data elements that need to be recorded and/or calculated. Highlighted in blue is some decision-support logic that can be automated in the system. Highlighted in green are some key functional and non-functional requirements that should be included in the system, and bolded are some adolescent-specific considerations that should be accounted for.

For example, the interpretation of the user scenario for an adolescent is shown in Table 4.

Table 4. Interpretation of the adolescent user scenario

Data elements to be collected	Decision logic to be embedded	Functional and non-functional requirements	Adolescent-specific considerations that should be triggered if the client's entered age is 19 years or younger
 » Date of birth » Age » New client or returning client » Marital status » Last menstrual period » Risk factors » Height » Weight 	 Calculation of age based on date of birth Decision logic to trigger certain pop-ups and reminders based on the client's age Calculation of BMI based on weight and height 	 » Password protection » User management (login system) » Pop-up messages (so-called 'toaster messages'and reminders » Information icon for more detailed information and guidance » Recording data for later use 	» Home, education, activities/employment, drugs, suicidality and sex (HEADSS) assessment guidance

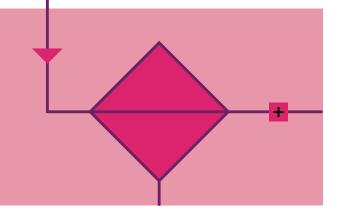
HPV: human papillomavirus.







Business processes and workflows



A business process, or process, is a set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling and referrals (1,16). Workflows are a visual representation of the progression of activities (tasks, events and interactions) that are performed within the business process (16). The workflow provides a story for the business process being diagrammed and is used to enhance communication and collaboration among users, stakeholders and engineers.

This DAK focuses on key business processes conducted by the nurse midwife persona within family planning counselling and service provision. These business processes are described in <u>Table 5</u>. For each of these business processes, the corresponding business processes, data elements and decision-support needs are detailed within the following sections of this document.



Table 5. Overview of key family planning module business processes

	Process name	Process ID	Personas	Objectives	Task set
	Title	ID used to reference this process throughout the DAK	Individuals interacting to complete the process	A concrete statement describing what the process seeks to achieve	The general set of activities performed within the process
Α	Registration	FP.A	» Client» Clerk or health-care provider	To ensure client is located in the system with updated personal details or, if not located, entered into the system to be put into a queue to await counselling	Starting point: Client arrives at facility and checks in with clerk » Search for client record » Review and update client record » Create a new client record
В	Family planning counselling	FP.B	 » Client » Health-care provider (clinician, nurse midwife or community health worker) 	To discuss possible family planning methods with client and for client to select a method that they are medically eligible for	Starting point: Client has been registered at the health-care facility and called in for counselling. Family planning counselling can happen alongside other health services (e.g. nutrition counselling, child immunizations) » Take client history » Conduct a risk assessment » Discuss issues and concerns if a returning client or a client already on a method » Counsel on possible family planning methods and reproductive intentions » Check medical eligibility criteria » Select method » Check stock and skills for delivering method » If facility is not equipped to provide the method, refer
С	Service provision	FP.C	» Client» Health-care provider	To provide the method(s) or service(s) the client requires, if the client is medically eligible for them	Starting point: Client has selected a method and is medically eligible or eligible with clinical judgement » Obtain informed consent » Determine when to start method » Provide method and/or explain how to use method » Discuss dual protection » Determine follow-up requirements and schedule follow-up, if needed

	Process name	Process ID	Personas	Objectives	Task set
D	Referral	FP.D	» Client» Health-care provider	To direct clients to services that are not available within this facility	Starting point: Clinician determined client needs for services that are not available in this facility
			» Referral facility		» Determine whether it is an emergency referral
					» Discuss referral locations
					» Contact destination facility
					» Provide information to destination facility
					» Discuss any questions with client
Е	Aggregate reporting and data use	FP.E	» Facility staff	To aggregate client-level data into validated,	Starting point: Time for periodic (usually monthly)
			» Person in charge of	aggregate reports, use the data, and submit reports at the facility level	reporting
			facility		» Check data quality
			» District health officer/ staff		» Correct fixable errors
					» Generate and review aggregate reports
					» Submit for approval
					» Provide feedback and any changes required

Processes that are a part of family planning service delivery but are not included in this DAK include: configuration, billing, dispensing, and how to follow up (although follow-up visits are part of the family planning counselling workflow). These processes may be required, although it is highly country and context specific. If applicable, the business process could include an insurance or coverage check, which could take place at any one of many points during a family planning visit.

4.1 Overview of key processes

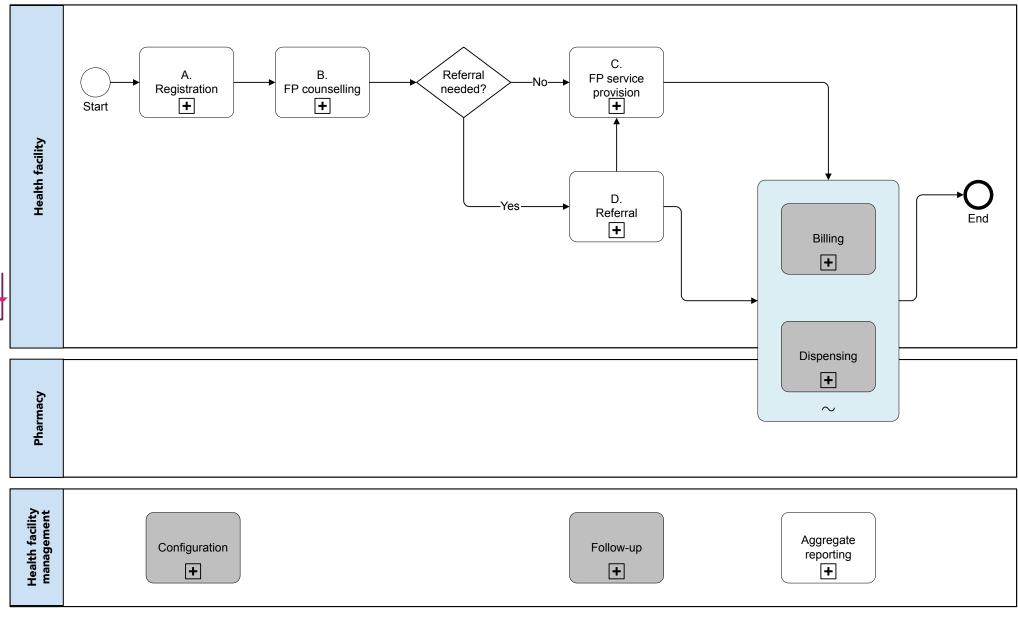
This section illustrates the workflows of the identified processes, using standardized notation for business process mapping. Table 6 first provides an overview of this notation. Fig. 5 provides an overview of key family planning processes.

Table 6. Business process symbols used in workflows

Symbol	Symbol name	Description
Pool Lane 2 Lane 1	Pool	A pool consists of multiple swim lanes that depict all the individuals or types of users that are involved in carrying out the business process or workflow. Diagrams should be clear and neat, and it should be easy for all viewers to understand the relationship across the different swim lanes. For example, a pool would depict the business process of conducting an outreach activity, which involves multiple stakeholders represented by different lanes in that pool.
Pool Lane 3 Lane 1	Swim lane	Each individual or type of user is assigned to a swim lane , a designated area for noting the activities performed or expected by that specific actor. For example, an antenatal care health worker may have one swim lane; the supervisor would be in another swim lane; the clients/patients would be classified in another swim lane.

Symbol	Symbol name	Description
\bigcirc	Start event or Trigger event	The workflow diagram should contain both a start and an end event , defining the beginning and completion of the task, respectively.
0	End event	There can be multiple end events depicted across multiple swim lanes in a business process diagram. However, for diagram clarity, there should only be one end event per swim lane.
	Activity, Process, Step or Task	Each activity should start with a verb, e.g. "Register client", "Calculate risk". Between the start and end of a task, there should be a series of activities noting the successive actions performed by the actor in that swim lane. There can also be subprocesses within each activity.
•	Activity with subprocess	This denotes an activity that has a much longer subprocess to be detailed in another diagram. If the diagram starts to become too complex and unhelpful, the subprocess symbol should be used to reference another process depicted on another page.
	Activity with business rule	This denotes a decision-making activity that requires the business rule, or decision-support logic, to be detailed in a decision-support table. This means that the logic described in the decision-support table will come into play during this activity, as outlined in the business process. This is usually reserved for complex decisions.
	Sequence flow	This denotes the flow direction from one process to the next. The end event should not have any output arrows. All symbols (except start event) may have an unlimited number of input arrows. All symbols (except end event and gateway) should have one, and only one, output arrow. All other symbols should have one output arrow leading to a new symbol or looping back to a previously used symbol or to the end event symbol. Connecting arrows should not intersect (cross) each other.
o>	Message flow	This denotes the flow of data or information from one process to another. This is usually used for when data are shared across swim lanes or stakeholder groups.
	Gateway	This symbol is used to depict a fork, or decision point, in the workflow, which may be a simple binary (e.g. yes/no) filter with two corresponding output arrows or a different set of outputs. There should only be two different outputs that originate from the decision point. If you find yourself needing more than two output or sequence flow arrows, you most likely are trying to depict decision-support logic or a business rule. This should be depicted as an activity with business rule (above) instead.
	Throw – Link	The Throw – Link serves as the start of an off-page connector. It is the end of the process when there is no more room on your page for that workflow. It is the end of a process on your current page or the end of a subprocess that is part of a larger process. There will need to be a Catch – Link that follows the Throw – Link.
	Catch – Link	The Catch – Link serves as the end of an off-page connector. It is the start of the new process on a different page from the Throw – Link or the start of a subprocess that is part of a larger process. There needs to be a Throw – Link that is aligned to the Catch – Link.
~	Ad hoc subprocess	An ad hoc subprocess can contain multiple tasks. One or more tasks in this shape should be performed, and they can be performed in any order. However, not all of these activities need to be finished before moving on to the next activity.

Fig. 5. Overview of key family planning processes^a



FP: family planning.



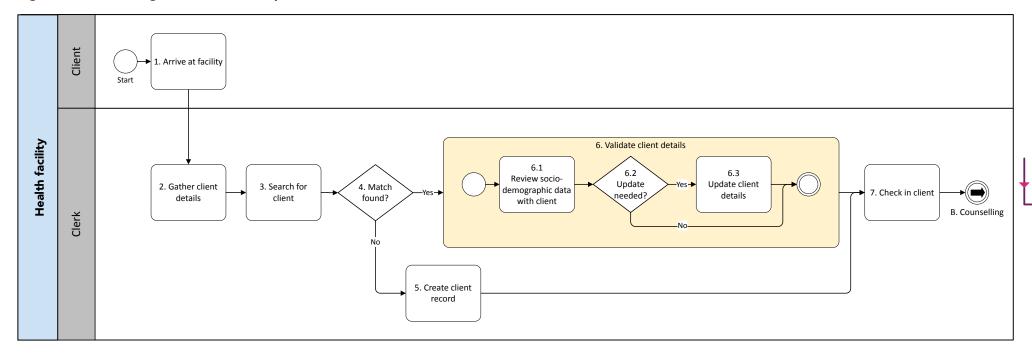
^a For key, see Table 6 (page 28).

4.2 Workflows

A. Business process for registration

Objective: To ensure client is found in the system with up-to-date personal details or, if not located, entered into the system, and is ready for counselling.

Fig. 6. Workflow: Registration business process^a



^a For key, see Table 6 (page 28).

Source: Adapted from PATH (23).

REGISTRATION BUSINESS PROCESS NOTES AND ANNOTATIONS

General note

Registration may be conducted as a stand-alone process by a data clerk/administrative persona ahead of the family planning encounter, or it may be conducted directly by the counsellor as part of the overall family planning encounter.

1. Arrive at facility

- » Client arrives at the health-care facility.
- Client could already be registered at the health-care facility for another service, e.g. a client could be receiving postpartum family planning counselling during an antenatal care visit.

NOTE:

Clients should be directed to an area where auditory privacy can be maintained while gathering client details, so that adults known to them cannot overhear.

2. Gather client details

- » Ask the client whether they have previously been issued a unique ID.
- » Does the client have a card/number/barcode?
- » Does client say they are a returning or a referred client?
- » If a referral, check for referral slip or data from the community.
- » Determine whether the client is new to the health-care facility/health post.
- » For returning clients, details will be retrieved from the registry of clients at this facility or, if possible, from a central client registry.

3. Search for client

» This search process can be done through a variety of means, depending on what mechanisms are available in country. For example, clients can be searched for by using their name, unique ID, a QR code or even biometrics.

4. Match found?

If multiple records are found with no unique ID, provide option to merge records.

5. Create client record

» Issue a unique ID if used and possible at the facility.

6. Validate client details

Review an update client record.

6.1. Review sociodemographic data with client

» Review client's non-clinical information – name, address, contact information, etc.

6.2. Update needed?

» Has the client moved? Have they changed their contact information or has any other sociodemographic information changed?

6.3. Update client details

» Client can provide updated information if they have moved or changed their details recently.

Merge/update client records.

May also happen during counselling process.



For adolescents:

For adolescents, a few special things need to be noted here.

- » Is the adolescent married?
- » Is there an accompanying adult (e.g. parent, family member)?
- » Does the accompanying adult know the reason of their visit?
- » Can information about them be shared with the accompanying adult or their parents later?
- » Any emergency contact number the adolescent provides apart from their own mobile phone should belong to someone the client is comfortable the clinic discussing their condition with, if required.
- » Have there been any recent changes in the adolescent's home situation?
- » How does the adolescent feel at home?

7. Check in client

- » Record client's updated details in the client registry.
- » Add client to the relevant queue for counselling services.
- » Send/share intake confirmation to/with referring facility, as warranted.

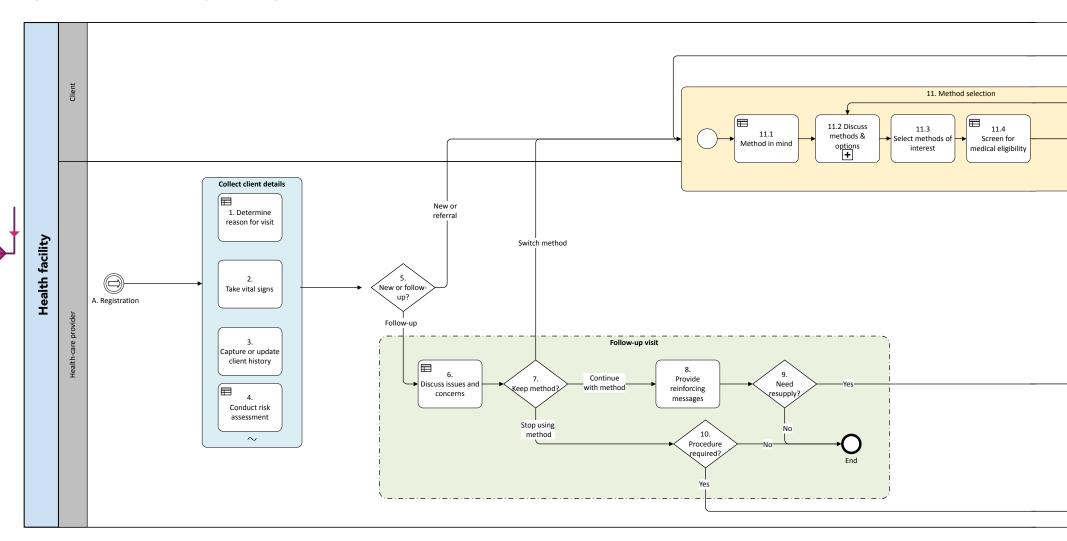
8. Counselling

» After a client is registered, move on to the counselling workflow.

B. Business process for counselling

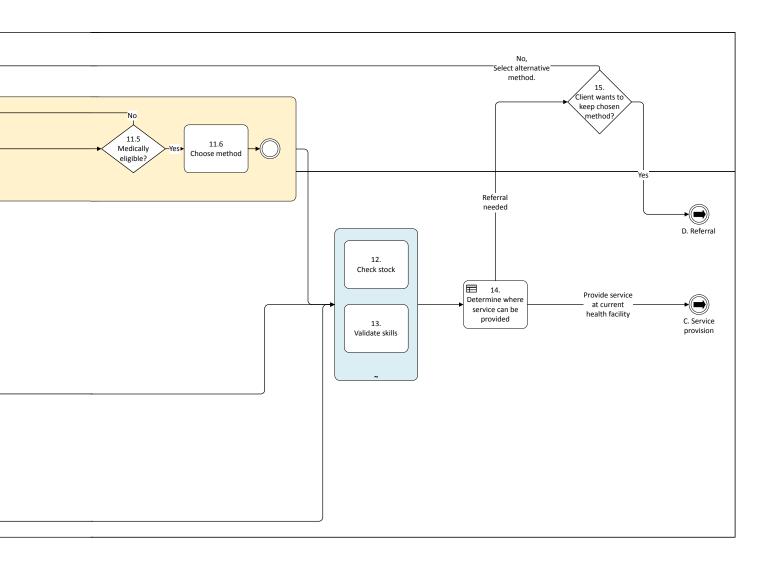
Objective: To provide client with advice and consultation services, and to decide on a course of action.

Fig. 7. Workflow: Counselling business process^a



^a For key, see Table 6 (page 28).





COUNSELLING BUSINESS PROCESS NOTES AND ANNOTATIONS

General notes

For adolescents:

- » Establish rapport with the adolescent.
- » If accompanied by an adult, explain that the adult may need to step out.
- » Ask non-threatening questions.
- » Conduct HEADSS assessment throughout the counselling process.

Counselling should happen in a private place.

Group information sharing may happen in the waiting room before counselling.

The essential elements of counselling reminders that can be built into your tool as counselling tips include reminders to explain the following.

- » What is the method?
- » How does the method work?
- » How effective is the method?
- » How is the method used? / When do you take the method?
- » What are possible side-effects from the method? / What are possible adverse events from the method?
- » What are the method's other benefits?
- » Is the method compatible with breastfeeding?
- » Does the method protect against STIs and HIV/AIDS?

Guidelines and guidance:

- » Selected practice recommendations for contraceptive use (13)
- » Family planning: a global handbook for providers "Successful counseling", page 370 (14)

» Family planning/contraception methods fact sheet (24).

1. Determine reason for visit

- Search for client details in the system and determine reason for visit.
- » Decision-support table to guide workflow:
 - FP.DT.01 "Reason for visit".

Note: Steps 2, 3, 4 and 5 may occur in parallel. Not all steps may be completed.

2. Take vital signs

- » Vital signs, e.g. blood pressure and weight, may be taken and recorded.
- » Additional physical information might need to be taken as part of the method selection.

3. Capture or update client history

- » Discuss medical history with client and review available records.
- » Include an investigation of contraceptive history, i.e. past methods used.

4. Conduct risk assessment

- » Not required but may be done, depending on the national policies and existing support systems, and at the health worker's discretion.
- » Some risk assessments that can be conducted include determining whether a client has a high risk of STI and whether they have been subjected to intimate partner or sexual violence.
- » Possible risk assessments to be included:
 - FP.DT.03 "STI risk assessment"
 - FP.DT.04 "Intimate partner violence (IPV) assessment and first-line support".
 - Provide general sexual and reproductive health education.



For adolescents:

For female adolescents it is mandatory to assess the risk of pregnancy. If there is a risk, the contraceptive method provided should be something they are able to control. The HEADSS assessment can help with this.

5. New or follow-up?

» Based on reason for visit, determine the counseling and services needed.

6. Discuss issues and concerns

- » Investigate problems, such as side-effects the client is experiencing or has concerns about.
- » Additional tests or even referral may be required for this, depending on the complexity and seriousness of the health condition.
- » Guidelines and guidance:
 - Selected practice recommendations for contraceptive use (13)
 - Family planning: a global handbook for providers "Managing any problems: problems reported as side effects", "New problems that may require switching methods" and "Helping continuing users" (14).

7. Keep method?

- » Is the client satisfied with the method being used?
- » Does the client want to continue using their current method?
- » Does the client want to switch to a different contraceptive method?
- » Or does the client want to stop using contraceptive methods completely?

8. Provide reinforcing messages

» Provide reinforcing messages regarding the client's method of choice.

9. Need resupply?

» Does the client need a resupply to continue with their method?

10.ls a procedure required?

Is a procedure required for the client to continue using the method, to stop using the method, or to switch methods? For example, not all providers may be able to provide or remove certain methods, such as implants and IUDs.

Counselling has succeeded when:

- » Client feels they received the help they wanted
- » Client knows what to do and feels confident that they can do it
- » Client feels respected and appreciated
- » Client comes back when they need to
- » Client uses their methods effectively and with satisfaction.

11. Method selection

11.1. Method in mind

- » Discuss whether the client has a method in mind.
- » Decision-support table to guide counselling:
 - FP.DT.06 "Method in mind".
- » Regardless of the answer, move on to 11.2 "Discuss methods and options".

11.2. Discuss methods and options

- » If the client had a method in mind, check:
 - If the method suits the client's needs and preferences
 - The client's understanding of the method and whether they need more information; if the client's answers suggest misunderstanding or incorrect information, discuss the method and ensure clear understanding.

- » If the client has no method in mind, discuss possible methods based on client's needs/preferences and review method options.
- The health-care provider should provide client education and inform the client of what the method is, how effective it is, how to use it properly, when to start, what to remember when using the method, possible side-effects and how to manage them, possible health risks and health benefits, correct misunderstandings, explain how certain methods compare with other methods, and more. Additional information can be found in:
 - Family planning: a global handbook for providers (14)
 - Decision-making tool for family planning clients and providers (25).

11.3. Select methods of interest

» Support client in making an informed choice.

11.4. Screen for medical eligibility

- » Check client's medical eligibility for method of interest.
- » This may require additional laboratory testing, depending on the complexity of the health condition and the method.
- » Decisions to be made:
 - FP.DT.08 "Medical eligibility criteria (MEC)".
- » Guidelines and guidance:
 - Medical eligibility criteria for contraceptive use (12)
 - Family planning: a global handbook for providers "Using clinical judgement in special cases" (14)
 - Selected practice recommendations for contraceptive use (13).

11.5. Medically eligible?

- » Depending on the results of FP.DT.08, the client may or may not be medically eligible for a method.
- » If the client is not medically eligible for that selected method, continue counselling and provide alternative options for contraceptive methods.

For adolescents:

- » In general, adolescents are eligible to use any contraceptive method and must have access to a variety of contraceptive choices.
- Age alone does not constitute a medical reason for denying any contraceptive method to adolescents.
- » Also consider asking, "Do you smoke, consume alcohol or take recreational drugs on a regular basis?"

11.6. Choose method

- » Once the client has received enough counselling, and medical eligibility has been determined, the client decides on their method of choice.
- » The method of choice is the contraceptive method that the client chooses based on their contraceptive preferences and their medical eligibility.

12.Check stock

- » Does the facility have the necessary supplies to provide the chosen method?
- » Is the method in stock?
- » Are the related supplies required to provide the method (e.g. forceps, speculum, gloves) in stock?

13. Validate skills

- » Are there health workers at the facility who are trained to provide the selected method (e.g. IUD insertion) or service (e.g. IUD removal)?
- » Is provision of this method within the roles and responsibilities of the nurse midwife?

14. Determine where service can be provided

- Depending on the availability of stock and the skills of the health-care provider, determine whether the method or service can be provided on site or a referral is needed:
 - FP.DT.09 "Where services can be provided".



15. Client wants to keep chosen method?

- » If the method is not in stock, regardless of the health-care provider's skillset, the client can decide to choose an alternative method.
- » If the health-care provider does not have the skillset to provide that method, then the client can decide to choose an alternative method.
- » However, if the client does not want to choose an alternative method, then refer to another facility or schedule follow-up visit.

16. Service provision

» If the method is in stock and the health-care provider has the skill to provide that method, then move to service delivery workflow.

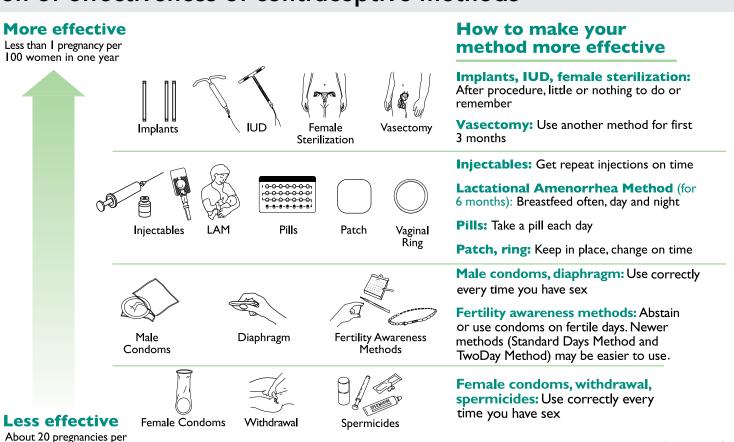
17.Referral

» If the client is not able to receive the chosen method at the current health-care facility, and the client does not want to choose an alternative method, then refer them to another facility.

FIG. 8

Source: WHO/RHR and CCP (14).

Comparison of effectiveness of contraceptive methods

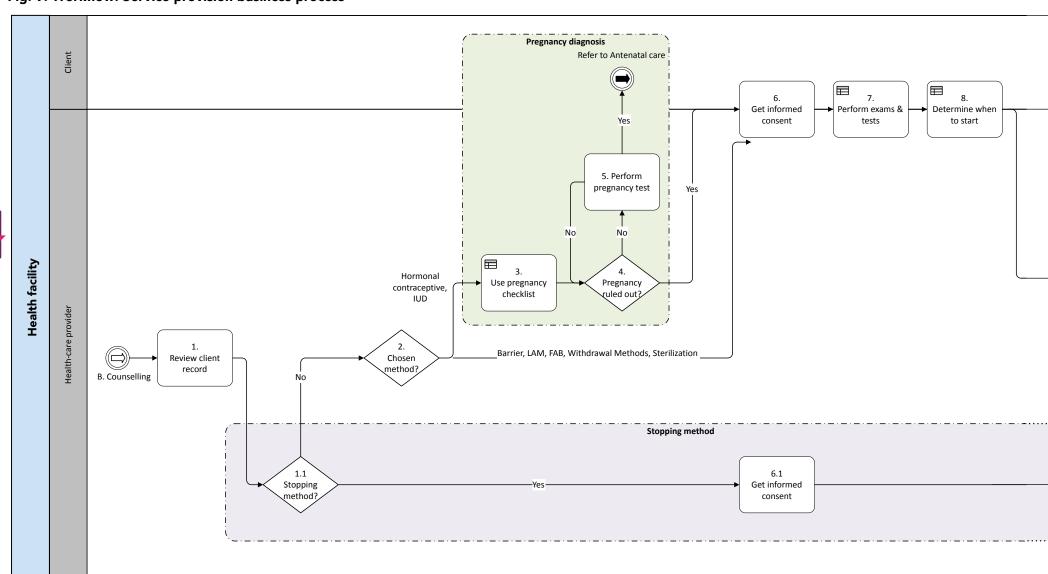


100 women in one year

C. Business process for service provision

Objective: To provide services, with instruction and methods, if the client is medically eligible for them.

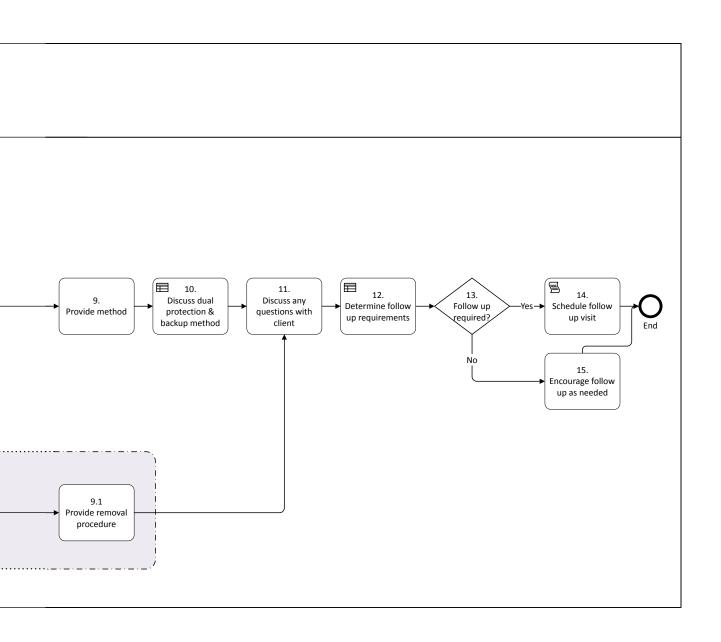
Fig. 9. Workflow: Service provision business process^a



FAB: fertility awareness-based method; IUD: intrauterine device; LAM: lactational amenorrhoea method.



^a For key, see Table 6 (page 28).



SERVICE PROVISION BUSINESS PROCESS NOTES AND ANNOTATIONS

General notes

Depending on where the client received counselling, the client could receive service provision at the same time, in the same place. The client could also receive services at a referral facility. Alternatively, service provision could also happen at the same place of counselling, but at a later date.

1. Review client record

» Search for client details in the system and review the client's record, including medically eligibility.

1.1 Stopping method?

If the client is stopping the method (e.g. having the IUD or implant removed) go straight to 6.1 "Get informed consent" and 9.1 "Provide removal procedure".

2. Chosen method?

» Depending on the chosen method, the health-care provider must first determine whether the client is not pregnant – through the use of the pregnancy checklist, or, if needed, a pregnancy test.

3. Use pregnancy checklist

- » The pregnancy checklist is needed for clients starting hormonal contraceptives and/or an IUD.
- » Decision-support logic to calculate pregnancy status:
 - FP.DT.10 "Pregnancy checklist".

4. Pregnancy ruled out?

- » If pregnancy can be ruled out using the pregnancy checklist, move on to 6 "Get informed consent".
- » If pregnancy cannot be ruled out, perform a pregnancy test (step 5).

5. Perform a pregnancy test

- » Depending on the sensitivity of the pregnancy test, a follow-up visit may be required.
- » Guidelines and guidance:
 - Family planning: a global handbook for providers "Pregnancy checklist" (14).

6. Get informed consent

- » Special counselling may be required.
- » Local policies and requirements for informed consent should be used here.

7. Perform examinations and tests

- » Depending on the method, some additional examinations and tests would be needed to determine whether or not the client would be able to receive the method and/or determine when the most appropriate time would be to start the method. Alternatively, some examinations and tests are done to ensure safety of method provision.
- » The examinations or tests that are considered for each type of contraceptive apply to persons who are presumed to be healthy. Those with known medical problems or other special conditions may need additional examinations or tests.
- Whether the exam or test could be done needs to also be evaluated. For example, if the health-care facility does not have a means to conduct a haemoglobin test, then a haemoglobin test may not be required and its absence should not be used to prevent a client from receiving contraceptive methods.
- » Decision-support logic to determine whether exams and/or tests are needed:
 - FP.DT.11 "Examinations and tests".



8. Determine when to start

- » Decision-support logic to determine when to start, based on method and health condition:
 - FP.DT.12 "When to start".

9. Provide method

- » Explain to the user how the method works; discuss how to use the method, when to start, and how to recognize and cope with any side-effects. Also, certain methods, such as subcutaneous depot medroxyprogesterone acetate (DMPA-SC), may require guided training if being self-administered (26).
- » In the case of long-acting and permanent methods, a procedure will be performed.
- » Guidelines and guidance:
 - Selected practice recommendations for contraceptive use (13)
 - Family planning: a global handbook for providers (14).
- » Certain methods, such as IUDs and implants, may require an in-clinic observation and rest period.

10. Discuss dual protection

- » Promote dual protection to prevent STIs, reproductive tract infection and pregnancy.
- » Decision-support logic to determine if back-up method is needed:
 - FP.DT.13 "Back-up method".
- » If a back-up method is needed, the user should use condoms or abstain from sex for the recommended number of days.
- Where appropriate, provide condoms, promote use of condoms, and counsel about reducing number of partners or delaying sexual activity to reduce STI risk.

For adolescents:

It is especially important for adolescents to receive appropriate counselling on dual protection for prevention of STIs.

11. Discuss any questions with client

- » Provide reinforcing messages.
- » For a method a client plans to self-administer, ensure client has received guidance and knows that they can come back at any time.
- » Where appropriate, recommend referral to other services (e.g. STI or HPV screening).
- » Guidelines and guidance:
 - Family planning: a global handbook for providers "'Come back any time': reasons to return" (14).

12. Determine follow-up requirements

- Although clients are encouraged to come back at any time, some methods require more regular follow-up.
- » Follow-up decision-support logic:
 - FP.DT.14 "Follow-up requirements"
 - FP.S.1 "Schedule follow-up visit".
- » Guidelines and guidance:
 - Selected practice recommendations for contraceptive use (13)
 - Family planning: a global handbook for providers (14).
- » Update client's digital record.
- » Update blue card or book, if used in the country. Information written in the book should consider privacy needs.

DATA

13. Follow-up required?

- » If follow-up is required, schedule follow-up.
- » If follow-up is not required, encourage follow-up as needed.

14. Schedule follow-up

- » Explain importance of follow-up.
- » If client consents to being contacted, confirm client's contact data and set to allow follow-up.
- » Guidelines and guidance:
 - Family planning: a global handbook for providers "'Come back any time': reasons to return" (14).

15. Encourage follow-up as needed

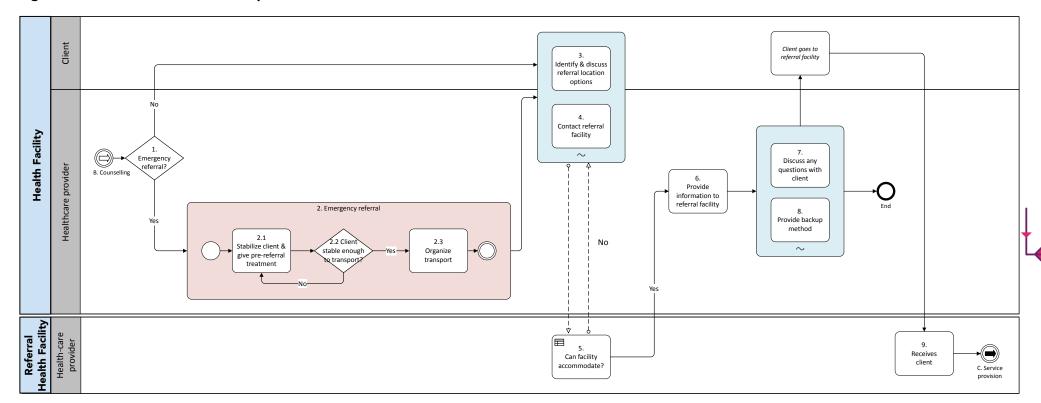
- » Although a routine follow-up might not be needed for the client's chosen method, the health-care provider should state that the client is welcome back at any time to discuss any side-effects or complications, if they want to change methods, and/or if she thinks she is pregnant.
- Where appropriate, recommend referral to other services (e.g. STI or HIV screening).
- » Guidelines and guidance:
 - Family planning: a global handbook for providers "'Come back any time': reasons to return" (14).



D. Business process for referral

Objective: To direct clients to services they need which are not available at this point of service.

Fig. 10. Workflow: Referral business process^a



^a For key, see Table 6 (page 28).

DATA

REFERRAL PROCESS NOTES AND ANNOTATIONS

General notes

Examples of reasons why a referral may be needed include:

- » Health worker cannot provide the method due to lack of training and skills
- Facility does not have method in stock or supplies needed to provide method in stock
- » The facility cannot perform the service for some reason
- » There is an emergency, and the client needs immediate referral.

1. Emergency referral?

- » If client needs an immediate referral due to an emergency situation, bypass standard referral steps.
- » In the case of an emergency, a referral can be made at any time, including during registration, counselling or service provision.

2. Emergency referral

2.1 Stabilize client and give prereferral treatment

» The client is assumed to need emergency referral if their condition requires immediate medical attention. Thus, stabilize the client's condition and provide any necessary treatment.

2.2 Client stable enough to transport?

- » Once the client is stable enough to transport, then immediately transport.
- » If the client is still not stable, provide prereferral treatment for stabilization.

2.3 Organize transport

- » Organize emergency transport for the client.
- » For emergency referrals, the health-care facility arranges transport, usually by phoning for an ambulance or other vehicle.

3. Identify and discuss referral location options

- » In discussion with the client and their relatives, decide on where the client will be referred. Discussions include:
 - How to get to the referral facility, including location and transportation options
 - Who to see and what is likely to happen
 - Follow-up on return, if needed.
- » If there are various possible referral facilities, either the client or their relatives should indicate their and referred referral location.

4. Contact referral facility

» Health workers should contact the referral facility to determine whether that facility can accommodate such a referral.

5. Can facility accommodate?

- » Check whether the facility can accommodate the client and provide the services they need.
- » If the facility can accommodate the client, move on to step 6 "Provide information to referral facility".
- » Otherwise, find a different facility that is able to accommodate the client.
- » A system can be set up to validate that a facility has both supplies and skills to accommodate the client.

6. Provide information to referral facility

- » Make appointment, if necessary.
- » Client or family arranges own transport.
- » For emergency referrals, the health-care facility arranges transport usually by phoning for an ambulance or other vehicle.
- » Complete referral form, which can include notification of the referral destination.



- Provide the necessary clinical, sociodemographic and identity information to the referral facility.
- » This can be done digitally if the appropriate systems are in place.

7. Discuss any questions with client

» Discuss any questions or concerns the client may have.

For adolescents:

If an unaccompanied adolescent needs a referral, ensure that a responsible adult is sent as an accompanying person.

8. Provide back-up method and discuss dual protection

» Provide back-up method based on chosen method and initiation date as well as discussing dual protection with condoms.

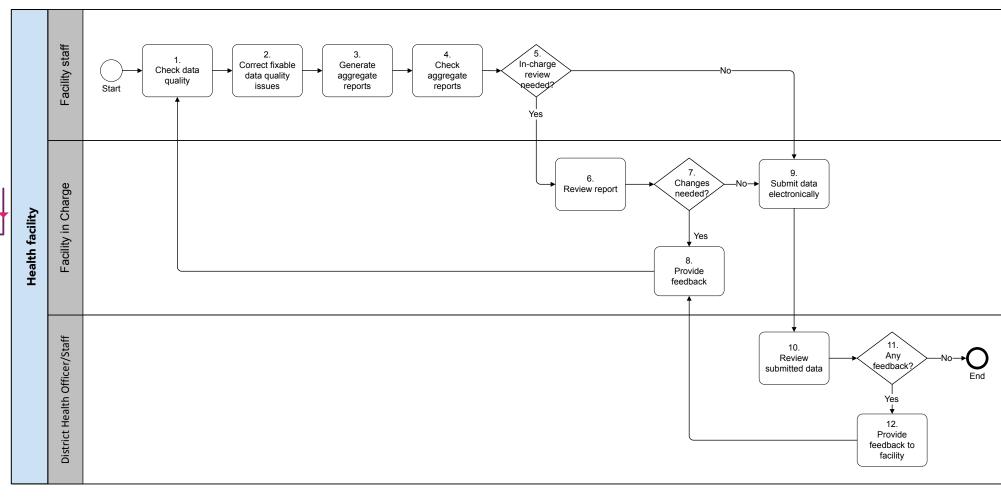
9. Receipt of client

- » Referral facility receives client along with all the necessary clinical, sociodemographic and identification information.
- » Once the referral facility receives the client, move to provide services at the receiving referral facility (C. Business process for service provision).

E. Business process for aggregate reporting and data use

Objective: To aggregate client-level data into validated, aggregate reports, use the data and submit reports.

Fig. 11. Workflow: Aggregate reporting business process^a



^a For key, see Table 6 (page 28).



REPORTING AND DATA USE BUSINESS PROCESS NOTES AND ANNOTATIONS

1. Check data

- » Health-care facility reviews accuracy, validity and completeness of data in system.
- » This can be automated and done digitally.

2. Correct fixable data quality issues

» Depending on local policy this step might not be required.

3. Generate aggregate reports

» This can be automated and done digitally.

4. Check aggregate reports

» Depending on local policy this step might not be required.

5. Facility supervisor/in-charge review needed?

- » Determine whether the report needs to be reviewed by the person in charge of the facility.
- » Some facility in-charges do not review reports.

6. Review report

- » The reports are reviewed by person in charge.
- » This can be done digitally.

7. Changes needed?

» Determine whether the report is accurate or has any issues.

8. Provide feedback

- If there is any issue with the report, the person in charge will provide feedback for the responsible person to make corrections to client-level data.
- » This can be done digitally.

9. Submit data electronically

- » Reports and data may be used by the facility at multiple points during the business process, such as here, earlier in the process or outside the business process.
- » This can be automated and done digitally.
- » Depending on the local policies, an active submission may not be needed, and the district-, provincial- and national-level MOH would be able to access data directly for reporting purposes.

10. Review submitted data

Use data in report to review progress and make decisions on improvements and actions to take.

11. Any feedback?

» Determine whether there is any feedback after review of the data.

12. Provide feedback to facility

» If there is any feedback, the focal person will provide the feedback to the facility. If there are errors, the facility may be required to restart the process and resubmit.

4.3 Additional considerations for adapting workflows

As a reminder, these workflows are meant to be generic and high level. They will require a level of customization and adaptation as they are being translated into a digital system for a specific context. These workflows are considered to be 80% complete, whereby the other 20% will need to be done through a series of human-centred design methods and mechanisms to complete the workflows for an implementation. For example, there might be additional workflows that need to be drawn out, or there might be additional activities expected of a health worker in the facility. Some workflows are not included due to the high level of contextualization required, including: billing, dispensing (if separate from service provision), configuration (of facility-level specifics) and follow-up (which can be automated). Alternatively, there might be some activities and tasks a health worker would not be expected to do. Although these workflows can be considered as a starting point, it is helpful to conduct further validation through interviews with the targeted personas or shadowing their work to obtain a better sense of the differences that would need to be reflected in the digital system.



Core data elements

This section outlines the minimum set of data corresponding to different points of the workflow within the identified business processes. This data set can be used on any software system and lists the data elements relevant for service delivery and executing decision-support logic, as well as for populating indicators and performance metrics. Although this section provides a high-level overview of the data elements, a more complete data dictionary in spreadsheet form detailing the input options, validation checks and concept dictionary codes is available in *Web Annex A*.

Inclusion of a data element in the table does not by itself indicate that collection of the data is required. Additionally, some data elements are dependent on other data elements (e.g. test results are only entered when a test has been performed). Collection of data should not prevent clients from accepting a contraceptive method or affect clinical care. This will require review and adaptation.

5.1 Simplified list of core data elements

<u>Table 7</u> provides a simplified list of core data elements and is merely a snapshot of the comprehensive data dictionary found in <u>Web Annex A</u>. As with the workflows, we view this data dictionary as 80% generic, with the expectation that the other 20% will be supplemented and modified through country adaptation.

Table 7. Workflow core data elements for identified business processes

Activity ID. Activity name	Data element ID	Data element name	Description and definition			
Business process FP.A: R	Business process FP.A: Registration					
FP.A1. Arrive at facility	N/A – No data is recorded during this activity					
FP.A2.	FP.A.DE1	Visit date	The date and time of the client's visit			
Gather client details	FP.A.DE2	Administrative Area	This should be a context-specific list of administrative areas – villages, districts, etc. to allow for grouping and flagging of client data to a particular facility's catchment area.			
	FP.A.DE3-6	Referral	If client was referred for care			
	FP.A.DE7	Unique identification	Unique identifier generated for new clients or a universal ID, if used in the country			
	FP.A.DE8	First name	Client's first name			
	FP.A.DE9	Last name	Client's family name or last name			
	FP.A.DE10	Date of birth	The client's date of birth (DOB), if known			
	FP.A.DE11-15	Age	Age (number of years) of the client calculated based on the DOB; if DOB is unknown, enter the client's estimated age			
	FP.A.DE16-19	Sex	Sex of the client			
	FP.A.DE20	Address	Client's home address or address that the client is consenting to disclose			
	FP.A.DE21-32	Marital Status	Client's current marital status			
	FP.A.DE33-39	Co-habitants	Who the client lives with (e.g. parents, other family members, partner, friends, no one)			
	FP.A.DE40-45	Highest level of education achieved	The highest level of education the client has reached			
	FP.A.DE46-52	Occupation	The client's primary occupation			
	FP.A.DE53-55	Mobile phone number	Mobile phone number (and consent for being contacted)			
	FP.A.DE56-63	Communication preferences	How the client would like to receive family planning communications			
	FP.A.DE64-68	FP.A.DE64-68 Payment How will the client pay for health services and commodities				
FP.A3. Search for clients	N/A – No data is recorded during this activity, can be based off previous activity FP.A2.Gather client details					
FP.A4. Match found	N/A – No data is	N/A – No data is recorded during this activity, can be based off previous activity FP.A2.Gather client details				
FP.A5. Create client record	N/A – No data is recorded during this activity, can be based off previous activity FP.A2.Gather client details					



Activity ID. Activity name	Data element ID	Data element name	Description and definition		
FP.A6. Validate client details	N/A – No data is	N/A – No data is recorded during this activity, can be based off previous activity FP.A2.Gather client details			
FP.A7. Check in client	N/A – No data is	N/A – No data is recorded during this activity, can be based off previous activity FP.A2.Gather client details			
Business process FP.B: Co	unselling				
FP.B1.	FP.B.DE1-11	Reason for visit	Establish reason for visit		
Determine reason for visit	FP.B.DE12-15	Reason for stopping contraception or method	If stopping a method, the reason why		
	FP.B.DE16-19	Pregnancy intention	Client's intention or desire in the next year is either to become pregnant or to prevent a future pregnancy		
FP.B2.	FP.B.DE20-22	Height/weight	Client's current height in centimetres and weight in kilograms		
Take vital signs	FP.B.DE23-25	Blood pressure	Client's blood pressure, if possible, to be taken		
FP.B3.	FP.B.DE26-29	Sexual history	If the client has been or is sexually active and days since unprotected sex		
Capture or update client history	FP.B.DE30-35	Pregnancy history	The number of pregnancies (gravidity), current and past, regardless of pregnancy outcome, number of pregnancies reaching parity, and time postpartum		
	FP.B.DE36-40	Breastfeeding status	The client's breastfeeding status		
	FP.B.DE41-46	Miscarriage or abortion stage of pregnancy	If the woman recently had a miscarriage or abortion, stage of pregnancy when the abortion took place		
	FP.B.DE47-50	Start date of last normal menses	The date when the client had her first day of her last normal menses		
	FP.B.DE51-78	Method at intake	Family planning method the client reports currently using at intake		
	FP.B.DE79-82	Date method administered	Date of IUD insertion, implant, injection, or sterilization—as appropriate		
	FP.B.DE83-104	Reason for no contraceptive method	If client is not currently using a method, the reason should be recorded		
	FP.B.DE105-132	Methods previously used	Record all the contraceptive methods the client has a history of using		
FP.B4. Conduct risk assessment	FP.B.DE133-148	STI risk assessment	Whether or not an assessment was conducted to determine if the client is at high risk of sexually transmitted infections (STIs)		
See decision-support tables	in Component 6 a	nd Web Annex C.			
FP.B6. Discuss issues and concerns	FP.B.DE149-208	Issues and concerns	Side-effects or symptoms with current method, administration, missed pills and late injections		

Core data elements

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System-generated medical eligibility value for numerical ratings based on medical eligibility criteria (MEC) decision-support logic	
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Activity ID.	Data element	Data element name	Description and definition	
Activity name	ID			
FP.C6. Get informed consent	FP.C.DE12	Informed consent	Does the client give informed consent to receiving the services?	
FP.C7. Perform exams and tests	FP.C.DE13-16	Exams and tests performed	Whether a pelvic/genital examination and STI/HIV laboratory tests were conducted, if needed	
FP.C9. Provide method	FP.C.DE17-46	Method or service provided	Contraceptive method that was provided to the client; including supplies, and whether she was told/shown how to use the method?	
	FP.C.DE47-53	Reason for no method at exit	Reason for no contraceptive method use reported at exit (as the client leaves the health service provider)	
	FP.C.DE54-59	Reason client did not receive chosen method	If the client had a chosen method, but was not able to receive that chosen method, the reason should be documented here	
FP.C10. Discuss dual protection and back-up method	FP.C.DE60-67	Back-up method needed	Whether a back-up method is advised given client history, choice of primary method and start date of primary method	
FP.C11. Discuss any questions with client	N/A – No data is recorded during this activity			
FP.C12. Determine follow-up requirements	FP.C.DE68 Follow-up recommended Whether a follow-up appointment is recommended		Whether a follow-up appointment is recommended	
FP.C13. Determine follow-up requirements	FP.C.DE69	FP.C.DE69 Recommended follow-up date Date when follow up is recommended based on follow-up requirements		
Business process FP.D: Re	ferral			
FP.D1. Emergency referral?		Emergency referral	Whether the referral is for urgent care	
FP.D2. Emergency referral	N/A – No data is recorded during this activity			
FP.D3. Identify and discuss referral local and options	N/A – No data is recorded during this activity			
FP.D4. Contact referral facility	N/A – No data is	recorded during this activ	ity	
FP.D5. Can facility accommodate?	N/A – No data is recorded during this activity			

Core data elements

Activity ID. Activity name	Data element ID	Data element name	Description and definition	
FP.D6.	FP.D.DE2-5	Reason for referral	Reason why the client is being referred; if diagnosed, this may include the diagnosis	
Provide information to referral facility	FP.D.DE6-8	Date of scheduled referral and location	When the referral is scheduled and where the client is being referred to	
	FP.D.DE9-11	Provider who made referral	The name of the provider who made the referral	
	FP.D.DE12-13	Referral notes	Any additional relevant details of clinical significance for the referral facility to provide continuity of care	
FP.D7. Discuss any questions with client	N/A – No data is recorded during this activity			
FP.D8. Provide back-up method	N/A – No data is recorded during this activity			
FP.D9. Receives client	N/A – No data is recorded during this activity			

5.2 List of calculated data elements

The section above outlines the core data elements that should be included within digital systems to facilitate the decision-support logic or indicators. There are additional derived data elements that are based on calculations from core data elements.

Table 8. Calculated data elements

Calculated data element label	Core data elements used for calculation (i.e. the variables)	Calculation
Body mass index (BMI)	Body weight Height	"Body weight (kg)"/[("Height (cm)"/100)^2]
Postpartum	Date of delivery Visit date	IF "Visit date" – "Date of delivery" ≤ 6 weeks, THEN "Postpartum" = TRUE
Recent miscarriage or abortion	Date of miscarriage or abortion Visit date	IF "Visit date" – "Date of miscarriage or abortion" ≤ 4 weeks, THEN "Recent miscarriage or post-abortion" = TRUE



5.3 Additional considerations for adapting the data dictionary

Some settings may require the inclusion of additional data elements into the full data set or changes to response options based on contextual differences. Additionally, the transition from paper-based forms to digital systems may require some reflection on whether data elements currently on the paper forms should be incorporated into the digital system. Table 9 is an initial list of considerations anticipated for each implementation to review and customize based on the national guidelines and local context.

Table 9. Characteristics for local customization and configuration

Points of customization	Description
and configuration	
Unique ID	Unique ID of the client can be based on a national unique ID, a national health ID, biometrics, a system-generated unique ID or something else.
Services provided	Services provided at the facility. These workflows primarily focus on family planning services. However, other services and linkages to them likely need to be included as well, e.g. STI testing, antenatal care, postnatal care.
Counselling provided	Beyond the counselling provided for family planning services, there might be other counselling mechanisms that are built in. This could include, but is not limited to, other reproductive health counselling, nutrition counselling and HIV counselling. In some contexts, counselling for family planning is also conducted in a group setting. This would also affect the workflows that should be considered in the digital tracking and decision-support system.
Methods provided	List of methods available in the country, with further customization of list of methods available at the facility.
Facility ID	Unique ID of the facility. A reference to a facility registry or a reporting system (e.g. DHIS2) should be included where possible.
Facility name	Name of the different health-care facilities, based on a facility registry or a reporting system (e.g. DHIS2), should be included where possible.
Ownership	Denoting whether the facility is public or private, where relevant.
Type of health-care facility	Type of facility, based on country terminology (e.g. health centre, health post, dispensary, hospital).
GPS coordinates	Latitude and longitude coordinates can be included if relevant for mapping purposes. This can be helpful, especially in the context of community health workers who could be given family planning tasks based on their catchment area and client's visit history.
Administrative areas	Administrative areas can be based on geographic location, catchment area or another mechanism the country uses for managing health-care facilities.
Catchment population	If known, the catchment population would be useful to include in automated calculation of indicators.
Lab tests available	Whether or not certain lab tests (e.g. haemoglobin tests, STI/HIV screening, blood pressure measurement, other rapid diagnostic tests) were available at the health-care facility could impact the health worker's workflow as well as the client's family planning service experience.
Sensitivity of pregnancy test	Depending on the pregnancy tests that are procured at the national level and those that are available at the health-care facility, the sensitivity of the pregnancy test could affect the follow-up scheduling and workflow. The guidance provided regarding sensitivity of pregnancy test is as follows.
	While determining if a woman is not pregnant: "if using a highly sensitive pregnancy test (e.g. 25 mIU/ml) and it is negative, provide her desired method. If using a test with lower sensitivity (e.g. 50 mIU/ml) and it is negative during the time of her missed period, wait until at least 10 days after expected date of menses and repeat the test. Advise the woman to use condoms or abstain in the meantime. If the test is still negative, provide her desired method. If test sensitivity is not specified, assume lower sensitivity" (14).

Core data elements



The decision-support logic component of the DAK provides the decision logic and algorithms, as well as the scheduling of services, in accordance with WHO guidelines. In this DAK, the decision logic and algorithms deconstruct the recommendations within the family planning guidelines and guidance into a format that clearly labels the inputs and outputs that would be operationalized in a digital decision-support system.

6.1 Decision-support logic overview

<u>Table 10</u> provides an overview of the decision-support tables and algorithms for the different family planning module business processes. The structure of the decision-support tables is based on an adaptation of the Decision Model and Notation (DMN), an industry standard for modelling and executing decision logic (27). These decision-support tables detail the business rules, data inputs and outputs to support family planning module business processes.



Table 10. Overview of decision-support tables for family planning module

Activity ID. Activity name	Decision- support table ID	Decision-support table description	Reference/source	
FP.B1. Determine reason for visit	FP.DT.01	Reason for visit	» Family planning: a global handbook for providers (2018) (14)	
FP.B4. Conduct risk assessment	FP.DT.02	HEADSS assessment for adolescents	 Adolescent job aid (2010) (28) WHO recommendations on adolescent sexual and reproductive health and rights (2018) (29) 	
FP.B4. Conduct risk assessment	FP.DT.03	STI risk assessment	» Family planning: a global handbook for providers (2018) (14)	
FP.B4. Conduct risk assessment	FP.DT.04	Intimate partner violence (IPV) assessment and first-line support	 Health care for women subjected to intimate partner violence or sexual violence: a clinical handbook (2014) (30) Responding to intimate partner violence and sexual violence against women (2013) (31) Family planning: a global handbook for providers (2018) (14) 	
FP.B6. Discuss issues and concerns	FP.DT.05	Issues and concerns related to methods	 Selected practice recommendations for contraceptive use (2016) (13) Family planning: a global handbook for providers (2018) (14) WHO consolidated guideline on self-care interventions for health (2019) (26) 	
FP.B11.1 Method in mind	FP.DT.06	Method in mind	» Family planning: a global handbook for providers (2018) (14)	
FP.B6. Discuss issues and concerns	FP.DT.07	Client preferences	» Family planning: a global handbook for providers (2018) (14)	

Activity ID. Activity name	Decision- support table ID	Decision-support table description	Reference/source	
FP.B11.4		Medical eligibility criteria (MEC)	» Medical eligibility criteria for contraceptive use (2015) (12)	
Screen for medical eligibility	FP.DT.08.1	MEC for copper-bearing intrauterine devices (Cu-IUDs)	» Family planning: a global handbook for providers (2018) (14)	
	FP.DT.08.2	MEC for levonorgestrel-releasing intrauterine device (LNG-IUD)		
	FP.DT.08.3	MEC for etonogestrel (ETG) one-rod and levonorgestrel (LNG) two-rod		
	FP.DT.08.4	MEC for DMPA-IM, DMPA-SC and NET-EN	 » Medical eligibility criteria for contraceptive use (2015) (12) » Family planning: a global handbook for providers (2018) (14) » Contraceptive eligibility for women at high risk of HIV (2019) (32) 	
	FP.DT.08.5	MEC for progestogen-only pills (POPs)	» Medical eligibility criteria for contraceptive use (2015) (12)	
	FP.DT.08.6	MEC for combined oral contraceptives (COCs), combined contraceptive patch and combined contraceptive vaginal ring (CVR)	» Family planning: a global handbook for providers (2018) (14)	
	FP.DT.08.7	MEC for progesterone-releasing vaginal ring (PVR), lactational amenorrhoea method (LAM) and withdrawal		
	FP.DT.08.8	MEC for male condoms and female condoms		
	FP.DT.08.9	MEC for emergency contraceptive pills (ECPs)		
_	FP.DT.08.10	MEC for fertility awareness-based methods (FABs)		
	FP.DT.08.11	MEC for male sterilization		
	FP.DT.08.12	MEC for female sterilization		
FP.B14. Determine where services can be provided	FP.DT.09	Where services can be provided	» Based on expert consultation	
FP.C3. Use pregnancy checklist	FP.DT.10	Pregnancy checklist	» Family planning: a global handbook for providers (2018) (14)	



Activity ID. Activity name	Decision- support table ID	Decision-support table description	Reference/source
FP.C7. Perform exams and tests	FP.DT.11	Examinations and tests	 » Selected practice recommendations for contraceptive use (2016) (13) » Family planning: a global handbook for providers (2018) (14)
FP.C8. Determine when to start	FP.DT.12	When to start	 » Selected practice recommendations for contraceptive use (2016) (13) » Family planning: a global handbook for providers (2018) (14)
FP.C10. Discuss dual protection and back-up method	FP.DT.13	Back-up method	 Selected practice recommendations for contraceptive use (2016) (13) Family planning: a global handbook for providers (2018) (14)
FP.C12. Determine follow-up requirements	FP.DT.14	Follow-up requirements	 » Family planning: a global handbook for providers (2018) (14) » Selected practice recommendations for contraceptive use (2016) (13)

DMPA-IM: intramuscular depot medroxyprogesterone acetate; DMPA-SC: subcutaneous depot medroxyprogesterone acetate; HEADSS: home, education, activities/employment, drugs, suicidality and sex; STI: sexually transmitted infection.

6.2 Decision-support tables

The decision logic listed in the overview table is elaborated in <u>Web Annex B</u>. These decision-support tables comprise the components described in <u>Table 11</u>.

Note that the decision-support logic here is translated directly from the WHO guidelines and guidance documents, and has been reviewed by the panel of experts who have created those guidelines documents. We do not anticipate the decision-support logic to change much, as the logic has been created and reviewed by clinical experts. However, some level of adaptation may be needed depending on changes to the workflow and/or changes to the data dictionary.

Any changes to the decision-support logic should be considered carefully, as an embedded decision-support system can greatly affect the quality of care at the point of care. As helpful as decision-support logic can be to the health worker, incorrect decision-support logic can also be detrimental. Thus, any new decision-support logic should be carefully reviewed and agreed upon by in-country clinical experts.

Decision-support logic

Table 11. Components of the decision-support tables

•						
Decision ID		The name of the decision, describing what algorithm or logic is represented (e.g. pre-eclampsia risk counselling). The decision ID should correspond to the number in the overview table (<i>Table 10</i>).				
Business rule		The description of the decision that needs to be made, based on IF/THEN statements with the appropriate data element name for the variables. The rule should demonstrate the relationship between the input variables and the expected outputs and actions within the decision-support logic – e.g. if blood pressure is higher than 140 systolic/90 diastolic then the client should be flagged as a high-risk pregnancy.				
Trigger		The event that would indicate when this decision-support logic should appear within the workflow, such as the activity that would trigger this decision to be made.				
Inputs		Output	Action	Annotations		
These are the variables or conditions that need to be considered to determine the consequent actions or outputs. Inputs placed on different rows are considered as "OR" conditions that can be considered independently of the inputs on other rows.		The resulting action or decision, based on the combination of input entries. This is the statement that immediately follows the "THEN". Examples of outputs may include a diagnosis or alerts/prompts for referral and/or counselling.	Concrete measures to be taken based on the output (refer, provide treatment and/ or counselling, conduct test, etc.). In some cases, output and action may be the same.	Additional explanations or descriptions, including possible pop-up alert messages and relevant background information. This section can also include the written content which would appear in the pop-up messages notifying the health worker of the appropriate next steps, which can include counselling, case management approach, or referral.		



Table 12. Example decision-support logic table for medical eligibility for copper-bearing intrauterine devices (Cu-IUDs)

Decision ID	FP.DT.08.1 Medical eligibility criteria for copper-bearing intrauterine devices (Cu-IUDs)						
Business rule	FP.B11.4 Screen for medical eligibility						
Trigger	IF "Method requested" = "Copper-bearing intrauterine device (Cu-IUD)"						
Inputs		Output		Action	Annotations	References	
"Method requested" = "Copper-bearing intrauterine devices (Cu-IUDs)"	"Health condition(s)" = "Irregular vaginal bleeding patterns"		"Medical eligibility category" = 1	"Medically eligible" = TRUE	Counsel client that she is medically eligible for this method.	Client is medically eligible for this method, with a medical eligibility category of 1 – Use method in any circumstance.	Medical eligibility criteria for contraceptive use (2015) (12) Family planning: a global handbook for providers (2018) (14)
"Method requested" = "Copper-bearing intrauterine devices (Cu-IUDs)"	"Health condition(s)" = "Heavy or prolonged vaginal bleeding patterns"		"Medical eligibility category" = 2	"Medically eligible" = TRUE	Counsel client that she is medically eligible for this method.	Client is medically eligible for this method, with a medical eligibility category of 2 - Generally use method.	
"Method requested" = "Copper-bearing intrauterine devices (Cu-IUDs)"	"Health condition(s)" = "Unexplained vaginal bleeding"	"Method at intake" ≠ "Copper-bearing intrauterine devices (Cu-IUDs)"	"Medical eligibility category" = 4	"Medically eligible" = FALSE	Counsel client that she is NOT medically eligible for this method if this is for initiation. Discuss methods and options to find alternative options for the client.	Client is NOT medically eligible for this method, with a medical eligibility category of 4 - Method NOT to be used.	

For all the decision-support tables that are available for the family planning DAK, please refer to this linked spreadsheet: Web Annex B.

6.3 Scheduling logic overview

In addition to specific decision-support logic that needs to be detailed, there is also scheduling logic that can be used to facilitate the digital tracking of clients. For example, it will be important for the health worker to know when the client's next visit is due based on the recommendations for follow-up. The follow-up schedule is based on the client's method at exit or the service that was provided. The overview of the follow-up schedules is provided in *Table 13* and the corresponding logic is elaborated in *Web Annex B*.

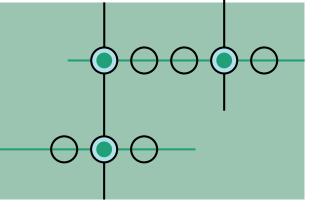
Decision-support logic 63

Table 13. Overview of scheduling logic

Scheduling logic ID	Scheduling logic description	Reference/source		
FP.S.1-1	Copper-bearing intrauterine device (Cu-IUD) insertion follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-2	Levonorgestrel-releasing intrauterine device (LNG-IUD) insertion follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-3	Copper-bearing intrauterine device (Cu-IUD) removal	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-4	Levonorgestrel-releasing intrauterine device (LNG-IUD) removal	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-5	Etonogestrel (ETG) one-rod implant insertion follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-6	Levonorgestrel (LNG) two-rod implant insertion follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-7	ETG one-rod implant removal	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-8	LNG two-rod implant removal	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-9	Intramuscular depot medroxyprogesterone acetate (DMPA-IM) injection follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-10	Subcutaneous DMPA (DMPA-SC) injection follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-11	Norethisterone enanthate (NET-EN) injection follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-12	Progestogen-only pills (POPs) follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-13	Combined oral contraceptives (COCs) follow-up	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-14	COCs – annual visit	Family planning: a global handbook for providers (2018) (14)		
FP.S.1-15	Combined contraceptive patch follow-up	Selected practice recommendations for contraceptive use (2016) (13)		
FP.S.1-16	Combined contraceptive patch – annual visit	Selected practice recommendations for contraceptive use (2016) (13)		
FP.S.1-17	Combined contraceptive vaginal ring (CVR) follow-up	Selected practice recommendations for contraceptive use (2016) (13)		
FP.S.1-18	CVR – annual visit	Selected practice recommendations for contraceptive use (2016) (13)		
FP.S.1-19	Progesterone-releasing vaginal ring (PVR) follow-up	Selected practice recommendations for contraceptive use (2016) (13)		
FP.S.1-20	Male sterilization follow-up	Selected practice recommendations for contraceptive use (2016) (13)		
FP.S.1-21	Female sterilization follow-up	Family planning: a global handbook for providers (2018) (14)		



Indicators and performance metrics



This section details indicators and performance metrics that would be aggregated from core data elements identified in <u>Component 5</u>. The list in Table 14 is a minimum set of indicators that can be aggregated for decision-making, performance metrics, and subnational and national reporting based on data collected from individual-level routine health systems. These indicators may be aggregated automatically from the digital tracking tool to populate a digital HMIS, such as DHIS2. This table is detailed in *Web Annex C*.

Table 14. Indicators and performance metrics

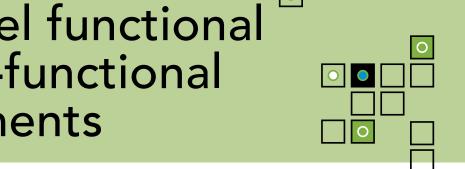
Indicator ID	Indicator name	Definition	Numerator description	Denominator description	Disaggregations	References
FP.IND.1	New users of modern contraceptive methods	The number of women (or their partners) of reproductive age initiating use of a modern contraceptive method	COUNT of "Never used contraception" = TRUE recoded in the period OR COUNT of women who have not used contraception in 6 months OR COUNT of women who previously used traditional methods (withdrawal or fertility awareness-based method [FAB])	COUNT total new and continuing users of modern contraception methods	» Gender» Age (10–14, 15–19, 20+)» Method» Service site	Measuring family planning service delivery (33) Decision-making tool for family planning clients and providers (25) Family planning 2020 core indicators (34)
FP.IND.2	Continuing users of contraception	Number of clients returning to a facility for contraceptive methods	COUNT of clients with "Reason for visit" = "Contraceptive continuation"	COUNT total users of modern contraception methods	» Gender» Age» Contraceptive method» Service site	Measuring family planning service delivery (33) Decision-making tool for family planning clients and providers (25

Indicator ID	Indicator name	Definition	Numerator description	Denominator description	Disaggregations	References
FP.IND.3	Number of visits	Number of visits at which clients receive contraceptive services	Count of clients "Method or service provided" ≠ No method provided	COUNT total number of clients registered	» Gender» Age» Method» Service site	Measuring family planning service delivery (33) Decision-making tool for family planning clients and providers (25)
FP.IND.4	Method switching	Number of clients using a contraceptive method stopping its use and switching to a different one	COUNT number of clients " Contraceptive method switch" = TRUE	COUNT total users of modern contraception methods	» Age» Method» Reason» Service site	Measuring family planning service delivery (33) Decision-making tool for family planning clients and providers (25) Family planning 2020 core indicators (34)
FP.IND.5	Method discontinuation	Number of clients using a contraceptive method stopping its use	COUNT number of clients " Stopping contraception" = TRUE	COUNT total users of modern contraception methods	» Age» Method» Reason» Service site	Measuring family planning service delivery (33) Decision-making tool for family planning clients and providers (25) Family planning 2020 core indicators (34)
FP.IND.6	Received method of choice	Number of clients receiving their method of choice	COUNT of clients where "Chosen method"= "Method or service provided"	COUNT total users of modern contraception methods	» Age» Method» Service site	Measuring family planning service delivery (33) Decision-making tool for family planning clients and providers (25) Family planning 2020 core indicators (34)
FP.IND.7	Post-abortion contraception	Number of post- abortion care clients who leave the facility with a contraceptive method	COUNT of clients "Method or service provided" ≠ No method provided	COUNT of clients with miscarriage/abortion	» Age» Method» Facility type» Medical vs surgical abortion	Safe abortion: technical and policy guidance for health systems (35)
FP.IND.8	Postpartum contraception	Number of clients initiating a modern contraceptive method within 1 year of delivery	COUNT of clients "Method or service provided" ≠ No method provided	COUNT of clients that were postpartum within last year	 » Timing (in 48 hours, 6 weeks or 1 year) » Service delivery site: maternity, immunization, community or family planning clinic 	Programming strategies for postpartum family planning (36)



Component

High-level functional and non-functional requirements



This section provides an overview of illustrative functional and non-functional requirements that may be considered to kick-start the process of designing or adapting the digital tracking and decision-support system. Functional requirements describe the capabilities the system must have in order to meet the end-users' needs and achieve tasks within the business process. Non-functional requirements provide the general attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include ability to work offline, multiple language settings and password protection.

Table 15 highlights some key functional requirements for executing the business processes listed in Component 4 of this document, and the complete set of functional requirements can be accessed in Web Annex D. Table 16 provides non-functional requirements as general characteristics of the overall system. Please note that these are not exhaustive lists and should be modified according to context and user persona needs.

8.1 Functional requirements

Table 15. Functional requirements^a

Requirement ID	Activity ID and description	As a	I want	So that
Business process A	: Registration			
FP.FXNREQ.001	Rapid assessment and management	Health worker or clerk	To bypass the standard flow at any point if an urgent case is identified	The woman can receive immediate attention
FP.FXNREQ.002	Search for clientb name and record	Health worker or clerk	To search to see whether client is already in the system (using at least two identifiers)	I can check whether this is a new or existing client
FP.FXNREQ.003	Search for client name and record	Health worker or clerk	The system to display sufficient data to identify the client	I can confirm that it is the correct client

Requirement ID	Activity ID and description	As a	I want	So that
FP.FXNREQ.004	Search for client name and record	Health worker or clerk	The system to require me (a user) to search to see whether a client is already in the system prior to starting a new medical record entry	I can confirm that it is the correct client and update information as necessary
FP.FXNREQ.005	Search for client name and record	Health worker or clerk	To use patient identification system (e.g. QR code, barcode, fingerprint) and pull up patient information	I can confirm that it is the correct client and update information as necessary
FP.FXNREQ.006	Search for patient name and record	Health worker or clerk	To provide sufficient data to rule out the possibility that this patient is already in the system	I can avoid duplicates
FP.FXNREQ.007	Create client record	Health worker or clerk	To be able to enter identification information	I can enter new client information or update an existing client record
FP.FXNREQ.008	Create client record	Health worker or clerk	The system to indicate mandatory fields that must be filled out for registration to be valid	I can ensure all necessary information has been completed
FP.FXNREQ.009	Create client record	Health worker or clerk	To generate encounter number for contact	I can initiate the required antenatal care services
FP.FXNREQ.010	Create client record	Health worker or clerk	To generate or associate to existing hospital or clinic medical record number	I can check and confirm the information
FP.FXNREQ.011	Create client record	Health worker or clerk	To edit fields on screen before information is committed	I can ensure information has been checked before submission
FP.FXNREQ.012	Create client record	Health worker or clerk	To enter a temporary identification in emergency situations when full identity unknown	I can proceed with registration
FP.FXNREQ.013	Validate client details	Health worker or clerk	To display patient information for validation (and be able to edit it)	I can ensure information has been checked before submission
FP.FXNREQ.014	Validate client details	Health worker or clerk	To be able to update demographic information	The most current information on client can be recorded
FP.FXNREQ.015	Validate client details	Health worker or clerk	To retain previous history of updated information	I can review past information
FP.FXNREQ.016	Validate client details	Health worker or clerk	To be able to include other multiple ways of identifying the client (e.g. photo, biometrics), as needed and based on consent and national standards	I have additional ways of identifying client
FP.FXNREQ.017	Validate client details	Health worker or clerk	To be able to confirm client identity	I can be sure it is the right person
FP.FXNREQ.018	Validate client details	Health worker or clerk	If this is a returning contact, to add the information to their previous contact	I can link the information across different contacts
FP.FXNREQ.019	Check in client	Health worker or clerk	To record a time- and date-stamped new contact (encounter)	I can confirm when the client came



Requirement ID	Activity ID and description	As a	I want	So that	
Business process	Business process B: Counselling				
FP.REQ.020	Conduct risk assessment	Health-care provider (e.g. nurse midwife)	To have different questions and language prompts when clients are adolescents	I can better support adolescents with their unique needs	
FP.REQ.021	Conduct risk assessment	Health-care provider (e.g. nurse midwife)	To have the option of conducting a screening at multiple steps during a client's visit, such as for sexually transmitted infections (STIs) or HIV	I can better support the client	
FP.REQ.022	Discuss methods and options	Health-care provider (e.g. nurse midwife)	To know which contraceptive methods are available at my facility	I can better serve the client in getting their method of choice or refer them elsewhere	
FP.REQ.023	Discuss methods and options	Health-care provider (e.g. nurse midwife)	To have educational information available about different types of methods	I can better answer the client's questions to support their selection of a method	
FP.REQ.024	Discuss methods and options	Health-care provider (e.g. nurse midwife)	To have access to a graphic which shows what methods look like and how effective they are	I have a visual aid to support clients in selecting a method	
FP.REQ.025	Discuss methods and options	Health-care provider (e.g. nurse midwife)	To have available general information about methods to share with clients	I have a quick reference to help clients pick a method	
FP.REQ.026	Discuss methods and options	Health-care provider (e.g. nurse midwife)	To have available general sexual and reproductive health education information	I will not have to look elsewhere to find information	
FP.REQ.027	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To have questions that guide me in counselling clients	I can better match method suggestions with client's needs, values and preferences for contraception	
FP.REQ.028	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To have the option to check a returning client's medical eligibility for their current method	I can re-evaluate a client's eligibility, but will not be required to do so	
FP.REQ.029	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To be prompted to ask about conditions that would exclude a client from using a method	Clients are not given a method that may not be safe for them	
FP.REQ.030	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To be able to use my clinical judgement when a client has a medical condition indicating a method should not be used	I do not prevent clients from selecting a family planning method when they are eligible, with clinical judgement (e.g. when other methods are not available)	
FP.REQ.031	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To have the option to restrict classifying a woman as medically eligible where resources for clinical judgement are limited	Clients are better protected, such as when clinical judgement is needed to determine the severity of the condition and the availability, practicality and acceptability of alternative methods	
FP.REQ.032	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To log the reason a client is not medically eligible for a method	The next provider has this information, client safety is better protected, and on a future visit it is easier to check whether a client is now eligible	
FP.REQ.033	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To see history of past medical eligibility screenings to see if anything has changed	I better protect client safety and reduce time spent on methods the client is still ineligible for due to known conditions	

Requirement ID	Activity ID and description	As a	I want	So that
FP.REQ.034	Screen for medical eligibility	Health-care provider (e.g. nurse midwife)	To be alerted if a client was previously not eligible for a method	I do not have to search through records, given I have limited time
Business process	C: Service provision			
FP.REQ.035	Get informed consent	Programme manager	To ensure the system prompts the health worker to get informed consent from the client	Jurisdictional requirements are adhered to and clients' rights are protected
FP.REQ.036	Schedule follow-up	Health-care provider (e.g. nurse midwife)	To have the system automatically calculate a date when the client should return for care, based on method, quantity of the method provided, etc.	I do not have to calculate this myself
FP.REQ.037	Encourage follow-up as needed	Health-care provider (e.g. nurse midwife)	To be able to still send communications to a client, even if follow-up is not necessarily required	The client's ongoing family planning needs may be better served

Complete business processes C, D and E are available in the full spreadsheet of "FP functional and non-functional requirements".

8.2 Non-functional requirements

Table 16. Non-functional requirements

Requirement ID	Category	Non-functional requirement
FP.NFXNREQ.001	Security – confidentiality	Provide password-protected access for authorized users
FP.NFXNREQ.002	Security – confidentiality	Provide a means to ensure confidentiality and privacy of personal health information
FP.NFXNREQ.003	Security – confidentiality	Provide ability for allowed users to view confidential data
FP.NFXNREQ.004	Security – confidentiality	Anonymize data that is exported from the system
FP.NFXNREQ.005	Security – confidentiality	Prevent remembering username and password
FP.NFXNREQ.006	Security – confidentiality	Automatically log out the user after specified time of inactivity
FP.NFXNREQ.007	Security – confidentiality	Provide encrypted communication between components
FP.NFXNREQ.008	Security – authentication	Notify the user to change their password the first time they log in
FP.NFXNREQ.009	Security – authentication	Adhere to complex password requirements
FP.NFXNREQ.010	Security – authentication	Provide a mechanism to securely change a user's password
FP.NFXNREQ.011	Security – authentication	Notify the user of password change to their account
FP.NFXNREQ.012	Security – authentication	Reset a user's password in a secure manner
FP.NFXNREQ.013	Security – authentication	Lock a user out after a specified number of wrong password attempts

b The term "client" is used for the registration workflow, as this is applicable to other health domains, and "woman" is used for the family planning-specific business processes.

Requirement ID	Category	Non-functional requirement
FP.NFXNREQ.014	Security – authentication	Notify a user if their account is locked due to wrong password attempts
FP.NFXNREQ.015	Security – authentication	Provide role-based access to the system
FP.NFXNREQ.016	Security – audit trail and logs	Log system logins and logouts
FP.NFXNREQ.017	Security – audit trail and logs	Record all authentication violations
FP.NFXNREQ.018	Security – audit trail and logs	Log all activities performed by the user, including date and time stamp
FP.NFXNREQ.019	Security – audit trail and logs	Log access to views of individual client records
FP.NFXNREQ.020	Security – audit trail and logs	Log access to data summaries, reports, analysis and visualization features
FP.NFXNREQ.021	Security – audit trail and logs	Log exchange of data with other systems
FP.NFXNREQ.022	Security – audit trail and logs	Generate analysis of the usage of different system features and reports
FP.NFXNREQ.023	Security – audit trail and logs	Log all data and system errors
FP.NFXNREQ.024	Security – user management	Allow user with permission to create a new user and temporary password
FP.NFXNREQ.025	Security – user management	Provide role-based access
FP.NFXNREQ.026	Security – user management	Allow roles to be associated with specific geographical areas and/or health-care facilities
FP.NFXNREQ.027	Security – user management	Allow cascading user management and assignment of roles
FP.NFXNREQ.028	Security – user management	Allow user to change their own password
FP.NFXNREQ.029	Security – user management	Allow admin user to request password reset
FP.NFXNREQ.030	Security – user management	Notify the user to regularly change their password
FP.NFXNREQ.031	Security – user management	Allow each user to be assigned to one or more roles
FP.NFXNREQ.032	Security – user management	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing and auditing
FP.NFXNREQ.033	System requirements – general	Provide a unique version number for each revision
FP.NFXNREQ.034	System requirements – general	Enable earlier versions of a record to be recoverable
FP.NFXNREQ.035	System requirements – general	Enable deployment in an environment subject to power loss
FP.NFXNREQ.036	System requirements – general	Work in an environment that is subject to loss of connectivity
FP.NFXNREQ.037	System requirements – general	Generate IDs that are unique across different installations or sites
FP.NFXNREQ.038	System requirements – general	Report version number when saving data to the database
FP.NFXNREQ.039	System requirements – general	Be designed to be flexible enough to accommodate necessary changes in the future
FP.NFXNREQ.040	System requirements – general	Allow for offline and online functionality
FP.NFXNREQ.041	System requirements – general	Show the number of records that are not yet synchronized
FP.NFXNREQ.042	System requirements – general	Have ability to easily back up information

Requirement ID	Category	Non-functional requirement	
FP.NFXNREQ.043	System requirements – general	Warn user if no valid backup for more than a predefined number of days	
FP.NFXNREQ.044	System requirements – general	Have the ability to store images and other unstructured data	
FP.NFXNREQ.045	System requirements – scalability	Be scalable to accommodate new demands	
FP.NFXNREQ.046	System requirements – scalability	Be able to accommodate at least [x number of] health-care facilities	
FP.NFXNREQ.047	System requirements – scalability	Be able to accommodate at least [x number of] concurrent users	
FP.NFXNREQ.048	System requirements – usability	Be user-friendly for people with low computer literacy	
FP.NFXNREQ.049	System requirements – usability	Provide informative error messages and tool-tips	
FP.NFXNREQ.050	System requirements – usability	Alert the user when navigating away from a form without saving	
FP.NFXNREQ.051	System requirements – usability	Support real-time data-entry validation and feedback to prevent data-entry errors from being recorded	
FP.NFXNREQ.052	System requirements – usability	Simplify data recording through predefined drop-down menu or searchable lists, radio buttons, check boxes	
FP.NFXNREQ.053	System requirements – usability	Support multiple languages	
FP.NFXNREQ.054	System requirements – usability	Use industry-standard user interface practices and apply them consistently throughout the system	
FP.NFXNREQ.055	System requirements – usability	Be easy to learn and intuitive to enable user to navigate between pages	
FP.NFXNREQ.056	System requirements – usability	Provide guidance to users to better support clinical guidelines and best clinical practices	
FP.NFXNREQ.057	System requirements – usability	Be reliable and robust (minimize the number of system crashes)	
FP.NFXNREQ.058	System requirements – usability	Adjust display to fit small screens (e.g. mobile phones)	
FP.NFXNREQ.059	System requirements – configuration	Configure the system centrally	
FP.NFXNREQ.060	System requirements – configuration	Configure business rules in line with guidelines and standard operating procedures (SOPs)	
FP.NFXNREQ.061	System requirements – configuration	Configure error messages	
FP.NFXNREQ.062	System requirements – configuration	Configure workflows and business rules to accommodate differences between facilities	
FP.NFXNREQ.063	System requirements – interoperability	Communicate with external systems through mediators	
FP.NFXNREQ.064	System requirements – interoperability	Provide access to data through application programming interfaces (APIs)	
FP.NFXNREQ.065	System requirements – interoperability	Be interoperable with external systems through mediators	
FP.NFXNREQ.066	System requirements – interoperability	Exchange data with other approved systems	
FP.NFXNREQ.067	System requirements – interoperability	Accept data from multiple input methods, including paper and geocoding via Global Positioning System (GPS)	
FP.NFXNREQ.068	System requirements – hardware and connectivity	Allow for data exchange and efficient synchronization across multiple facilities and points of service when Interne is available, even when it is intermittent and slow	



Glossary

Note: Terms in definitions also defined in this glossary are shown in *italics*.

Business process	A set of related activities or <i>tasks</i> performed together to achieve the objectives of the health programme area, such as registration, counselling, referrals (1,16).		
Data dictionary	A centralized repository of information about the <i>data elements</i> that contains their definition, relationships, origin, usage, and type of data. For this digital adaptation kit, the data dictionary is provided as a spreadsheet in <i>Web Annex A</i> .		
Data element	A unit of data that has specific and precise meaning.		
Decision-support logic	A set of decision rules for standard and exceptional cases that is separate from the <i>business process</i> . This would help reduce the complexity of the <i>business process</i> depiction without losing the detail necessary for coding the rules required for system functionality.		
Decision support (for health workers)	Digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions (7,8).		
Decision-support table	Semi-structured way to depict each discrete decision that will need to be embedded in the system. Depending on the complexity of the clinical guidelines, there will likely be multiple decision-support tables.		
Digital health The systematic application of information and communications technologies, computer science and dainformed decision-making by individuals, the health-care workforce and health systems, to strengthen disease and improve health and wellness (1,37).			
Digital tracking	The use of a digitized record to capture and store clients' health information to enable follow-up of their health status and services received. This may include digital forms of paper-based registers and case management logs within specific target populations, as well as electronic medical records linked to uniquely identified individuals (7,8).		
Functional requirement	Capabilities the system must have in order to meet the end-users' needs and achieve tasks within the business process.		
Health information system A system that integrates data collection, processing, reporting and use of the information necessary for ir service effectiveness and efficiency through better management at all levels of health services (38).			
Health management information system (HMIS)	An information system specifically designed to assist in the management and planning of health programmes, as opposed to delivery of care (38).		

Glossary

Interoperability	The ability of different applications to access, exchange, integrate and use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes.
Non-functional requirement	General attributes and features of the digital system to ensure usability and overcome technical and physical constraints Examples of non-functional requirements include ability to work offline, multiple language settings, and password protection.
Persona	A generic aggregate description of a person involved in or benefitting from a health programme.
Standard	In software, a standard is a specification used in digital application development that has been established, approved and published by an authoritative organization. These rules allow information to be shared and processed in a uniform, consistent manner independent of a particular application.
Task	A specific action in a business process.
Terminologies For clinical care, terminologies are structured vocabularies covering health-related concepts – such diagnoses, laboratory tests and treatments – to enable the storage, analysis and exchange of data is standard way (39).	
Workflow	A visual representation of the progression of activities (tasks, events, decision points) in a logical flow illustrating the interactions within the business process (16).



Annex 1. Examples of detailed personas

Jamilla

Community Health Worker (CHW)







My Tasks

80% of my time is in the community, checking in with families and counseling

- · I visit each of my families at least once a month I pay special attention to mothers who need post-natal care every day
- I dispense a few services and refer clients to the local health facility for services I cannot provide Sometimes households call me on my mobile for
- additional counseling in the case of an

20% of my time is spent on administrative duties

- commistrative duties.

 Recording data from my household visits in the ministry's Service Delivery Logbook and Household Register Meeting with the community health coordinator and other CHWs from my
- facility every month for a meeting to discuss our community's health and for short trainings



My Workload

- I serve between 25-30 households in my community in total
- I schedule my home visits around other work, because I have another job (either casual labor or a small business)
- I provide two types of household visits: monthly service calls and scheduled check-ins for women who have recently given birth
- My household visits are typically 20-30 minutes long, 45 maximum for monthly service visits
- I try to visit around three households per day

My Typical Day

8am I begin the day with a scheduled check-in with a mother who has recently given birth

9am I check in on a few households nearby, finding one I had not yet visited. During my monthly reporting visit. I ask general questions about illness, newborns, deworming. HIV (to see if anything has changed). I also counsel on a number of health areas, including family planning and then may dispense condoms and/or pills

11am I take a pause in the middle of the day to attend to my small business

7pm In the evening I may take calls from the village households if someone has questions or if a mother is in labor

(5) 3pm In the afternoon, I'll try to visit two more households before the end of the day And then I will transcribe the household visits from my notebook into the logbook and register

"It's essential to be informed to keep trust from my community."

Barriers to providing reproductive health services



While most of my clients have responded to counseling about family planning, there are cultural and religious reasons why clients or their husbands do reasons why clients or their husbands or not accept family planning methods. Some elents select discrete long-term methods that a husband can't find, but some still fear that a husband will find a referral or follow-up card.

TRACKING CLIENTS



Many of the clients in my community are nomadic, so it can be difficult to track their current and past services. This can lead to double counting of clients for the facility and means that the service depends on

INCENTIVE



It's challenging to do this work unpaid-It anything, I receive a small stipend per month for my work as a CHV and sometimes those stipends are paid by programs for specific activities. In addition, transportation into the community can be difficult and costly along with paying for my own airtime

WORKLOAD



Sometimes, I can have over 50 households, making it very difficult for me to visit each household once a month and complete the required reporting. I have to balance the demand for household visits with the need to earn a full income.



Grace Nurse-Midwife



My Tasks

Administering immunizations

75% of my time is dedicated to providing maternal and child health along with comprehensive obstetric care

- Meeting with women for routine antenatal care appointments
- Promoting reproductive health interventions
- Supplying sexual and reproductive health services including initiating and maintaining use of contraceptives such as injectables, intrauterine
- devices, and implants Providing skilled delivery in the maternity ward



25% of my time is spent on administrative duties such as:

- Setting up the clinic area
 Filing out registers along with maternal and child health cards Managing reproductive health and other supplies

My Workplace

Sub-County Hospital

- The sub-county hospital provides services for seven wards and serves about 150,000 people, mostly subsistence farmers.
- The hospital operates 24 hours, although the clinic is only open from 8:00am 5:00pm Monday through Saturday.
- Two nurses rotate through the maternity ward, reproductive health, and child health
- Two nurses and four community health workers have received training that was focused on adolescent sexual and reproductive health.

My Typical Day

8am Arrive at work, begin my normal nursing agenda, check stock, and round on each service area

9am Check clients that have arrived, provide group education and begin working queue

11am Mother in maternity ward is about to give birth Pause reproductive health services and attend to mother and child

1pm Deliver birth dose of immunizations, take a quick lunch Check on other units and reproductive health queue

3pm Community Health Worker alerts that a young girl has arrived and move her to the front of queue

4pm Review stock levels and discuss with the sub-county reproductive health coordinator

"Tools are never enough. The regimen changes daily and needs to be continually updated."

Barriers to providing reproductive health services

PAPERWORK





Roselyn must fill out a lot of paperwork for every patient, including a family planning register, a procedure register, She also has requisition and issue youthers, and summary reports. When trying to keep visits to around 15 minutes each, she is often rapidly working to fill out the paperwork while the client waits.

UNKNOWN DEMAND



Family planning and reproductive health raminy painting and reproductive realist services seems anything but routine. Roselyn often doesn't know how many dients she'll see in the day. Sometimes, a local NGO has generated demand in the community for a particular day. Youth will arrive when school is out. It is difficult to see demand patterns. HIGH TURNOVER



Despite being short-staffed, the county has invested in the youth-friendly education of Roselyn and a few of the community health workers. In addition the facility will soon have five more nurses. Unfortunately, Roselyn has received orders to move to another facility and may not have the opportunity STOCK OUTS



Individuals will often have a method in mind when they arrive, and yet there may be stockouts across the entire county. And while many methods are available Roselyn often has to counsel a client or



Annex 2. Additional user scenario

User scenario for community health worker

Key personas Community health worker: Jane

Client: Safia

Safia is a 20-year-old woman who has recently given birth and has a 3-week-old baby, Said. Her community health worker, Jane, comes to her household (one of 25 or so that Jane monitors) every other day to check up on her and the newborn baby.

After Jane has completed her questions and counselling regarding postnatal care, they began discussing Safia's future and desire for more children. As she is looking to space out the next birth by more than a year, Jane suggests they talk more about family planning. Since Safia is already registered in Jane's app as an existing member of one of the households she has responsibility for, Jane looks up Safia's profile.

Jane asks for a few more details about her interest in family planning. While they are having the conversation, Jane checks Safia's blood pressure and finds that it is slightly high. Safia has used condoms in the past, but uses no contraceptive currently. When asked if she has a method in mind, Safia mentions she has heard about the new injectable contraceptives available and wonders if that would be right for her. Seeing in her app that hormonal methods are not recommended for users with high blood pressure, Jane counsels Safia against injectables, and informs her about progestogen-only pills (POPs), intrauterine devices (IUDs) and other non-hormonal methods. As Safia is currently breastfeeding Said, she decides to start with the use of POPs and monitor its effects, but she may switch to an injectable in the future, once her blood pressure returns to normal.

While Jane does not have any pills to dispense on this visit, she gives Safia a referral slip that she can take to the nearest health post in order to get a supply. Jane makes a note to follow up with Safia on her next visit to make sure she has collected the pills. Jane informs Safia that once she has them, she can start the pills at any time; Jane also promotes the use of dual protection, asking if Safia would also like a supply of condoms. Jane tells Safia that she will follow up on the referral at her next visit and asks if Safia has any other concerns or questions.

Two days later, when Jane is doing morning preparations for her household visits, she checks the app and sees the note to follow up with Safia about her prescription for pills.

Corresponding business processes

(see Component 4)

This scenario refers to the following business processes:

- » Family planning counselling
- » Referral

Annex 3. Guidance for adding data elements to or amending existing data elements in the data dictionary

When adapting the data dictionary, data elements may need to be modified or added as a result of the structure of existing paper registers or local reporting requirements. If starting from paper-based registers and forms, you can find additional guidance in the *Handbook for digitizing primary health care (17)*, and below is an overview of the data mapping to provide a template for standardizing the data dictionary. When amending the wording of data elements, it is important to ensure that the standard terminology codes still reflect the data element as originally intended.

What to note	Description
Activity ID	The ID number of the task in the workflow in which the data element is collected. This will denote the point in time at which this data element is collected.
Data element code	Each data element should have an ID number or code that is unique across the entire project. Use existing serial or ID numbers when available. If no identifiers exist, fields should be enumerated in a logical format.
Form ID and form data element label	The Form ID is important for ensuring that the design of the digital system has taken into account all the required paper forms and data elements on those paper forms. Also list the label of the data element as written on the original form (or translated as closely as possible). This will be key in keeping track of which data elements from the original paper forms are duplicated. Note that duplicate data fields can be included purposely (patient identifiers, such as name, date of birth, village, ID number, etc., would be included in multiple data instruments to identify an individual patient).
Data element label	The label of the data element written in a way in which the end-users can easily understand, e.g. "education level", "weight", "height", "reasons for coming into facility", "which medication(s) is your client taking?" The data element label is what will be used in the digital form. The digital register should not simply replace the paper registers, but it should also streamline processes and link duplicated data elements; thus the data element label listed here should be what will be used in the digital system.
Data element name	The shorthand name for the data element (e.g. "educ_level" for "education level". This will be key when coding the system and determining calculations required. This data element name is what will reconcile any duplicate data elements in the digital system.
Description and definition	The description of the data field, including any units that define the field (e.g. "weight in kilograms (kg)"). Provide a clear explanation of what this data point is requesting, assuming the reader has never seen the form. Be sure to use consistent and easy-to-understand terminology across all forms. This is particularly important if the data element name differs across forms but requires the same input.



What to note	Description
Data type	The data type should be aligned with data types outlined by Fast Healthcare Interoperability Resources (FHIR) standards. Some common data types are:
	» Boolean (e.g. True/False, Yes/No)
	» String (a sequence of Unicode characters, e.g. name)
	» Date (e.g. date of birth)
	» Time (e.g. time of appointment)
	» ID (e.g. unique identifier assigned to the client)
	» Integer (a whole number, e.g. number of previous appointments)
	» Decimal (rational numbers that have a decimal representation, e.g. exact duration of time, location coordinates, all percentages)
	» Observation (health status observations collected from the client, e.g. height, weight, eye colour, pulse, blood pressure, temperature, glucose level)
	» Codeable concept (a value that is usually supplied by providing a reference to one or more data points, e.g. body mass index [BMI], contraceptive prevalence rate)
	» Signature (an electronic representation of a signature that is either cryptographic or a graphical image that represents a signature or a signature process, e.g. supervisor's approval)
	» Attachment (additional data content defined in other formats, e.g. images)
	» Note that if there are multiple-choice data fields, the "parent" data field should be labelled "Multiple choice – Select one" or "Multiple choice – Select all that apply". Then each individual option should be listed in the "Input" options column and be classified with one of the data types listed above.
	Although the list above should be sufficient to relay this information to a health informaticist or technology vendor, there are many more data codes that can be applied to achieve a more precise classification. For other possible data types, please refer to the HL7 FHIR guide on data types (40).
Input options	For multiple-choice fields only; otherwise leave this column blank. Write the list of responses from which the health worker may select. Each of these input options should be in a separate row. Each of these options should be labelled with a data type as indicated above.
Calculation	For "codeable concept" data type fields, write the formula that defines the field. Leave this column blank for all other data types. Use standard mathematical symbols and the data element label of the data element names included in the formula (e.g. for the BMI calculation: "weight_kg/([height_m]^2)").
Validation required	"Yes" or "No" to indicate whether there needs to be some form of validation given the constraints provided by a range of acceptable responses.
Validation condition	The range of acceptable responses, if validation is required (e.g. for a phone number, only 10 digits allowed; for a birthday, only past dates allowed).
Editable	"Yes" or "No" to indicate whether the end-user, or health worker, would be able to edit the field after it has been input to the system.
Required	Note whether this field is:
	» Required – R
	» Required, but can be left empty – RE
	» Optional – O
	» Conditional on answers from other data fields – C
	» Conditional, but can be left empty – CE

What to note	Description
Reason for required data	If this field is required (R), state the reason here – whether for: » Accountability for national-level reporting » Service delivery or clinical decision-making » Client identification. The digital system should not simply replace paper registers, but it should also streamline processes; thus, it is important to understand why a certain data field is actually required and seek opportunities to optimize data flows.
	Given the high volume of data collection required of health service providers, it might be better to remove a data entry field if it serves no real purpose for the clinician, public health reporting, or any other identified purpose.
Skip logic	If this field is conditional on answers from other data fields (C) or conditional but can be left empty (CE), denote what the skip logic is here. This is common for data elements that are a part of follow-up questions. If the input of one data element field has a value lower than a certain threshold, then some data inputs can be skipped. Those data elements will have skip logic that is defined by a preset threshold.
Linked to aggregate indicator	Aggregate indicators should be called out and specified. If this data element is linked to an aggregate reporting indicator, then indicate accordingly.
Notes	If there is an issue or inconsistency in how a data field is defined, make a note of the issue here. Irregularities and inconsistencies will need to be resolved at a later stage through a process of team discussion and triangulation. This column should also be used for any other notes, annotations or communication messages within the team.
Concept mappings	Depending on which systems the system is planned to interoperate with, other columns will most likely need to be added to map to the concepts used in the other system (e.g. ICD-11, SNOMED). One column should be used for each concept dictionary.



Annex 4. Guidance for each method

This annex is intended to provide additional information that can be used for developing further decision-support logic and counselling aids. This information is extracted from the Family planning global handbook for providers (2018) (14).

Copper-bearing intrauterine device (Cu-IUD)

What is it?

- » The Cu-IUD is a small, flexible plastic frame with copper sleeves or wire around it. A specifically trained health-care provider inserts it into a woman's uterus through her vagina and cervix.
- » Almost all types of IUDs have one or two strings, or threads, tied to them. The strings hang through the cervix into the vagina.
- » Works by causing a chemical change that damages sperm and egg before they can meet.

How effective is the method?

- » One of the most effective and long-lasting methods:
 - Less than 1 pregnancy per 100 women using a Cu-IUD over the first year (6 per 1000 women who use the IUD perfectly, and 8 per 1000 women as commonly used). This means that 992–994 of every 1000 women using Cu-IUDs will not become pregnant.
 - A small risk of pregnancy remains beyond the first year of use and continues as long as the woman is using the Cu-IUD.
 - Over 10 years of IUD use: About 2 pregnancies per 100 women.
 - Studies have found that the TCu-380A is effective for 12 years. The TCu-380A is labelled for up to 10 years of use. (Providers should follow national guidelines for when the IUD should be removed.)
- » Return of fertility after IUD is removed: No delay.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

- » Safe and suitable for nearly all women. Most women can use Cu-IUDs safely and effectively, including women who:
 - Have or have not had children
 - Are married or are not married
 - Are of any age, including adolescents and women over 40 years old
 - Have just had an abortion or miscarriage (if no evidence of infection)
 - Are breastfeeding
 - Do hard physical work
 - Have had an ectopic pregnancy
 - Have had pelvic inflammatory disease (PID)
 - Have vaginal infections
 - Have anaemia
- Have HIV clinical disease that is mild or with no symptoms, whether or not they are on antiretroviral therapy.

How do you use the method?

Client needs to have the Cu-IUD inserted by a trained health-care provider. A follow-up visit after her first monthly bleeding or 3–6 weeks after IUD insertion is recommended. No woman should be denied an IUD, however, just because follow-up would be difficult or not possible.

Some users report the following:

- » Changes in bleeding patterns (especially in the first 3–6 months), including:
 - Prolonged and heavy monthly bleeding
 - Irregular bleeding
 - More cramps and pain during monthly bleeding.

Known health benefits

- » Helps protect against: Risks of pregnancy.
- » May help protect against:
 - Cancer of the lining of the uterus (endometrial cancer)
 - Cervical cancer.
- » Reduces: Risk of ectopic pregnancy.

Known health risks

- » Uncommon: May contribute to anaemia if a woman already has low iron blood stores before insertion and the IUD causes heavier monthly bleeding.
- » Rare: Pelvic inflammatory disease (PID) may occur if the woman has chlamydia or gonorrhoea at the time of IUD insertion.
- » Complications, rare:
 - Puncturing (perforation) of the wall of the uterus by the Cu-IUD or an instrument used for insertion; usually heals without treatment
- Miscarriage, preterm birth, or infection in the rare case that the woman becomes pregnant with the IUD in place.

Giving advice on side-effects

Describe the most common side-effects

- » Changes in her bleeding pattern:
 - Prolonged and heavy monthly bleeding
 - Irregular bleeding
 - More cramps and pain during monthly bleeding.

Explain about these side-effects

- » Bleeding changes are not signs of illness.
- » They usually become less a few months after insertion.
- $\,{\rm **}\,$ Client can come back for help if problems bother her or if she has other concerns.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not have a Cu-IUD inserted. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use a Cu-IUD. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

- » Between 48 hours and 4 weeks after giving birth
- » Noncancerous (benign) gestational trophoblast disease
- » Current ovarian cancer
- » Is at very high individual risk for STIs at the time of insertion
- » Has severe or advanced HIV clinical disease
- » Has systemic lupus erythematosus with severe thrombocytopenia.



Helping continuing users

Post-insertion follow-up visit (3-6 weeks)

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Ask her if she has:
 - Increasing or severe abdominal pain or pain during sex or urination
 - Unusual vaginal discharge
 - Fever or chills
 - Signs or symptoms of pregnancy
 - Felt the hard plastic of an IUD that has partially come out

A routine pelvic examination at the follow-up visit is not required; however, it may be appropriate in some settings or for some clients. Conduct a pelvic examination particularly if the client's answers lead you to suspect infection or that the IUD has partially or completely come out.

Any visit

- 1. Ask how the client is doing with the method and about bleeding changes (see "Post-insertion follow-up visit", items 1 and 2, above).
- 2. Ask a long-term client if she has had any new health problems. Address problems as appropriate. For new health problems, this may require switching methods.
- 3. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.
- 4. Remind her how much longer the IUD will protect her from pregnancy and when she will need to have the IUD removed or replaced.

Levonorgestrel-releasing IUD (LNG-IUD)

What is it?

- » The LNG-IUD is a T-shaped plastic device that steadily releases a small amount of levonorgestrel each day. (Levonorgestrel is a progestin hormone also used in some contraceptive implants and oral contraceptive pills.)
- ightharpoonup A specifically trained health-care provider inserts it into a woman's uterus through her vagina and cervix.
- » Also called the levonorgestrel-releasing intrauterine system, or hormonal IUD.
- » Marketed under such brand names as Jaydess, Kyleena, Liletta, Mirena and Skyla. The Jaydess, Kyleena and Skyla LNG-IUDs and their inserters are slightly smaller than the Liletta and Mirena ones.
- » Works by preventing sperm from fertilizing an egg.

How effective is the method?

- » One of the most effective and long-lasting methods.
 - Less than 1 pregnancy per 100 women using an LNG-IUD over the first year (2 per 1000 women). This means that 998 of every 1000 women using LNG-IUDs will not become pregnant.
 - A small risk of pregnancy remains beyond the first year of use and continues as long as the woman is using the LNG-IUD.
 - Over 5 years of use of the Mirena LNG-IUD: Less than 1 pregnancy per 100 women (5–8 per 1000 women).
 - Kyleena and Mirena are approved for up to 5 years of use.
 - Research suggests that Mirena may remain highly effective for up to 7 years.
 - Jaydess, Liletta and Skyla are approved for up to 3 years of use.
- » Return of fertility after LNG-IUD is removed: No delay.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Nearly all women can use LNG-IUDs. LNG-IUDs are safe and effective for nearly all women, including women who:

- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have just had an abortion or miscarriage (if no evidence of infection)
- » Are breastfeeding
- » Do hard physical work
- » Have had an ectopic pregnancy
- » Have had pelvic inflammatory disease (PID)
- » Have vaginal infections
- » Have anaemia
- » Have HIV clinical disease that is mild or with no symptoms, whether or not they are on antiretroviral therapy.

How do you use the method?

Client needs to have the LNG-IUD inserted by a trained health-care provider. A follow-up visit after her first monthly bleeding or 3–6 weeks after IUD insertion is recommended. No woman should be denied an IUD, however, just because follow-up would be difficult or not possible.



Some users report the following:

- » Most commonly, changes in bleeding patterns, including:
 - Lighter bleeding and fewer days of bleeding
 - Infrequent bleeding
 - Irregular bleeding
 - No monthly bleeding
 - Prolonged bleeding
- » Acne
- » Headaches
- » Breast tenderness or pain
- » Nausea
- » Weight gain
- » Dizziness
- » Mood changes
- » Other possible physical changes: Ovarian cysts.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy
 - Iron-deficiency anaemia.
- » May help protect against:
 - Endometrial cancer
 - Cervical cancer.
- » Reduces:
 - Menstrual cramps
 - Heavy monthly bleeding
 - Symptoms of endometriosis (pelvic pain, irregular bleeding)
 - Risk of ectopic pregnancy.

Known health risks, rare

» In the short term, PID may occur if the woman has gonorrhoea or chlamydia at the time of insertion.

Complications

- » Rare: Puncturing (perforation) of the wall of the uterus by the LNG-IUD or an instrument used for insertion. Usually heals without treatment.
- » Very rare: Miscarriage, preterm birth, or infection in the very rare case that the woman becomes pregnant with the LNG-IUD in place.

Giving advice on side-effects

Describe the most common side-effects

- » Changes in bleeding patterns: Irregular bleeding followed by lighter bleeding, fewer days of bleeding, infrequent bleeding, and then no monthly bleeding.
- » Acne, headaches, breast tenderness and pain, and possibly other side-effects.

Explain about these side-effects

- » Bleeding changes usually are not signs of illness.
- » Lack of bleeding does not mean pregnancy.
- » Bleeding irregularities usually become less 3–6 months after insertion. Many women have no bleeding at all after using the LNG-IUD for a year or two. Other side-effects also become less a few months after insertion.
- » The client can come back for help if side-effects bother her or if she has other concerns.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use an LNG-IUD. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use an LNG-IUD. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

- » Between 48 hours and 4 weeks after giving birth
- » Acute blood clot in deep veins of legs or lungs
- » Had breast cancer more than 5 years ago, and it has not returned
- » Severe cirrhosis or severe liver tumour
- » Noncancerous (benign) gestational trophoblast disease
- » Has current ovarian cancer
- » Is at very high individual risk for STIs at the time of insertion
- » Has severe or advanced HIV clinical disease
- » Has systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies and is not receiving immunosuppressive treatment.

Helping continuing users

Post-insertion follow-up visit (3-6 weeks)

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Ask her if she has:
 - Increasing or severe abdominal pain or pain during sex or urination
 - Unusual vaginal discharge
 - Fever or chills
 - Signs or symptoms of pregnancy
 - Felt the hard plastic of an IUD that has partially come out.

A routine pelvic examination at the follow-up visit is not required; however, It may be appropriate in some settings or for some clients. Conduct a pelvic examination particularly if the client's answers lead you to suspect infection or that the IUD has partially or completely come out.

Any visit

- 1. Ask how the client is doing with the method and about bleeding changes.
- 2. Ask a long-term client if she has had any new health problems. Address problems as appropriate. New health problems may require switching methods.
- 3. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.
- 4. Remind her how much longer the IUD will protect her from pregnancy.



Etonogestrel (ETG) one-rod implant

What is it? the method? Who can and method?

- » A small plastic rod, about the size of a matchstick, that releases a progestin, which is similar to the natural hormone progesterone in a woman's body.
- » A specifically trained provider performs a minor surgical procedure to place one rod under the skin on the inside of a woman's upper arm.
- » Does **not** contain estrogen, and so can be used throughout breastfeeding and by women who cannot use methods with estrogen.
- » Implanon NXT (Nexplanon): One rod containing etonogestrel, labelled for up to 3 years of use (a recent study shows it may be highly effective for 5 years). Replaces Implanon; Implanon NXT can be seen on X-ray and has an improved insertion device.
- » Works primarily by:
 - Preventing the release of eggs from the ovaries (ovulation)
 - Thickening cervical mucus (this blocks sperm from reaching an egg).

How effective is

- » One of the most effective and long-lasting methods.
 - Far less than 1 pregnancy per 100 women using implants over the first year (1 per 1000 women). This means that 999 of every 1000 women using implants will not become pregnant. Less than 1 pregnancy per 100 women over the duration of use.
 - A small risk of pregnancy remains beyond the first year of use and continues as long as the woman is using implants.
- » Return of fertility after implants are removed: No delay.
- » Protection against sexually transmitted infections (STIs): None.

cannot use the

- » Nearly all women can use implants safely and effectively, including women who:
 - Have or have not had children
 - Are married or are not married
 - Are of any age, including adolescents and women over 40 years old
 - Have just had an abortion, miscarriage or ectopic pregnancy
 - Smoke cigarettes, regardless of woman's age or number of cigarettes smoked
 - Are breastfeeding
 - Have anaemia now or had it in the past
 - Have varicose veins
- Are living with HIV, whether or not on antiretroviral therapy.

How do you use the method?

Insertion of implants must be done by a trained provider. It is important to have implants removed before they start to lose effectiveness. The woman can have a new set of implants inserted if she so wishes.

Some users report the following:

- » Changes in bleeding patterns, including:
 - First few months to a year:
 - Lighter bleeding and fewer days of bleeding
 - Prolonged bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding
 - After about 1 year:
 - Lighter bleeding and fewer days of bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding

Users of Implanon, Implanon NXT and Nexplanon are more likely to have infrequent bleeding, prolonged bleeding or no monthly bleeding than irregular bleeding.

- » Headaches
- » Abdominal pain
- » Acne (can improve or worsen)
- » Weight change
- » Breast tenderness
- » Dizziness
- » Mood changes
- » Nausea
- » Other possible physical changes: Enlarged ovarian follicles.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy, including ectopic pregnancy
 - Symptomatic pelvic inflammatory disease (PID).
- » May help protect against: Iron-deficiency anaemia.
- » Reduces: Risk of ectopic pregnancy.

Known health risks: None.



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Giving advice on side-effects

Describe the most common side-effects

- » Changes in bleeding pattern:
 - Irregular bleeding that lasts more than 8 days at a time over the first year
 - Later, regular, infrequent or no bleeding at all.
- » Headaches, abdominal pain, breast tenderness and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness. Lack of bleeding does not mean pregnancy.
- » Most side-effects usually become less or stop within the first year.
- » Side-effects are common, but some women do not have them.
- » Client can come back for help if side-effects bother her or if she has other concerns.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use implants. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use ETG one-rod. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

- » Acute blood clot in deep veins of legs or lungs
- » Unexplained vaginal bleeding before evaluation for possible serious underlying condition
- » Had breast cancer more than 5 years ago, and it has not returned
- » Severe cirrhosis of the liver or liver tumour
- » Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies, and not on immunosuppressive therapy.

Helping continuing users

Important: No routine return visit is required until it is time to remove the implants; however, the client should be clearly invited to return any time she wishes. **At any future visit:**

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
- 4. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.
- 5. If she wants to keep using implants and no new medical condition prevents it, remind her how much longer her implants will protect her from pregnancy.

Levonorgestrel (LNG) two-rod implant

What is it?

- » Small plastic rods, each about the size of a matchstick, that release a progestin, which is similar to the natural hormone progesterone in a woman's body.
- » A specifically trained provider performs a minor surgical procedure to place two rods under the skin on the inside of a woman's upper arm.
- » Does **not** contain estrogen, and so can be used throughout breastfeeding and by women who cannot use methods with estrogen.
- » Types of implants:
 - Jadelle: Two rods containing levonorgestrel, highly effective for 5 years
 - Levoplant (Sino-Implant (II)): Two rods containing levonorgestrel, labelled for up to 4 years of use
- » Work primarily by:
 - Preventing the release of eggs from the ovaries (ovulation)
 - Thickening cervical mucus (this blocks sperm from reaching an egg).

How effective is the method?

- » One of the most effective and long-lasting methods:
 - Far less than 1 pregnancy per 100 women using implants over the first year (1 per 1000 women). This means that 999 of every 1000 women using implants will not become pregnant. Less than 1 pregnancy per 100 women over the duration of use.
 - A small risk of pregnancy remains beyond the first year of use and continues as long as the woman is using implants.
 - For heavier women, the effectiveness of Jadelle and Levoplant may decrease near the end of the duration of use stated on the label. These users may
 want to replace their implants sooner.
- » Return of fertility after implants are removed: No delay.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Nearly all women can use implants safely and effectively, including women who:

- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have just had an abortion, miscarriage or ectopic pregnancy
- » Smoke cigarettes, regardless of woman's age or number of cigarettes smoked
- » Are breastfeeding
- » Have anaemia now or had it in the past
- » Have varicose veins
- » Are living with HIV, whether or not they are on antiretroviral therapy.

How do you use the method?

Insertion of implants must be done by a trained provider. It is important to have implants removed before they start to lose effectiveness. The woman can have a new set of implants inserted if she wants.



Some users report the following:

- » Changes in bleeding patterns, including:
 - First few months to a year:
 - Lighter bleeding and fewer days of bleeding
 - Prolonged bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding
 - After about 1 year:
 - Lighter bleeding and fewer days of bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding
- » Headaches
- » Abdominal pain
- » Acne (can improve or worsen)
- » Weight change
- » Breast tenderness
- » Dizziness
- » Mood changes
- » Nausea
- » Other possible physical changes: Enlarged ovarian follicles.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy, including ectopic pregnancy
 - Symptomatic pelvic inflammatory disease (PID).
- » May help protect against: Iron-deficiency anaemia.
- » Reduces: Risk of ectopic pregnancy.

Known health risks: None.

Giving advice on side-effects

Describe the most common side-effects

- » Changes in bleeding pattern:
 - Irregular bleeding that lasts more than 8 days at a time over the first year
 - Later, regular, infrequent or no bleeding at all.
- » Headaches, abdominal pain, breast tenderness and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness. Lack of bleeding does not mean pregnancy.
- » Most side-effects usually become less or stop within the first year.
- » Side-effects are common, but some women do not have them.
- » Client can come back for help if side-effects bother her or if she has other concerns.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use implants. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use LNG two-rod. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up. These conditions include:

- » Acute blood clot in deep veins of legs or lungs
- » Unexplained vaginal bleeding before evaluation for possible serious underlying condition
- » Breast cancer more than 5 years ago, and it has not returned
- » Severe cirrhosis of the liver or liver tumour
- » Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies, and not on immunosuppressive therapy.

Helping continuing users

Important: No routine return visit is required until it is time to remove the implants; however, the client should be clearly invited to return any time she wishes. **At any future visit:**

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
- 4. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.
- 5. If she wants to keep using implants and no new medical condition prevents it, remind her how much longer her implants will protect her from pregnancy.



DMPA injectable, administered intramuscularly

What is it? » Also known as DMPA-IM or progestin-only injectables. » The injectable contraceptive depot medroxyprogesterone acetate (DMPA) contains a progestin similar to the natural hormone progesterone in a woman's body. (In contrast, monthly injectables contain both estrogen and progestin.) » Does not contain estrogen, and so can be used throughout breastfeeding, starting 6 weeks after giving birth, and by women who cannot use methods with estrogen. » Given by injection into the muscle (intramuscular injection), the hormone is then released slowly into the bloodstream. » DMPA, the most widely used progestin-only injectable, is also known in its intramuscular form as "the shot", "the jab", "the injection", Depo, Depo-Provera and Petogen. » Works primarily by preventing the release of eggs from the ovaries (ovulation). How effective is » Effectiveness depends on getting injections regularly: Risk of pregnancy is greatest when a woman misses an injection. the method? As commonly used, about 4 pregnancies per 100 women using progestin-only injectables over the first year. This means that 96 of every 100 women using injectables will not become pregnant. When women have injections on time, less than 1 pregnancy per 100 women using progestin-only injectables over the first year (2 per 1000 women). » Return of fertility after injections are stopped: An average of about 4 months longer for DMPA than with most other methods. » Protection against sexually transmitted infections (STIs): None. Who can and Safe and suitable for nearly all women. Nearly all women can use progestin-only injectables safely and effectively, including women who: cannot use the » Have or have not had children method? » Are married or are not married » Are of any age, including adolescents and women over 40 years old » Have just had an abortion or miscarriage » Smoke cigarettes, regardless of woman's age or number of cigarettes smoked » Are breastfeeding, starting as soon as 6 weeks after childbirth » Are living with HIV, whether or not on antiretroviral therapy. How do you use 150 mg of DMPA given intramuscularly; should be given by a trained provider. the method?

Most users report some changes in monthly bleeding. Typically, these include:

- » First 3 months:
 - Irregular bleeding
 - Prolonged bleeding.
- » At 1 year:
 - No monthly bleeding
 - Infrequent bleeding
 - Irregular bleeding.

Some users report the following:

- » Weight gain
- » Headaches
- » Dizziness
- » Abdominal bloating and discomfort
- » Mood changes
- » Reduced sex drive
- » Other possible physical changes: Loss of bone density.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy
 - Cancer of the lining of the uterus (endometrial cancer)
 - Uterine fibroids.
- » May help protect against:
 - Symptomatic pelvic inflammatory disease (PID)
 - Iron-deficiency anaemia.
- » Reduces:
 - Sickle cell crises among women with sickle cell anaemia
 - Symptoms of endometriosis (pelvic pain, irregular bleeding).

Known health risks: None.



Giving advice on side-effects

Describe the most common side-effects

- » For the first few months, irregular bleeding, prolonged bleeding, frequent bleeding. Later, no monthly bleeding.
- » Weight gain (about 1–2 kg per year), headaches, dizziness and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness.
- » Side-effects are common, but some women do not have them.
- » The client can come back for help if side-effects bother her.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use progestin-only injectables. In special circumstances, however, when other more appropriate methods are not available or acceptabler, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use DMPA-IM. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

These conditions include:

- » Breastfeeding and less than 6 weeks since giving birth (considering the risks of another pregnancy and that a woman may have limited further access to injectables)
- » Severe high blood pressure (systolic 160 mmHg or higher or diastolic 100 mmHg or higher)
- » Acute blood clot in deep veins of legs or lungs
- » History of heart disease or current heart disease due to blocked or narrowed arteries (ischaemic heart disease)
- » History of stroke
- » Multiple risk factors for arterial cardiovascular disease, such as diabetes and high blood pressure
- » Unexplained vaginal bleeding before evaluation for possible serious underlying condition
- » Had breast cancer more than 5 years ago, and it has not returned
- » Diabetes for more than 20 years or damage to arteries, vision, kidneys or nervous system caused by diabetes
- » Severe cirrhosis or liver tumour
- » Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies and not on immunosuppressive treatment, or severe thrombocytopenia.

Helping continuing users

Repeat injection visits

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Give her the injection. Injection of DMPA can be given up to 4 weeks late.
- 4. Plan for her next injection. Agree on a date for her next injection (in 3 months or 13 weeks for DMPA). Remind her that she should try to come on time, but she should come back no matter how late she is.
- 5. Ask a long-term client if she has had any new health problems. Address problems as appropriate.
- 6. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.

DMPA injectable, administered subcutaneously

What is it?

- » Also known as DMPA-SC, progestin-only injectables, Depo-SubQ Provera and Sayana Press.
- » The injectable contraceptive depot medroxyprogesterone acetate (DMPA) contains a progestin similar to the natural hormone progesterone in a woman's body. (In contrast, monthly injectables contain both estrogen and progestin.)
- » Does not contain estrogen, and so can be used throughout breastfeeding, starting 6 weeks after giving birth, and by women who cannot use methods with estrogen.
- » Given by injection just under the skin (subcutaneous injection). The hormone is then released slowly into the bloodstream.
- » Works primarily by preventing the release of eggs from the ovaries (ovulation).
- » DMPA-SC can be self-injected.
- » DMPA-SC is meant only for subcutaneous injection (just under the skin) and not for injection into muscle.
- » DMPA-SC is available in two injection systems in the Uniject device (Sayana Press) and in prefilled, single-dose, conventional syringes (Depo-Provera). Both have short needles meant for injection just below the skin. With the Uniject system, the user squeezes a flexible reservoir that pushes the fluid through the needle. The Uniject system may be particularly useful for community-based programmes. Also, women can easily learn to give themselves subcutaneous injections with this system.

How effective is the method?

- » Effectiveness depends on getting injections regularly: Risk of pregnancy is greatest when a woman misses an injection.
 - As commonly used, about 4 pregnancies per 100 women using progestin-only injectables over the first year. This means that 96 of every 100 women using injectables will not become pregnant.
 - When women have injections on time, less than 1 pregnancy per 100 women using progestin-only injectables over the first year (2 per 1000 women).
- » Return of fertility after injections are stopped: An average of about 4 months longer for DMPA than with most other methods.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Safe and suitable for nearly all women. Nearly all women can use progestin-only injectables safely and effectively, including women who:

- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have just had an abortion or miscarriage
- » Smoke cigarettes, regardless of woman's age or number of cigarettes smoked
- » Are breastfeeding, starting as soon as 6 weeks after childbirth
- » Are living with HIV, whether or not they are on antiretroviral therapy.

How do you use the method?

104 mg of DMPA given subcutaneously (DMPA-SC), can be given by a trained provider **or the client can self-inject**. Make sure to teach the woman how to if she wishes to do so.



Most users report some changes in monthly bleeding.

- » First 3 months:
 - Irregular bleeding
 - Prolonged bleeding.
- » At 1 year:
 - No monthly bleeding
 - Infrequent bleeding
 - Irregular bleeding.

Some users report the following:

- » Weight gain
- » Headaches
- » Dizziness
- » Abdominal bloating and discomfort
- » Mood changes
- » Reduced sex drive
- » Other possible physical changes: Loss of bone density.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy
 - Cancer of the lining of the uterus (endometrial cancer)
 - Uterine fibroids.
- » May help protect against:
 - Symptomatic pelvic inflammatory disease (PID)
 - Iron-deficiency anaemia.
- » Reduces:
 - Sickle cell crises among women with sickle cell anaemia
 - Symptoms of endometriosis (pelvic pain, irregular bleeding).

Known health risks: None

Giving advice on side-effects

Describe the most common side-effects

- » For the first few months, irregular bleeding, prolonged bleeding, frequent bleeding. Later, no monthly bleeding.
- » Weight gain (about 1–2 kg per year), headaches, dizziness and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness.
- » Side-effects are common, but some women do not have them.
- » The client can come back for help if side-effects bother her.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use progestin-only injectables. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use DMPA-SC. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

- » Breastfeeding and less than 6 weeks since giving birth (considering the risks of another pregnancy and that a woman may have limited further access to injectables)
- » Severe high blood pressure (systolic 160 mmHg or higher, or diastolic 100 mmHg or higher)
- » Acute blood clot in deep veins of legs or lungs
- » History of heart disease or current heart disease due to blocked or narrowed arteries (ischaemic heart disease)
- » History of stroke
- » Multiple risk factors for arterial cardiovascular disease, such as diabetes and high blood pressure
- » Unexplained vaginal bleeding before evaluation for possible serious underlying condition
- » Had breast cancer more than 5 years ago, and it has not returned
- » Has had diabetes for more than 20 years or damage to arteries, vision, kidneys or nervous system caused by diabetes
- » Severe cirrhosis or liver tumour
- » Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies and not on immunosuppressive treatment, or severe thrombocytopenia.

Helping continuing users

Repeat injection visits

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Give her the injection or a supply for her to self-inject. Injection of DMPA can be given up to 4 weeks late.
- 4. Plan for her next injection. Agree on a date for her next injection (in 3 months or 13 weeks for DMPA). Remind her that she should try to come on time, but she should come back no matter how late she is.
- 5. Ask a long-term client if she has had any new health problems. Address problems as appropriate.
- 6. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.



Norethisterone enanthate injectable

What is it? » Also known as NET-EN, progestin-only injectables, Norigest, Noristerat and Syngestal. » The injectable contraceptive norethisterone enanthate (NET-EN) contains a progestin similar to the natural hormone progesterone in a woman's body. (In contrast, monthly injectables contain both estrogen and progestin.) » Does not contain estrogen, and so can be used throughout breastfeeding, starting 6 weeks after giving birth, and by women who cannot use methods with estrogen. » Given by injection into the muscle (intramuscular injection). The hormone is then released slowly into the bloodstream. » Works primarily by preventing the release of eggs from the ovaries (ovulation). How effective is » Effectiveness depends on getting injections regularly: Risk of pregnancy is greatest when a woman misses an injection. the method? As commonly used, about 4 pregnancies per 100 women using progestin-only injectables over the first year. This means that 96 of every 100 women using injectables will not become pregnant. When women have injections on time, less than 1 pregnancy per 100 women using progestin-only injectables over the first year (2 per 1000 women). » Return of fertility after injections are stopped: An average of about 1 month longer for NET-EN than with most other methods. » Protection against sexually transmitted infections (STIs): None. Who can and Safe and suitable for nearly all women. Nearly all women can use progestin-only injectables safely and effectively, including women who: cannot use the » Have or have not had children method? » Are married or are not married » Are of any age, including adolescents and women over 40 years old » Have just had an abortion or miscarriage » Smoke cigarettes, regardless of woman's age or number of cigarettes smoked » Are breastfeeding, starting as soon as 6 weeks after childbirth » Are living with HIV, whether or not they are on antiretroviral therapy. How do you use 200 mg of NET-EN given intramuscularly; should be given by a trained provider. the method?

NET-EN affects bleeding patterns less than DMPA. NET-EN users have fewer days of bleeding in the first 6 months and are less likely than DMPA users to have no monthly bleeding after 1 year. Some users report the following:

- » Weight gain
- » Headaches
- » Dizziness
- » Abdominal bloating and discomfort
- » Mood changes
- » Reduced sex drive
- » Other possible physical changes: Loss of bone density.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy
 - Iron-deficiency anaemia.
- » NET-EN may offer many of the same health benefits as DMPA, but this list of benefits comprises only those for which there is available research evidence.

Known health risks: None.

Giving advice on side-effects

Describe the most common side-effects

- » For the first few months, irregular bleeding, prolonged bleeding, frequent bleeding. Later, no monthly bleeding.
- » Weight gain (about 1–2 kg per year), headaches, dizziness and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness.
- » Side-effects are common, but some women do not have them.
- » The client can come back for help if side-effects bother her.



Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use progestin-only injectables. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use NET-EN. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

- » Breastfeeding and less than 6 weeks since giving birth (considering the risks of another pregnancy and that a woman may have limited further access to injectables)
- » Severe high blood pressure (systolic 160 mmHg or higher, or diastolic 100 mmHg or higher)
- » Acute blood clot in deep veins of legs or lungs
- » History of heart disease or current heart disease due to blocked or narrowed arteries (ischaemic heart disease)
- » History of stroke
- » Multiple risk factors for arterial cardiovascular disease, such as diabetes and high blood pressure
- » Unexplained vaginal bleeding before evaluation for possible serious underlying condition
- » Had breast cancer more than 5 years ago, and it has not returned
- » Has had diabetes for more than 20 years or damage to arteries, vision, kidneys or nervous system caused by diabetes
- » Severe cirrhosis or liver tumour
- » Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies and not on immunosuppressive treatment, or severe thrombocytopenia.

Helping continuing users

Repeat injection visits

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Give her the injection. Injection of NET-EN can be given up to 2 weeks late.
- 4. Plan for her next injection. Agree on a date for her next injection (in 2 months for NET-EN). Remind her that she should try to come on time, but she should come back no matter how late she is.
- 5. Ask a long-term client if she has had any new health problems. Address problems as appropriate.
- 6. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.

Progestogen-only pills (POPs)

What is it?

- » Pills that contain very low doses of a progestin similar to the natural hormone progesterone in a woman's body.
- » Do not contain estrogen, and so can be used throughout breastfeeding and by women who cannot use methods with estrogen.
- » POPs are also called "minipills" and progestin-only oral contraceptives.
- » Work primarily by:
 - Thickening cervical mucus (this blocks sperm from meeting an egg)
 - Disrupting the menstrual cycle, including preventing the release of eggs from the ovaries (ovulation).

How effective is the method?

- » Effectiveness depends on the user: For women who have monthly bleeding, risk of pregnancy is greatest if pills are taken late or missed completely.
 - Breastfeeding women:
 - As commonly used, about 1 pregnancy per 100 women using POPs over the first year. This means that 99 of every 100 women will not become pregnant.
 - When pills are taken every day, less than 1 pregnancy per 100 women using POPs over the first year (3 per 1000 women).
 - Less effective for women not breastfeeding:
 - As commonly used, about 7 pregnancies per 100 women using POPs over the first year. This means that 93 of every 100 women will not become pregnant.
 - When pills are taken every day at the same time, less than 1 pregnancy per 100 women using POPs over the first year (3 per 1000 women).
- » Return of fertility after POPs are stopped: No delay.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Safe and suitable for nearly all women. Nearly all women can use POPs safely and effectively, including women who:

- » Are breastfeeding (she can start immediately after childbirth)
- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have just had an abortion, miscarriage or ectopic pregnancy
- » Smoke cigarettes, regardless of woman's age or number of cigarettes smoked
- » Have anaemia now or had it in the past
- » Have varicose veins
- » Are living with HIV, whether or not on antiretroviral therapy.



How do you use the method?

- 1. Give pills give as many packs as possible, even as much as a year's supply (11 packs of 35 pills each or 13 packs of 28 pills each).
- 2. Explain pill pack.
 - Show which kind of pack 28 pills or 35 pills
 - Explain that all pills in POP packs are the same colour and all are active pills containing a hormone that prevents pregnancy.
 - Show how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills.
- 3. Give key instructions.
 - Take one pill each day until the pack is empty.
 - Women who are not breastfeeding should take a pill at the same time each day taking a pill more than 3 hours late makes it less effective.
 - Discuss cues for taking a pill every day: Linking pill-taking to a daily activity such as cleaning her teeth may help her remember.
- 4. Explain starting next pack.
 - When she finishes one pack, she should take the first pill from the next pack on the very next day.
 - It is very important to start the next pack on time starting a pack late risks pregnancy.
- 5. Provide back-up method and explain use.
 - Sometimes woman may need to use a back-up method, such as when she misses pills or is late taking a pill.
 - Back-up methods include abstinence, male or female condoms, spermicides, and withdrawal. Tell her that spermicides and withdrawal are the least
 effective contraceptive methods.
- 6. Give her condoms, if possible.
- 7. Explain that effectiveness decreases when breastfeeding stops.
 - Without the additional protection of breastfeeding itself, POPs are not as effective as most other hormonal methods.
 - When she stops breastfeeding, she can continue taking POPs if she is satisfied with the method, or she is welcome to come back for another method.

What are the side-effects?

Some users report the following:

- » Changes in bleeding patterns, including:
 - For breastfeeding women, longer delay in return of monthly bleeding after childbirth (lengthened postpartum amenorrhoea)
 - Frequent bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - Prolonged bleeding
 - No monthly bleeding

Breastfeeding also affects a woman's bleeding patterns.

- » Headaches
- » Dizziness
- » Mood changes
- » Breast tenderness
- » Abdominal pain
- » Nausea
- » Other possible physical changes: For women not breastfeeding, enlarged ovarian follicles.

Known health benefits

» Help protect against: Risks of pregnancy.

Known health risks: None.

Giving advice on side-effects

Describe the most common side-effects

- » Breastfeeding women normally do not have monthly bleeding for a few months after giving birth. POPs lengthen this period of time.
- » Women who are not breastfeeding may have frequent or irregular bleeding for the first few months, followed by regular bleeding or continued irregular bleeding.
- » Headaches, dizziness, breast tenderness and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness. Lack of bleeding does not mean pregnancy.
- » Some side-effects usually become less or stop within the first few months of using POPs. Bleeding changes, however, usually persist.
- » Side-effects are common, but some women do not have them.

Explain what to do in case of side-effects

- » Keep taking POPs. Skipping pills risks pregnancy.
- » Try taking pills with food or at bedtime to help avoid nausea.
- » The client can come back for help if side-effects bother her or if she has other concerns.



Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use POPs. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use POPs. The provider needs to consider the severity of the woman's condition and, for most conditions, whether she will have access to follow-up.

- » Acute blood clot in deep veins of legs or lungs
- » Had breast cancer more than 5 years ago, and it has not returned
- » Severe cirrhosis or severe liver tumour
- » Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies
- » Taking barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin or rifabutin. A back-up contraceptive method should also be used because these medications reduce the effectiveness of POPs.

Helping continuing users

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Ask if she often has problems remembering to take a pill every day. If so, discuss ways to remember, making up for missed pills, and emergency contraceptive pills (ECPs), or choosing another method. Adolescents may need extra support.
- 4. Give her more pill packs as much as a full year's supply (11 or 13 packs), if possible. Plan her next resupply visit before she will need more pills.
- 5. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
- 6. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.

Combined oral contraceptive (COC) pill

What is it?

- » Pills that contain low doses of two hormones a progestin and an estrogen similar to the natural hormones progesterone and estrogen in a woman's body.
- » COCs are also called "the pill", low-dose combined pills, oral contraceptive pills (OCPs) and oral contraceptives (OCs).
- » Work primarily by preventing the release of eggs from the ovaries (ovulation).

How effective is the method?

- » Effectiveness depends on the user: Risk of pregnancy is greatest when a woman starts a new pill pack 3 or more days late, or misses three or more pills near the beginning or end of a pill pack.
 - As commonly used, about 7 pregnancies per 100 women using COCs over the first year. This means that 93 of every 100 women using COCs will not become pregnant.
 - When no pill-taking mistakes are made, less than 1 pregnancy per 100 women using COCs over the first year (3 per 1000 women).
- » Return of fertility after COCs are stopped: No delay.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Safe and suitable for nearly all women. Nearly all women can use COCs safely and effectively, including women who:

- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have given birth and breastfeeding, after a period of time
- » Have just had an abortion, miscarriage or ectopic pregnancy
- » Smoke cigarettes if under 35 years old
- » Have anaemia now or had it in the past
- » Have varicose veins
- » Are living with HIV, whether or not they are on antiretroviral therapy.

How do you use the method?

- 1. Give pills give up to 1 year's supply (13 packs) depending on the woman's preference and planned use.
- 2. Explain pill pack.
 - Show which kind of pack 21 pills or 28 pills.
 - With 28-pill packs, point out that the last 7 pills are a different colour and do not contain hormones (some brands may differ).
 - Show how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills.
- 3. Give key instructions.
 - Take one pill each day until the pack is empty.
 - Discuss cues for taking a pill every day: Linking pill-taking to a daily activity such as cleaning her teeth may help a woman remember.
 - Taking pills at the same time each day helps a woman to remember them. It may also help reduce some side-effects.
- 4. Explain starting next pack.
 - 28-pill packs: When she finishes one pack, a woman should take the first pill from the next pack on the very next day.
 - 21-pill packs: After she takes the last pill from one pack, a woman should wait 7 days no more and then take the first pill from the next pack.
 - It is very important to start the next pack on time. Starting a pack late risks pregnancy.
- 5. Provide back-up method and explain use.
 - Sometimes the woman may need to use a back-up method, such as when she misses pills.
 - Back-up methods include abstinence, male or female condoms, spermicides, and withdrawal. Tell her that spermicides and withdrawal are the least effective contraceptive methods. Give her condoms, if possible.
 - If she misses three or more hormonal pills, she can consider emergency contraceptive pills (ECPs).



What are the side-effects?

Some users report the following:

- » Changes in bleeding patterns, including:
 - Lighter bleeding and fewer days of bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding
- » Headaches
- » Dizziness
- » Nausea
- » Breast tenderness
- » Weight change
- » Mood changes
- » Acne (can improve or worsen, but usually improves)
- » Other possible physical changes: Blood pressure increases a few points (mmHg); when increase is due to COCs, blood pressure declines quickly after use of COCs stops.

Known health benefits

- » Help protect against:
 - Risks of pregnancy
 - Cancer of the lining of the uterus (endometrial cancer)
 - Cancer of the ovary
 - Symptomatic pelvic inflammatory disease (PID).
- » May help protect against:
 - Ovarian cysts
 - Iron-deficiency anaemia.
- » Reduce:
 - Menstrual cramps
 - Menstrual bleeding problems
 - Ovulation pain
 - Excess hair on face or body
 - Symptoms of polycystic ovarian syndrome (irregular bleeding, acne, excess hair on face or body)
 - Symptoms of endometriosis (pelvic pain, irregular bleeding).

Known health risks

- » Very rare: Blood clot in deep veins of legs or lungs (deep-vein thrombosis or pulmonary embolism)
- » Extremely rare:
 - Stroke
 - Heart attack.

Giving advice on side-effects

Describe the most common side-effects

- » In the first few months, bleeding at unexpected times (irregular bleeding). Then lighter, shorter and more regular monthly bleeding.
- » Headaches, breast tenderness, weight change and possibly other side-effects.

Explain about these side-effects

- » Side-effects are not signs of illness.
- » Most side-effects usually become less or stop within the first few months of using COCs.
- » Side-effects are common, but some women do not have them.

Explain what to do in case of side-effects

- » Keep taking COCs. Skipping pills risks pregnancy and can make some side-effects worse.
- » Take each pill at the same time every day to help reduce irregular bleeding and also help with remembering to take pills.
- » Take pills with food or at bedtime to help avoid nausea.
- » The client can come back for help if side-effects bother her or if she has other concerns.

Using clinical judgement in special cases

Usually, a woman with any of the conditions listed below should not use COCs. In special circumstances, however, when other more appropriate methods are not available or acceptable, a qualified provider who can carefully assess a specific woman's condition and situation may decide that she can use COCs. The provider needs to consider the severity of her condition and, for most conditions, whether she will have access to follow-up.

- » Not breastfeeding and less than 3 weeks since giving birth, without additional risk that she might develop a blood clot in a deep vein thrombosis
- » Not breastfeeding and between 3 and 6 weeks postpartum with additional risk that she might develop venous thromboembolism (VTE)
- » Primarily breastfeeding between 6 weeks and 6 months since giving birth
- » Age 35 or older and smokes fewer than 15 cigarettes a day
- » High blood pressure (systolic blood pressure between 140 and 159 mmHg or diastolic blood pressure between 90 and 99 mmHg)
- » Controlled high blood pressure, where continuing evaluation is possible
- » History of high blood pressure, where blood pressure cannot be taken (including pregnancy-related high blood pressure)
- » History of jaundice while using COCs in the past $\,$
- » Gall bladder disease (current or medically treated)
- » Age 35 or older and has migraine headaches without aura $\,$
- » Younger than age 35 and has migraine headaches without aura that have developed or got worse while using COCs
- » Had breast cancer more than 5 years ago, and it has not returned
- » Has had diabetes for more than 20 years or damage to arteries, vision, kidneys or nervous system caused by diabetes
- » Multiple risk factors for arterial cardiovascular disease such as older age, smoking, diabetes and high blood pressure
- » Taking barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin or rifabutin. A back-up contraceptive method should also be used because these medications reduce the effectiveness of COCs
- $\,{}^{\mathrm{a}}$ Taking lamotrigine. Combined hormonal methods may make lamotrigine less effective.



Helping continuing users

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
- 3. Ask if she often has problems remembering to take a pill every day. If so, discuss ways to remember, making up missed pills, and ECPs, or choosing another method. Adolescents may need extra support.
- 4. Give her more pill packs a full year's supply (13 packs), if possible. Plan her next resupply visit before she will need more pills.
- 5. Every year or so, check blood pressure if possible.
- 6. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
- 7. Ask a long-term client about major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow up as needed.

Combined contraceptive patch

What is it?

- » A small, thin square of flexible plastic worn on the body.
- » Continuously releases two hormones a progestin and an estrogen, similar to the natural hormones progesterone and estrogen in a woman's body directly through the skin into the bloodstream.
- » The woman puts on a new patch every week for 3 weeks, then no patch for the fourth week. During this fourth week, the woman will have her monthly bleeding.
- » Also called Ortho Evra and Evra.
- » Works primarily by preventing the release of eggs from the ovaries (ovulation).

How effective is the method?

- » Effectiveness depends on the user: Risk of pregnancy is greatest when a woman is late to change the patch
 - As commonly used, about 7 pregnancies per 100 women using the combined patch over the first year. This means that 93 of every 100 women using the combined patch will not become pregnant
 - When no mistakes are made with use of the patch, less than 1 pregnancy per 100 women using a patch over the first year (3 per 1000 women)
 - Pregnancy rates may be slightly higher among women weighing 90 kg or more.
- » Return of fertility after patch use is stopped: No delay.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Safe and suitable for nearly all women. Nearly all women can use COCs safely and effectively, including women who:

- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have given birth and breastfeeding, after a period of time
- » Have just had an abortion, miscarriage or ectopic pregnancy
- » Smoke cigarettes if under 35 years old
- » Have anaemia now or had it in the past
- » Have varicose veins
- » Are living with HIV, whether or not they are on antiretroviral therapy.

How do you use the method?

- » Explain how to remove the patch from the pouch and remove backing.
 - Explain to the user that she should tear the foil pouch along the edge.
 - She should then pull out the patch and peel away the backing without touching the sticky surface.
- » Show her where and how to apply the patch.
 - Explain that she can apply it on the upper outer arm, back, stomach, abdomen or buttocks, wherever it is clean and dry, but not on the breasts.
 - She must press the sticky, medicated part against her skin for 10 seconds; she should run her finger along the edge to make sure it sticks.
- » The patch will stay on even during work, exercise, swimming and bathing.
- » She must change the patch every week for 3 weeks in a row.
- » She should apply each new patch on the same day of each week the patch-change day; for example, if she puts on her first patch on a Sunday, all of her patches should be applied on a Sunday.
- » Explain that to avoid irritation, she should not apply the new patch to the same place on the skin where the previous patch was.
- » She should not wear a patch on the fourth week; she will probably have monthly bleeding that week.
- » After the patch-free week, she should apply a new patch.
- » She should never go without wearing a patch for more than 7 days. Doing so risks pregnancy.



What are the side-effects?

Some users report the following:

- » Skin irritation or rash where the patch is applied
- » Changes in bleeding patterns:
 - Lighter bleeding and fewer days of bleeding
 - Irregular bleeding
 - Prolonged bleeding
 - No monthly bleeding
- » Headaches
- » Nausea
- » Vomiting
- » Breast tenderness and pain
- » Abdominal pain
- » Flu symptoms/upper respiratory infection
- » Irritation, redness or inflammation of the vagina (vaginitis).

Long-term studies of the patch are limited, but researchers expect that its health benefits and risks are similar to those of combined oral contraceptives.

Known health benefits

- » Helps protect against:
 - Risks of pregnancy
 - Cancer of the lining of the uterus (endometrial cancer)
 - Cancer of the ovary
 - Symptomatic pelvic inflammatory disease (PID).
- » May help protect against:
 - Ovarian cysts
 - Iron-deficiency anaemia.
- » Reduces:
 - Menstrual cramps
 - Menstrual bleeding problems
 - Ovulation pain
 - Excess hair on face or body
 - Symptoms of polycystic ovarian syndrome (irregular bleeding, acne, excess hair on face or body)
 - Symptoms of endometriosis (pelvic pain, irregular bleeding).

Known health risks of COCs

- » Very rare: Blood clot in deep veins of legs or lungs (deep vein thrombosis or pulmonary embolism).
- » Extremely rare:
 - Stroke
 - Heart attack.

Giving side-e	g advice on ffects	No guidance available.
judger	clinical ment in al cases	No guidance available.
Helpin contin	ng Juing users	 Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs. Ask if she often has problems remembering to take a pill every day. If so, discuss ways to remember, making up missed pills, and emergency contraceptive pills (ECPs), or choosing another method. Adolescents may need extra support. Give her more pill packs – a full year's supply (13 packs), if possible. Plan her next resupply visit before she will need more pills. Every year or so, check blood pressure if possible. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
		7. Ask a long-term client about major life changes that may affect her needs – particularly plans for having children and STI/HIV risk. Follow up as needed.

Combined contraceptive vaginal ring (CVR)

What is it?	» It is a flexible ring that a woman places in her vagina.
	» Continuously releases two hormones – a progestin and an estrogen, similar to the natural hormones progesterone and estrogen in a woman's body – from inside the ring. Hormones are absorbed through the wall of the vagina directly into the bloodstream.
	» She leaves the ring in place for 3 weeks, then removes it for the fourth week. During this fourth week the woman will have monthly bleeding.
	» Also called NuvaRing.
	» Works primarily by preventing the release of eggs from the ovaries (ovulation).
How effective is	Effectiveness depends on the user: Risk of pregnancy is greatest when a woman is late to start a new ring.
the method?	» As commonly used, about 7 pregnancies per 100 women using the CVR over the first year. This means that 93 of every 100 women using the CVR will not become pregnant.
	» When no mistakes are made with use of the CVR, less than 1 pregnancy per 100 women using the CVR over the first year (3 per 1000 women).
	– Return of fertility after ring use is stopped: No delay.
	 Protection against sexually transmitted infections (STIs): None.



Who can and cannot use the method?

Safe and suitable for nearly all women. Nearly all women can use COCs safely and effectively, including women who:

- » Have or have not had children
- » Are married or are not married
- » Are of any age, including adolescents and women over 40 years old
- » Have given birth and breastfeeding, after a period of time
- » Have just had an abortion, miscarriage or ectopic pregnancy
- » Smoke cigarettes if under 35 years old
- » Have anaemia now or had it in the past
- » Have varicose veins
- » Are living with HIV, whether or not they are on antiretroviral therapy.

How do you use the method?

- » Explain how to insert the ring.
 - The user can choose the position most comfortable for her for example, standing with one leg up, squatting or lying down.
 - She should press opposite sides of the ring together and gently push the folded ring entirely inside the vagina.
 - The exact position is not important, but inserting it deeply helps it to stay in place, and she is less likely to feel it; the muscles of the vagina naturally keep the ring in place.
- » Explain that the ring must be left in place for 3 weeks.
 - She should leave the ring in place at all times, every day and night for 3 weeks.
- » She can take the ring out at the end of the third week and dispose of it in a waste receptacle.
- » She should take out the ring for the fourth week.
 - To remove the ring, she can hook her index finger inside it, or squeeze the ring between her index and middle fingers, and pull it out
 - She will probably have monthly bleeding this week.
- » If she forgets and leaves the ring in for as long as a fourth week, no special action is needed.
- » Ring should never be left out for more than 48 hours until the fourth week.
- » The ring can be removed for sex, cleaning or other reasons, although removing it is not necessary and is not recommended because some women forget to put it back within 48 hours.
- » If the ring slips out, the woman should rinse it in clean water and immediately reinsert it.

What are the side-effects?

- » Long-term studies of the vaginal ring are limited, but researchers expect that its health benefits and risks are similar to those of combined oral contraceptives. Evidence to date has not shown adverse effects.
- » Side-effects reported by users of COCs include:
 - Changes in bleeding patterns, including:
 - Lighter bleeding and fewer days of bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding
 - Headaches
 - Dizziness
 - Nausea
 - Breast tenderness
 - Weight change
 - Mood changes
 - Acne (can improve or worsen, but usually improves)
 - Other possible physical changes: Blood pressure increases a few points (mmHg); when increase is due to COCs, blood pressure declines quickly after use of COCs stops.

Known health benefits of COCs

- » Help protect against:
 - Risks of pregnancy
 - Cancer of the lining of the uterus (endometrial cancer)
 - Cancer of the ovary
 - Symptomatic pelvic inflammatory disease (PID).
- » May help protect against:
 - Ovarian cysts
 - Iron-deficiency anaemia.
- » Reduce:
 - Menstrual cramps
 - Menstrual bleeding problems
 - Ovulation pain
 - Excess hair on face or body
 - Symptoms of polycystic ovarian syndrome (irregular bleeding, acne, excess hair on face or body)
 - Symptoms of endometriosis (pelvic pain, irregular bleeding).

Known health risks of COCs

- » Very rare: Blood clot in deep veins of legs or lungs (deep vein thrombosis or pulmonary embolism)
- » Extremely rare:
 - Stroke
 - Heart attack.



Giving advice on side-effects	No guidance available.
Using clinical	No guidance available.
judgement in	
special cases	
Helping	1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
continuing users	2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs.
	3. Ask if she often has problems remembering to take a pill every day. If so, discuss ways to remember, making up missed pills, and emergency contraceptive
	pills (ECPs), or choosing another method. Adolescents may need extra support.
	4. Give her more pill packs – a full year's supply (13 packs), if possible. Plan her next resupply visit before she will need more pills.
	5. Every year or so, check blood pressure if possible.
	6. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
	7. Ask a long-term client about major life changes that may affect her needs – particularly plans for having children and STI/HIV risk. Follow up as needed.

Progesterone-releasing vaginal ring (PVR)

What is it?	» A smooth, soft, flexible silicone ring placed in the vagina to prolong lactational amenorrhoea (postponing the return of monthly bleeding) and help breastfeeding women space pregnancies.
	» Continuously releases natural progesterone hormone – similar to that in a woman's body – from inside the ring. The hormone passes through the wall of the vagina directly into the bloodstream. This ring does not contain estrogen.
	» Use of the ring starts 4–9 weeks after giving birth. Each ring is kept in place for 90 days. The woman can then replace it with a new ring immediately. Up to 4 rings can be used, one after another, with no breaks.
	» Works by preventing release of an egg from the ovaries (ovulation). Progesterone extends the postpartum amenorrhoea of the breastfeeding woman. That is, it delays the return of monthly bleeding.
	» Safe and effective option for a woman:
	– Who has a baby at least 4 weeks old
	 Who is breastfeeding her baby at least four times per day and plans to continue breastfeeding
	 Whose monthly bleeding has not returned.
How effective is	» One or 2 pregnancies per 100 women using the PVR for a year.
the method?	» Return of fertility after use is stopped: No delay.
	» Protection against sexually transmitted infections (STIs): None.
Who can and cannot use the method?	Suitable for postpartum women who are actively breastfeeding at least four times per day. Refer to <i>Medical eligibility criteria</i> (12) for additional guidance on who can and cannot use the method.

How do you use the method?

- » Explain how to insert the ring.
 - The user can choose the position most comfortable for her for example, standing with one leg up, squatting or lying down
 - She should press opposite sides of the ring together and, with her index finger, gently push the ring entirely inside the vagina as far as she can; it can help to push down with the muscles of the vagina while inserting the ring.
 - The exact position of the ring in the vagina is not important, but inserting it deeply helps it to stay in place, and the user is less likely to feel it; the muscles of the vagina naturally keep the ring in place.
 - She should not feel the ring after she places it into her vagina. If she feels the ring in her vagina, she has a sensation of it slipping or it feels uncomfortable, she may not have pushed it far enough back into her vagina; instruct her to use a clean finger to gently push the ring as far as she can into her vagina.

 There is no danger of the ring being pushed too far up in the vagina, breaking during insertion or getting lost.
- » Explain that the ring must be left in for 90 days.
 - She should keep the ring in place at all times to maintain effectiveness.
- » To continue avoiding pregnancy, the user can take the ring out at the end of the 90 days and replace it immediately with a new ring. She can use four rings, for up to 1 year of use in the postpartum period.
- » The ring can be disposed of in a waste receptacle. Disposing of the ring in a flush toilet is not recommended.
- » The ring should never be left out for more than 2 hours.
 - The ring should be left in place always; some women may remove the ring for sex or for cleaning, but this is not necessary and not recommended because some women forget to put it back within 2 hours.
- » If the ring slips out completely, the woman should rinse it in clean water and immediately put it back in place.
- » Explain that her partner may be able to feel the ring; this generally does not interfere with sex or decrease sexual pleasure.

What are the side-effects?

Some users report the following:

- » Spotting or irregular bleeding
- » Low-abdominal pain
- » Breast pain
- » Vaginal discharge.

Known health benefits and health risks

- » No change in breast-milk production or composition; the method supports continued breastfeeding and healthy infant nutrition.
- » Safe and effective, based on several 1-year studies. Its health risks may be like those of progestin-only pills.
- » Women who are actively breastfeeding and are at least 4 weeks postpartum can safely use the PVR.

Giving advice on side-effects

No guidance available.

Using clinical judgement in special cases

No guidance available.

Helping continuing users

No guidance available.



Lactational amenorrhoea method (LAM)

What is it?

- » A temporary family planning method based on the natural effect of breastfeeding on fertility. ("Lactational" means related to breastfeeding; "amenorrhoea" means not having monthly bleeding.)
- » LAM requires three conditions all three must be met.
- 1. The mother's monthly bleeding has not returned.
- 2. The baby is fully or nearly fully breastfed and is fed often, day and night.
- 3. The baby is less than 6 months old.
- » "Fully breastfeeding" includes both exclusive breastfeeding (the infant receives no other liquid or food, not even water, in addition to breast-milk) and almost-exclusive breastfeeding (the infant receives vitamins, water, juice or other nutrients once in a while in addition to breast-milk).
- » "Nearly fully breastfeeding" means that the infant receives some liquid or food in addition to breast-milk, but the majority of feeds (more than three quarters of all feeds) are breast-milk.
- » Works primarily by preventing the release of eggs from the ovaries (ovulation). Frequent breastfeeding temporarily prevents the release of the natural hormones that cause ovulation.

How effective is the method?

- » Effectiveness depends on the user: Risk of pregnancy is greatest when a woman cannot fully or nearly fully breastfeed her infant.
 - As commonly used, about 2 pregnancies per 100 women using LAM in the first 6 months after childbirth. This means that 98 of every 100 women relying on LAM will not become pregnant.
 - When used correctly, less than 1 pregnancy per 100 women using LAM in the first 6 months after childbirth.
- » Return of fertility after LAM is stopped: Depends on how much the woman continues to breastfeed.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

All breastfeeding women can safely use LAM, but a woman may want to consider other contraceptive methods if she:

- » Has HIV infection
- » Is using certain medications during breastfeeding (including mood-altering drugs, reserpine, ergotamine, antimetabolites, cyclosporine, high doses of corticosteroids, bromocriptine, radioactive drugs, lithium and certain anticoagulants)
- » The newborn has a condition that makes it difficult to breastfeed (including being small-for-date or premature and needing intensive neonatal care, unable to digest food normally, or having deformities of the mouth, jaw or palate).

How do you use the method?

- » Breastfeed often an ideal pattern is feeding on demand (i.e. whenever the baby wants to be fed) and at least 10–12 times a day in the first few weeks after childbirth and thereafter 8–10 times a day, including at least once at night in the first months.
- » Daytime feedings should be no more than 4 hours apart, and night-time feedings no more than 6 hours apart.
- » Some babies may not want to breastfeed 8–10 times a day and may want to sleep through the night. These babies may need gentle encouragement to breastfeed more often.
- » Start other foods at 6 months.
 - Start giving other foods in addition to breast-milk when the baby is 6 months old; at this age, breast-milk can no longer fully nourish a growing baby.

What are the	» None, any problems are the same as for other breastfeeding women.
side-effects?	Known health benefits
	» Helps protect against risks of pregnancy.
	» Encourages the best breastfeeding patterns, with health benefits for both mother and baby.
	Known health risks: None.
Giving advice on side-effects	None
Using clinical judgement in special cases	None
Helping	Helping clients switch to a continuing method
continuing users	 A woman can switch to another method any time she wants while using LAM. If she still meets all three LAM criteria, it is reasonably certain she is not pregnant. She can start a new method with no need for a pregnancy test, examination or evaluation. To continue preventing pregnancy, a woman must switch to another method as soon as any one of the three LAM criteria no longer applies. Help the woman choose a new method before she needs it. If she will continue to breastfeed, she can choose from several hormonal or nonhormonal methods, depending on how much time has passed since childbirth. After 6 months, if a woman wants to continue breastfeeding, she can consider the progesterone-releasing vaginal ring (PVR).

Emergency contraceptive pills (ECPs)

What is it?	» ECPs are sometimes called "morning after" pills or postcoital contraceptives.
	» Work by preventing or delaying the release of eggs from the ovaries (ovulation). They do not work if a woman is already pregnant. (The copper-bearing IUD also can be used for emergency contraception.)
	» What pills can be used as ECPs?
	A special ECP product with levonorgestrel only or ulipristal acetate (UPA)
	 Progestin-only pills with levonorgestrel or norgestrel
	 Combined oral contraceptives with estrogen and a progestin – levonorgestrel, norgestrel or norethindrone (also called norethisterone).
How effective is	» If 100 women each had sex once during the second or third week of the menstrual cycle without using contraception, 8 women would likely become pregnant.
the method?	– If all 100 women used ulipristal acetate ECPs, fewer than 1 woman would likely become pregnant.
	– If all 100 women used progestin-only ECPs, 1 woman would likely become pregnant.
	 If all 100 women used combined estrogen and progestin ECPs, 2 women would likely become pregnant.
	» Return of fertility after taking ECPs: No delay. A woman can become pregnant immediately after taking ECPs. Taking ECPs prevents pregnancy only from acts of sex that took place in the 5 days before. They will not protect a woman from pregnancy from acts of sex more than 24 hours after she takes ECPs. To stay protected from pregnancy, women must begin to use another contraceptive method.
	» Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?	Safe and suitable for all women. » Tests and examinations are not necessary for using ECPs.
How do you use the method?	When to take them » As soon as possible after unprotected sex. The sooner ECPs are taken after unprotected sex, the better they prevent pregnancy. » Can help to prevent pregnancy when taken any time up to 5 days after unprotected sex.
	Give pill (or pills) » She can take the pill or pills immediately. » If she is using a two-dose regimen, tell her to take the next dose in 12 hours.
What are the side-effects?	Some users report the following: » Changes in bleeding patterns, including: – Slight irregular bleeding for 1–2 days after taking ECPs – Monthly bleeding that starts earlier or later than expected.
	 » In the first few days after taking ECPs: — Nausea — Abdominal pain — Fatigue — Headaches
	 Breast tenderness Dizziness Vomiting. Known health benefits
	 Help protect against: Risks of pregnancy. Known health risks: None.

Giving advice on side-effects

- » Describe the most common side-effects
 - Nausea, abdominal pain, possibly others
 - Slight bleeding or change in timing of monthly bleeding
 - Side-effects are not signs of illness and they do not last long most women have no side-effects.
- » Explain what to do about side-effects
 - Nausea:
 - Routine use of antinausea medications is not recommended.
 - Women who have had nausea with previous ECP use or with the first dose of a two-dose regimen can take antinausea medication such as 25–50 mg meclizine hydrochloride (e.g. Agyrax, Antivert, Bonine, Postafene) half to 1 hour before taking ECPs.
 - Vomiting:
 - If the woman vomits within 2 hours after taking progestin-only or combined ECPs, she should take another dose.
 - If she vomits within 3 hours of taking ulipristal acetate ECPs, she should take another dose. (She can use antinausea medication with this repeat dose, as above.)
 - If vomiting continues, she can take a repeat dose of progestin-only or combined ECPs by placing the pills high in her vagina.
 - If vomiting occurs more than 2 hours after taking progestin-only or combined ECPs, or 3 hours after taking UPA-ECPs, then she does not need to take any extra pills.
- » Give more ECPs and help her start an ongoing method. If possible, give her more ECPs to take home in case she needs them in the future.
- » Follow-up: Encourage her to return for an early pregnancy test if her monthly bleeding is more than 7 days late.

Using clinical judgement in special cases

Helping continuing users

All women can use ECPs safely and effectively, including women who cannot use ongoing hormonal contraceptive methods. Because of the short-term nature of their use, there are no medical conditions that make ECPs unsafe for any woman.

ECPs may be needed in many different situations. Many women do not know about ECPs, however. Women who use contraceptive methods that depend on the user, such as pills and condoms, particularly benefit from learning about ECPs. If possible, give all women who may need ECPs a supply in advance. If giving an advance supply is not possible, an advance prescription may be given in some settings, or a woman can be told where to obtain ECPs locally. An advance supply is helpful because a woman can keep them in case she needs them. Women are more likely to use ECPs if they already have them when needed. Also, having them on hand enables women to take them as soon as possible after unprotected sex, when they will be most effective. No routine return visit is required. Assure every client that she is welcome to come back any time, however, and also if:

- » She thinks she might be pregnant, especially if she has no monthly bleeding or her next monthly bleeding is delayed by more than 7 days
- » She did not start a continuing method immediately and now wants one.



Fertility awareness-based (FAB) methods

What is it?

- » "Fertility awareness" means that a woman knows how to tell when the fertile time of her menstrual cycle starts and ends. (The fertile time is when she can become pregnant.)
- » Sometimes called periodic abstinence or natural family planning.
- » A woman can use several ways, alone or in combination, to tell when her fertile time begins and ends.
- » Calendar-based methods involve keeping track of days of the menstrual cycle to identify the start and end of the fertile time.
 - Examples: Standard days method, which avoids unprotected vaginal sex on days 8 19 of the menstrual cycle, and calendar rhythm method.
- » Symptoms-based methods depend on observing signs of fertility.
 - Cervical secretions: When a woman sees or feels cervical secretions, she may be fertile. She may feel just a little vaginal wetness.
 - Basal body temperature (BBT): A woman's resting body temperature goes up slightly after the release of an egg (ovulation). She is not likely to become
 pregnant from 3 days after this temperature rise through to the start of her next monthly bleeding. Her temperature stays higher until the beginning of her
 next monthly bleeding.
 - Examples: TwoDay method, BBT method, ovulation method (also known as Billings method or cervical mucus method), and symptothermal method.
- » Work primarily by helping a woman know when she could become pregnant. The couple prevents pregnancy by avoiding unprotected vaginal sex during these fertile days usually by abstaining or by using condoms or a diaphragm. Some couples use spermicides or withdrawal, but these are among the least effective methods.

How effective is the method?

- » Effectiveness depends on the user: Risk of pregnancy is greatest when couples have sex on the fertile days without using another method.
- As commonly used, in the first year about 15 pregnancies per 100 women using periodic abstinence. This means that 85 of every 100 women relying on periodic abstinence will not become pregnant. (Most of the couples in this study were using the calendar rhythm method.)
- Pregnancy rates with consistent and correct use vary for different types of fertility awareness-based methods.
- In general, abstaining during fertile times is more effective than using another method during fertile times.

Who can and cannot use the method?

- » All women can use calendar-based methods. No medical conditions prevent the use of these methods, but some conditions can make them harder to use effectively.
- » All women can use symptoms-based methods. No medical conditions prevent the use of these methods, but some conditions can make them harder to use effectively.

How do you use the method?

Important: A woman can use the Standard Days Method if most of her menstrual cycles are 26–32 days long. If she has more than two longer or shorter cycles within a year, the Standard Days Method will be less effective, and she may want to choose another method.

- » Standard Days Method
 - Keep track of the days of the menstrual cycle.
 - Avoid unprotected sex on days 8–19.
 - Use memory aids if needed.
- » Calendar rhythm method
 - Keep track of the days of the menstrual cycle.
 - Estimate the fertile time.
 - Avoid unprotected sex during fertile time.
 - Update calculations monthly.
- » Once trained, a woman or couple can usually begin using symptoms-based methods at any time. Women not using a hormonal method can practise monitoring their fertility signs before they start using symptoms-based methods. Give clients who cannot start immediately another method to use until they can start.
- » TwoDay method
 - Check for secretions.
 - Avoid sex or use another method on fertile days.
 - Resume unprotected sex after 2 dry days.
- » Basal Body Temperature (BBT) method
 - Take body temperature daily.
 - Avoid sex or use another method until 3 days after the temperature rise.
 - Resume unprotected sex until next monthly bleeding begins.
- » Ovulation method
 - Check cervical secretions daily.
 - Avoid unprotected sex on days of heavy monthly bleeding.
 - Resume unprotected sex until secretions begin.
 - Avoid unprotected sex when secretions begin and until 4 days after "peak day".
 - Resume unprotected sex.
- » Symptothermal method (BBT + cervical secretions + other fertility signs)
 - Avoid unprotected sex on fertile days.

What are the side-effects?

None

Known health benefits: Helps protect against risks of pregnancy.

Known health risks: None.

Giving advice on side-effects

None



Using clinical	None
judgement in special cases	
Helping	1. Ask clients how they are doing with the method and whether they are satisfied. Ask if they have any questions or anything to discuss.
continuing users	2. Ask especially if they are having difficulty identifying the woman's fertile days or trouble avoiding unprotected sex on the fertile days.
	3. Check whether the couple are using the method correctly. Review observations or records of fertility signs. If needed, plan for another visit.
	4. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate.
	5. Ask a long-term client about major life changes that may affect their needs – particularly plans for having children and STI/HIV risk. Follow up as needed.

Male condoms

101	
What is it?	» Sheaths, or coverings, that fit over a man's erect penis.
	» Also called rubbers, "raincoats", "umbrellas", "skins", prophylactics and preservatives; known by many different brand names.
	» Most are made of thin latex rubber. Male condoms also are made from other materials, including polyurethane, polyisoprene, lambskin and nitrile.
	» Work by forming a barrier that keeps sperm out of the vagina, preventing pregnancy. Also keep infections in semen, on the penis or in the vagina from infecting the other partner.
How effective is the method?	» Effectiveness depends on the user: risk of pregnancy or sexually transmitted infection (STI) is greatest when condoms are not used with every act of sex. Very few pregnancies or infections occur due to incorrect use, slips or breaks.
	» Protection against pregnancy:
	 As commonly used, about 13 pregnancies per 100 women whose partners use male condoms over the first year. This means that 87 of every 100 women whose partners use male condoms will not become pregnant.
	- When used correctly with every act of sex, about 2 pregnancies per 100 women whose partners use male condoms over the first year.
	» Return of fertility after use of condoms is stopped: No delay.
	Protection against HIV and other STIs:
	» Male condoms significantly reduce the risk of becoming infected with HIV when used correctly with every act of vaginal or anal sex.
	» When used consistently and correctly, condom use prevents 80% – 95% of HIV transmission that would have occurred without condoms.
	» Condoms reduce the risk of becoming infected with many STIs when used consistently and correctly during vaginal or anal sex.
	» Protect best against STIs spread by discharge, such as HIV, gonorrhoea and chlamydia.
	» Also protect against STIs spread by skin-to-skin contact, such as herpes and human papillomavirus (HPV).
Who can and	All men and women can safely use latex male condoms, except those with:
cannot use the	» Severe allergic reaction to latex rubber
method?	 In special circumstances, such as high risk of STIs or HIV, if non-latex condoms are not available, a qualified provider who can carefully assess the man's or woman's condition and situation may decide that he or she can use latex condoms.
	» Male condoms made from materials other than latex do not cause allergic reactions.

How do you use the method?

Important: Whenever possible, show clients how to put on a condom. Use a model of a penis, if available, or other item, such as a banana, to demonstrate.

- » Explain the 5 basic steps of using a male condom.
- 1. Use a new condom for each act of sex.
 - Check the condom package. Do not use if torn or damaged. Avoid using a condom past the expiration date, unless a newer condom is not available.
 - Tear open the package carefully. Do not use fingernails, teeth or anything that can damage the condom.
- 2. Before any physical contact, place the condom on the tip of the erect penis with the rolled side out.
 - For the most protection, put the condom on before the penis makes any genital, oral or anal contact.
- 3. Unroll the condom all the way to the base of the erect penis.
 - The condom should unroll easily. Forcing it on could cause it to break during use.
 - If the condom does not unroll easily, it may be on backwards, damaged or too old. Throw it away and use a new condom.
- If the condom is on backwards and another one is not available, turn it over and unroll it onto the penis.
- 4. Immediately after ejaculation, hold the rim of the condom in place and withdraw the penis while it is still erect.
 - Withdraw the penis.
 - Slide the condom off, avoiding spilling semen.
 - If having sex again or switching from one sex act to another, use a new condom.
- 5. Dispose of the used condom safely.
 - Wrap the condom in its package and put it in the rubbish bin or latrine. Do not put the condom into a flush toilet, as it can cause problems with plumbing.
- » What condom users should not do: Some practices can increase the risk that the condom will break, and should be avoided.
 - Do not unroll the condom first and then try to put it on the penis.
 - Do not use lubricants with an oil base these lubricants can damage latex.
 - Do not use a condom if the colour is uneven or changed.
 - Do not use a condom that feels brittle, dried out or very sticky.
 - Do not reuse condoms.
 - Do not have dry sex.
 - Do not use more than one condom at the same time.
 - Do not use a male and female condom at the same time.
 - Use a new condom when switching between penetrative sex acts such as from anal to vaginal sex, which can transfer bacteria and cause infection.
- » Lubricants for latex condoms: Lubrication helps encourage condom use and avoid condom breakage. There are three ways to provide lubrication natural vaginal secretions, adding a lubricant safe for use with condoms, or using condoms packaged with lubricant on them.
 - Clean water and saliva can be used for lubrication. The lubricants packaged with condoms are usually made of silicone. Silicone lubricants are also packaged separately. Lubricants made with water or glycol also are available and may be less expensive. They, too, are safe to use with condoms.
 - Lubricants should be applied on the outside of the condom, in the vagina or in the anus. Lubricants should not be put on the penis, as this can make the
 condom slip off. A drop or two of lubricant on the inside of the tip of the condom before it is unrolled can help increase the sensation of sex for some men.
 Too much lubricant inside, however, can make the condom slip off.
 - Do not use products made with oil as lubricants for latex condoms. They can damage latex.
 - Materials that should not be used with latex condoms include:
 - Any oils (cooking, baby, coconut, mineral) or products made with oil
 - Petroleum jelly
 - Lotions
 - Cold creams

- Butter
- Cocoa butter
- Margarine.



What are the side-effects?	None Known health benefits » Help protect against:
	 Risks of pregnancy STIs, including HIV.
	» May help protect against:
	- Conditions caused by STIs:
	 Recurring pelvic inflammatory disease (PID) and chronic pelvic pain Cervical cancer Infertility (male and female).
	Known health risks
	» Extremely rare: Severe allergic reaction (among people with latex allergy).
Giving advice on side-effects	None
Using clinical judgement in special cases	None
Helping continuing users	 Ask clients how they are doing with the method and whether they are satisfied. Ask if they have any questions or anything to discuss. Ask especially if they are having any trouble using condoms correctly and every time they have sex. Give clients any information or help that they need. Give clients more condoms and encourage them to come back for more before their supply runs out. Remind them where else they can obtain condoms. Ask a long-term client about major life changes that may affect her or his needs – particularly plans for having children and STI/HIV risk. Follow up as needed.

Female condoms

What is it?	» Sheaths, or linings, that fit loosely inside a woman's vagina, made of thin, transparent, soft film.
	– They have flexible rings at both ends.
	– One ring at the closed end helps to insert the condom.
	– The ring at the open end holds part of the condom outside the vagina.
	» Female condoms are made of various materials, such as latex, polyurethane and nitrile.
	» Work by forming a barrier that keeps sperm out of the vagina, preventing pregnancy. Also help to keep infections in semen, on the penis, or in the vagina from infecting the other partner.

How effective is the method?

- » Effectiveness depends on the user: Risk of pregnancy or sexually transmitted infection (STI) is greatest when female condoms are not used with every act of sex. Few pregnancies or infections occur due to incorrect use, slips or breaks.
 - Protection against pregnancy: As commonly used, about 21 pregnancies per 100 women using female condoms over the first year. This means that 79 of every 100 women using female condoms will not become pregnant.
 - When used correctly with every act of sex, about 5 pregnancies per 100 women using female condoms over the first year.
- » Return of fertility after use of female condom is stopped: No delay.
- » Protection against HIV and other STIs: Female condoms reduce the risk of infection with STIs, including HIV, when used correctly with every act of sex.

Who can and cannot use the method?

All women and men can use female condoms, except those with severe allergic reaction to latex, who should not use latex female condoms.

- » In special circumstances, such as high risk of STIs or HIV, if non-latex condoms are not available, a qualified provider who can carefully assess the woman's or man's condition and situation may decide that she or he can use latex condoms.
- » Condoms made from materials other than latex do not cause allergic reactions.

How do you use the method?

Important: Whenever possible, show the client how to insert the female condom. Use a model or picture, if available, or your hands to demonstrate. You can create an opening similar to a vagina with one hand and show how to insert the female condom with the other hand.

- » Explain the 5 basic steps of using a female condom.
- 1. Use a new female condom for each act of sex.
 - Check the condom package. Do not use if torn or damaged. Avoid using a condom past its expiration date. Do so only if newer condoms are not available.
 - If possible, wash your hands with mild soap and clean water before inserting the condom.
- 2. Before any physical contact, insert the condom into the vagina.
 - For maximum protection, insert the condom before the penis comes in contact with the vagina. Can be inserted up to 8 hours before sex.
 - Choose a position that is comfortable for insertion squat, raise one leg, sit or lie down.
 - Rub the sides of the female condom together to spread the lubricant evenly.
 - Grasp the ring at the closed end and squeeze it so it becomes long and narrow.
 - With the other hand, separate the outer lips (labia) and locate the opening of the vagina.
- Gently push the inner ring into the vagina as far up as it will go. Insert a finger into the condom to push it into place. About 2–3 cm of the condom and the outer ring remain outside the vagina.
- 3. Ensure that the penis enters the condom and stays inside the condom.
 - The man or woman should carefully guide the tip of his penis inside the condom not between the condom and the wall of the vagina. If his penis goes outside the condom, withdraw and try again.
 - If the condom is accidentally pulled out of the vagina or the outer ring is pushed into it during sex, put the condom back in place.
- 4. After the man withdraws his penis, hold the outer ring of the condom, twist to seal in fluids, and gently pull it out of the vagina.
 - The female condom does not need to be removed immediately after sex.
 - Remove the condom before standing up, to avoid spilling semen.
 - If the couple have sex again, they should use a new condom.
 - Reuse of female condoms is not recommended.
- 5. Dispose of the used condom safely.
 - Wrap the condom in its package and put it in the rubbish bin or latrine. Do not put the condom into a flush toilet, as it can cause problems with plumbing.



What are the	None
side-effects?	Known health benefits
	» Help protect against:
	- Risks of pregnancy
	 STIs, including HIV.
	Known health risks: None.
Giving advice on	None
side-effects	
Using clinical	None
judgement in	
special cases	
Helping	1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
continuing users	2. Ask especially if she has any trouble using female condoms correctly and every time she has sex. Give her any information or help that she needs.
	3. Give her more female condoms and encourage her to come back for more before her supply runs out. Remind her where else she can obtain female condoms.
	4. Ask a long-term client about major life changes that may affect her needs – particularly plans for having children and STI/HIV risk. Follow up as needed.

Male sterilization

What is it?	» Also known as vasectomy and male surgical contraception.
	» Permanent contraception for men who will not want more children.
	» Through a puncture or small incision in the scrotum, the provider locates each of the two tubes that carry sperm to the penis (vas deferens) and cuts or blocks them by cutting and tying them closed or by applying heat or electricity (cautery).
	» Works by closing off each vas deferens, keeping sperm out of semen. Semen is ejaculated, but it cannot cause pregnancy.

How effective is the method?

- » One of the most effective methods, but carries a small risk of failure.
 - Among the partners of men who have vasectomies, far less than 1 in every 100 will become pregnant in the first year of use of the method. In fact, less
 than 2 women in every 1000 will become pregnant. This means that 998 or 999 of 1000 women whose partners have had vasectomy will not become
 pregnant.
 - Sometimes men can have their semen examined at 3 months after the procedure to see if it still contains sperm. If no sperm is found, 1 woman in every 1000 of these men's partners will become pregnant in the first year.
 - Among partners of men who do not have their semen examined, pregnancies are slightly more common, but still less than 2 per 1000 women.
- » Vasectomy is not fully effective for 3 months after the procedure.
 - Some pregnancies occur within the first year because the couple do not use condoms or another effective method consistently and correctly in the first 3 months, before the vasectomy is fully effective.
- » A small risk of pregnancy remains beyond the first year after the vasectomy and until the man's partner reaches menopause.
 - Over three years of use: About 4 pregnancies per 1000 women.
- » If the partner of a man who has had a vasectomy becomes pregnant, it may be because:
 - The couple did not always use another method during the first 3 months after the procedure
 - The provider made a mistake
 - The cut ends of the vas deferens grew back together.
- » Fertility does not return, because male sterilization generally cannot be stopped or reversed. The procedure is intended to be permanent. Reversal surgery is difficult, expensive and not available in most areas. When performed, reversal surgery often does not lead to pregnancy.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

Safe for all men. With proper counselling and informed consent, any man can have a vasectomy safely, including men who:

- » Have no children or few children
- » Are married or are not married
- » Do not have wife's permission
- » Are young
- » Have sickle cell disease
- » Are at high risk of infection with HIV or another STI
- » Are living with HIV, whether or not they are on antiretroviral therapy

In some of these situations, especially careful counselling is important to make sure the man will not regret his decision.

How do you use the method?

- » Male sterilization must be done by a trained provider.
- » Following up within 7 days or at least within 2 weeks is strongly recommended. No man should be denied sterilization, however, simply because follow-up would be difficult or not possible.
- » Ask client to return in 3 months for semen analysis, if available.



What are the side-effects?

None

Known health benefits: Helps protect against risks of pregnancy in a partner.

Known health risks: None.

Complications

- » Uncommon to rare: Severe scrotal or testicular pain that lasts for months or years
- » Uncommon to very rare: Infection at the incision site or inside the incision (uncommon with conventional incision technique; very rare with no-scalpel technique)
- » Rare: Bleeding under the skin that may cause swelling or bruising (haematoma).

Giving advice on side-effects

- » Assure every client that he is welcome to come back any time for example, if he has problems or questions, or his partner thinks she might be pregnant. (A few vasectomies fail and the men's partners become pregnant.) Also if: He has bleeding, pain, pus, heat, swelling or redness in the genital area that becomes worse or does not go away.
- » General health advice: Anyone who suddenly feels that something is seriously wrong with his health after a vasectomy procedure should immediately seek medical care from a nurse or doctor. After a surgical procedure, any health problem must be assessed carefully and considered to be related to the procedure until it is medically demonstrated that it is not.

Using clinical judgement in special cases

Ensuring informed choice: A friendly counsellor who listens to a man's concerns, answers his questions, and gives adequate, clear and practical information about the procedure – especially its permanence – will help a man make an informed choice and be a successful and satisfied user, without later regret. Involving his partner in counselling can be helpful but is not necessary or required.

Helping continuing users

Problems affect men's satisfaction with vasectomy. They deserve the provider's attention. If the client reports complications of vasectomy, listen to his concerns, give advice and support, and, if appropriate, treat. Make sure he understands the advice and agrees.

Female sterilization

What is it?

- » Permanent surgical contraception for women who will not want more children.
- » The two surgical approaches most often used:
 - Minilaparotomy involves making a small incision in the abdomen. The fallopian tubes are brought to the incision to be cut or blocked.
 - Laparoscopy involves inserting a long, thin tube containing lenses into the abdomen through a small incision. This laparoscope enables the doctor to reach and block or cut the fallopian tubes in the abdomen.
- » Also called tubal sterilization, tubal ligation, voluntary surgical contraception, tubectomy, bi-tubal ligation, tying the tubes, minilap and "the operation".
- » Works because the fallopian tubes are blocked or cut. Eggs released from the ovaries cannot move down the tubes, and so they do not meet sperm.

How effective is the method?

- » One of the most effective contraceptive methods, but carries a small risk of failure.
 - Less than 1 pregnancy per 100 women over the first year after having the sterilization procedure (5 per 1000). This means that 995 of every 1000 women relying on female sterilization will not become pregnant.
- A small risk of pregnancy remains beyond the first year after the procedure and until the woman reaches menopause.
- Over 10 years of use: About 2 pregnancies per 100 women (18–19 per 1000 women).
- Effectiveness varies slightly depending on how the tubes are blocked, but pregnancy rates are low with all techniques. One of the most effective techniques is cutting and tying the cut ends of the fallopian tubes after childbirth (postpartum female sterilization).
- Fertility does not return, because sterilization generally cannot be reversed. The procedure is intended to be permanent. Reversal surgery is difficult, expensive and not available in most areas. When performed, reversal surgery often does not lead to pregnancy.
- » Protection against sexually transmitted infections (STIs): None.

Who can and cannot use the method?

With proper counselling and informed consent, any woman can have female sterilization safely, including women who:

- » Have no children or few children
- » Are married or are not married
- » Do not have husband's permission
- » Are young
- » Have given birth within the last 7 days
- » Are breastfeeding
- » Are living with HIV, whether or not they are on antiretroviral therapy.

In some of these situations, especially careful counselling is important to make sure the woman will not regret her decision.

How do you use the method?

- » Female sterilization must be done by a trained provider. There are two types of procedures that can be performed: The minilaparotomy procedure or the laparoscopy Procedure.
- » No woman should be denied a procedure, however, simply because follow-up would be difficult or not possible.

What are the side-effects?

None

Known health benefits

- » Helps protect against:
 - Risks of pregnancy
 - Pelvic inflammatory disease (PID).
- » May help protect against: Ovarian cancer.
- » Reduces: Risk of ectopic pregnancy.

Known health risks

» Uncommon to extremely rare: Complications of surgery and anaesthesia (see below).

Complications of surgery

- » Uncommon to extremely rare: Female sterilization is a safe method of contraception. It requires surgery and anaesthesia, however. Like other minor surgeries, female sterilization carries some risks, such as infection or abscess of the wound. Serious complications are uncommon. Death, due to the procedure or anaesthesia, is extremely rare.
- » The risk of complications with local anaesthesia, with or without sedation and analgesia, is significantly lower than with general anaesthesia. Complications can be kept to a minimum if appropriate techniques are used and if the procedure is performed in an appropriate setting by a skilled provider.

Giving advice on side-effects

- » Assure every client that she is welcome to come back any time for example, if she has problems or questions, or she thinks she might be pregnant. (A few sterilizations fail, and the woman becomes pregnant.) Also if:
 - She has bleeding, pain, pus, heat, swelling or redness of the wound that becomes worse or does not go away
 - She develops high fever (> 38 °C / 101 °F)
 - She experiences fainting, persistent light-headedness, or extreme dizziness in the first 4 weeks and especially in the first week.
- » General health advice: Anyone who suddenly feels that something is seriously wrong with her health after the female sterilization procedure should immediately seek medical care from a nurse or doctor. After a surgical procedure, any health problem must be assessed carefully and considered to be related to the procedure until it is medically demonstrated that it is not.



Using clinical judgement in special cases

Because female sterilization involves a surgical procedure and the administration of local anaesthesia (with or without mild sedation and analgesia), the client must undergo a careful, comprehensive yet focused clinical assessment. This assessment is important in every case, but it is even more important when the procedure is performed in hard-to-reach areas, in an outreach service, or in facilities far from supporting higher-level health services. The assessment must include review of the medical eligibility criteria and a pelvic/genital examination.

Helping continuing users

Problems affect women's satisfaction with female sterilization. They deserve the provider's attention. If the client reports complications of female sterilization, listen to her concerns, give advice and support, and, if appropriate, treat. Make sure she understands the advice and agrees.

Withdrawal

What is it? » Just before ejaculation, the man withdraws his penis from his partner's vagina and ejaculates outside the vagina, keeping his semen away from her external » Also known as coitus interruptus and "pulling out". » Works by keeping sperm out of the woman's body. » Effectiveness depends on the user: Risk of pregnancy is greatest when the man does not withdraw his penis from the vagina before he ejaculates with every act How effective is of sex. the method? One of the least effective methods, as commonly used. As commonly used, about 20 pregnancies per 100 women whose partners use withdrawal over the first year. This means that 80 of every 100 women whose partners use withdrawal will not become pregnant. When used correctly with every act of sex, about 4 pregnancies per 100 women whose partners use withdrawal over the first year. » Return of fertility after use of withdrawal is stopped: No delay. » Protection against sexually transmitted infections (STIs): None. Who can use All men can use withdrawal. No medical conditions prevent its use. the method? How do you use » When the man feels close to ejaculating, he should withdraw his penis from the woman's vagina and ejaculate outside the vagina, keeping his semen away from her external genitalia. the method? » If the man has ejaculated recently: Before sex he should urinate and wash the tip of his penis to remove any remaining semen. What are the Known health benefits: None. side-effects? Known health risks: None. **Using clinical** None judgement in special cases Helping » Learning proper use can take time. Suggest the couple also use another method until the man feels that he can use withdrawal correctly with every act of sex. continuing users » Greater protection from pregnancy is available. Suggest an additional or alternative family planning method. (Couples who have been using withdrawal effectively should not be discouraged from continuing.) » Some men may have difficulty using withdrawal: Men who cannot sense consistently when ejaculation is about to occur; men who ejaculate prematurely. » Can use emergency contraceptive pills (ECPs). Explain ECP use in case a man ejaculates before withdrawing. Give ECPs if available.



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