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Guideline Uptake In Digital Ecosystems (GUIDE) study: implementation research on the impact of Digital Adaptation Kits on quality of care

Submission date
27/10/2022

Recruitment status
Recruiting

Registration date
21/12/2022

Overall study status
Ongoing

Last Edited
01/10/2024

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
WHO launched the SMART Guidelines initiative to support countries' digitization journeys and facilitate a structured approach to embedding WHO recommendations and standards within digital systems. "Digital Adaptation Kits" (DAKs) are one of the steps within the SMART guidelines approach. The DAKs distil WHO guidelines into operational components that can be more easily executed within the digital systems countries are adopting, and thereby accelerate the uptake of WHO clinical, public health and data use guidelines. DAKs include the package of business process workflows, core data needs, decision support algorithms, linkages to indicators, and functional requirements for a health domain area, which can then be operationalized more easily into a digital system. In creating these operational tools derived from WHO guidelines, the DAKs provide a unique way to reinforce recommendations and service delivery linkages.

The research aims to identify processes and the resources needed for adapting and incorporating the DAKs into countries' existing digital systems for strengthening primary care, as well as the impact of introducing the DAKs on service delivery and routine health information systems. The study is split into two phases: (i) formative phase for adapting the DAKs and providing the necessary support for uptake of DAK content into digital systems and (ii) assessment phase for evaluating the effect of the DAK integration on quality of care and data use related outcomes. The duration of the study is 16 months, with four months for the formative phase (phase 1) and 12 months for the impact evaluation (phase 2). The study will be conducted in Ghana.

Who can participate?
Public primary health care facilities in Ghana and Ethiopia that are using the national digital system for service delivery and data reporting.

What does the study involve?
Using a digital health record and decision support tool that has been aligned to national and WHO clinical, public health and data recommendations.

What are the possible benefits and risks of participating?
The ability to improve the impact of digital tools used for health service delivery, risks include potentially having to provide feedback on the experience of using the digital tool and changes to service delivery workflows.

Where is the study run from?
UNDP/UNFPA/UNICEF/World Bank Special Program of Research, Development and Research Training in Human Reproduction (HRP), Department of Sexual and Reproductive Health and Research, World Health Organization, Geneva, Switzerland

When is the study starting and how long is it expected to run for?
October 2022 to September 2025

Who is funding the study?
1. UNDP/UNFPA/UNICEF/World Bank Special Program of Research, Development and Research Training in Human Reproduction (HRP), Department of Sexual and Reproductive Health and Research, World Health Organization, Geneva, Switzerland
2. Government of Canada

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
A66031

Study information

Scientific Title
Digitizing primary healthcare: Implementation research on the impact of Digital Adaptation Kits for strengthening quality of care and accountability

Acronym
GUIDE

Study objectives
The hypothesis of this study is that by packaging WHO clinical, public health and data recommendations in the format of the WHO SMART Guidelines-Digital Adaptation Kits and integrating them into digital systems, primary care facilities in countries can better benefit from the WHO recommendations in real-time. Furthermore, unlike common approaches to digital health research where a new digital system is introduced, this research study leverages the digital systems that countries already have in places, thereby aiming to reduce the costs associated with the maintenance of parallel digital systems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/10/2022, WHO Ethical Review Committee (Avenue Appia 20, 1211 Geneva, Switzerland; no telephone number provided; ercsec@who.int), ref: A66031

Study design
Qualitative process evaluation followed by stepped wedge cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Antenatal care, family planning, and HIV/AIDS, sexual and reproductive health

Interventions

Current interventions as of 01/10/2024:
WHO launched the SMART Guidelines initiative to support countries' digitization journeys and facilitate a structured approach to embedding WHO recommendations and standards within digital systems. "Digital Adaptation Kits" (DAKs) are one of the steps within the SMART guidelines approach. The DAKs distil WHO guidelines into operational components that can be more easily executed within the digital systems countries are adopting, and thereby accelerate the uptake of WHO clinical, public health and data use guidelines.

The intervention consists of embedding the adapted ANC, FP, and HIV DAK content within a country-supported digital system.

The first phase will consist of a formative assessment to understand the requirements for adapting customizing the generic DAKs to specific country contexts. This phase will use qualitative methods with key stakeholders and apply health information systems requirements design methodologies, such as mapping workflows and adapting data dictionaries. During this phase, each DAK will undergo a consultative process with MOH stakeholders and software development teams to review the content and determine enhancements to the digital systems that can be made based on an analysis of the DAK and national guidelines. The DAK-related upgrades to the digital system may consist of updates to data elements, review and inclusion of ICD terminology, addition/modification of decision-support logic, and other needs as identified in this phase.

The second phase, which consists of the impact evaluation, will be conducted through a stepped wedge design in Ghana and prepost in Ethiopia where outcome measures will be collected at baseline as well as in regular intervals throughout the study period to compare facilities using the country adapted DAK content in their digital systems versus the standard practice. With the stepped wedge design, we aim for all facilities in the study to eventually be using the adapted DAK content in their digital systems by the end of the study.

The Ethiopian arm of the study will be conducted in Bahir Dar City Amhara region, northwest Ethiopia. This study in Ethiopia will take place at the primary health care level at 3 health centers of Bahir Dar City, as they are currently the only public health facilities that are deploying the Bahmni electronic medical record system (which will be used for the DAK update). To account for this change in the number of facilities, we will be sampling a greater number of records per facility.

The Ghana arm of the research study will be conducted in primary healthcare facilities in five districts: three districts (Bongo, Kasena-Nankana and Bolgatanga) are located in the Upper East Region and two districts (Upper West Akin and Akuapim South Districts in the Eastern region.

Previous interventions:
WHO launched the SMART Guidelines initiative to support countries' digitization journeys and facilitate a structured approach to embedding WHO recommendations and standards within digital systems. "Digital Adaptation Kits" (DAKs) are one of the steps within the SMART guidelines approach. The DAKs distil WHO guidelines into operational components that can be more easily executed within the digital systems countries are adopting, and thereby accelerate the uptake of WHO clinical, public health and data use guidelines.

The intervention consists of embedding the adapted ANC, FP, and HIV DAK content within a country-supported digital system.

The first phase will consist of a formative country adaptation and preparation phase to understand the requirements for adapting customizing the generic DAKs to specific country contexts. This phase will use qualitative methods with key stakeholders and apply health information systems requirements design methodologies, such as mapping workflows and adapting data dictionaries. During this phase, each DAK will undergo a consultative process with MOH stakeholders and software development teams to review the content and determine enhancements to the digital systems that can be made based on an analysis of the DAK and national guidelines. The DAK-related upgrades to the digital system may consist of updates to data elements, review and inclusion of ICD terminology, addition/modification of decision-support logic, and other needs as identified in this phase.

For the qualitative research, this study will employ purposive sampling techniques to select health management information system managers and directors of the units/ departments, health workers, health system managers and software teams. With this approach, the study team will strive to identify all the core-staff working within these units at the national and selected regional levels and where possible, the district levels. This approach will ensure maximum variation sampling such that all the different types of health care workers (general nurses, midwives, health assistants) working in the selected units/ departments are well represented.

The second phase, which consists of the impact evaluation, will be conducted through a stepped wedge cluster randomized design where outcome measures will be collected at baseline as well as in regular intervals throughout the study period to compare facilities using the country-adapted DAK content in their digital systems versus the standard practice. With the stepped wedge design, we aim for all facilities in the study to eventually be using the adapted DAK content in their digital systems by the end of the study.

In addition, this phase will include a process evaluation to document the utilisation of DAKs among digital health and health programme leads. Focus-group discussions (FGDs) with health workers and managerial staff will also supplement the process evaluation to understand experiences in using the digital systems with the DAK-updated content. The FGDs will be conducted at various intervals of the study, as well as at the completion of the study to learn about their overall experience. The qualitative information collected during the study intervals will be used to also help inform the study procedures.

In Ethiopia, we will randomly sample from 9 health centers from the two study districts that meet the inclusion criteria. In addition, one facility in a non-study district will be used for piloting and user-testing the DAK-upgraded digital systems prior to being introduced into the stepped-wedge trial. Data collection for outcome indicators will not be conducted from the facility allocated for user testing.

In Ghana, we will randomly sample 4 facilities that fit the inclusion criteria (1 district hospital and 3 health centers) in each of the study districts, for a total of 12 facilities. Of the 12 facilities, 1 health center per district will be randomly selected to be used for user testing and getting preliminary feedback prior to deploying the upgraded digital system in the remaining 9 facilities. Similarly to Ethiopia, having one facility for piloting and user testing will help to check for bugs and ensure coherence with workflows prior to implementing the upgraded system for the stepped wedge design. Data collection for outcome indicators will not be collected from the 3 facilities allocated for user testing. In total there will be 9 health facilities for data collection, and 3 facilities for user testing.

Intervention Type

Behavioural

Primary outcome measure
Current primary outcome measures as of 01/10/2024:
Collected from extractions of de-identified data from clients' service delivery records/medical records at a single time point:
1. The proportion of pregnant women tested for HIV at first ANC contact
2. The proportion of pregnant women receiving haemoglobin/haematocrit test at first ANC contact
3. The proportion of clients screened for STI during FP consultation
4. The proportion of people living with HIV (PLHIV) clients receiving viral load testing within 6 months of HIV diagnosis
5. The proportion of pregnant women re-tested for HIV at ANC visit during 26-34 gestation weeks if negative for HIV at first ANC contact
6. The proportion of new Family Planning clients who were counselled all 7 family planning methods available in Ghana (progestin-only pill, implant, injectable, IUD, lactational amenorrhea, barrier methods, and sterilization)
7. The proportion of PLHIV who have defaulted to refill medication

Previous primary outcome measure:
Collected from extractions of de-identified data from clients' service delivery records/medical records at a single time point:
1. Proportion of pregnant women screened for syphilis during ANC of all pregnant women with ANC1 (main outcome for powering sample size)
2. Proportion of postpartum clients who initiate modern contraceptive method within 1 year of delivery
3. Proportion of women registered on the digital system as having prior initiation of modern contraception that are continuing users of modern contraception (main outcome for powering sample size)
4. Proportion of individuals seeking contraception/FP who were tested for HIV
5. HIV+ pregnant women on ART

Secondary outcome measures
Collected from extractions of de-identified data from clients' service delivery records/medical records at a single time point:
1. Proportion of data elements for selected indicators are available in the national HMIS
2. Time taken to prepare and submit indicator data reports into the national HMIS from the facility
3. Availability of disaggregated indicators (particularly for family planning)

For the qualitative component, the outcomes are related to experience of end-users (digital health, HIS, health programme leads and software development teams) in using the DAKs (through grounded theory and thematic analysis).

Overall study start date
21/10/2022

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 01/10/2024:
In a facility where:
1. Country-supported digital system for tracking health services/maintaining health records available
2. Existing digital system for SRH-HIV or willingness to digitize SRH-HIV services
3. SRH-HIV services provided by facility/health workers in the catchment area
4. Minimum volume of required sample size

Previous participant inclusion criteria:
In a facility where:
1. Country-supported digital system for tracking health services/maintaining health records available
2. Existing digital system for SRH-HIV or willingness to digitize SRH-HIV services
3. SRH-HIV services provided by facility/health workers in the catchment area
4. Minimum volume of monthly average of 100 pregnant women and women of reproductive age

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
1,500 Ethiopia, 1,920 Ghana

Key exclusion criteria
1. In a facility where settings where services could not be digitized
2. Single service facilities

Date of first enrolment
01/10/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Ethiopia

Ghana

Study participating centre

University of Ghana School of Public Health
P.O. Box LG 13
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Study participating centre
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Sponsor information

Organisation
UNDP/UNFPA/UNICEF/World Bank Special Program of Research, Development and Research Training in Human Reproduction (HRP), Department of Sexual and Reproductive Health and Research, World Health Organization, Geneva, Switzerland

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Sponsor type
Other

Website
https://www.who.int/teams/sexual-and-reproductive-health-and-research-(srh)/areas-of-work/digital-innovations

Funder(s)

Funder type
Research organisation

Funder Name
UNDP/UNFPA/UNICEF/World Bank Special Program of Research, Development and Research Training in Human Reproduction (HRP), Department of Sexual and Reproductive Health and Research, World Health Organization, Geneva, Switzerland

Funder Name
Government of Canada

Alternative Name(s)
Canadian Government, Gouvernement du Canada

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publications of in a high-impact peer-reviewed journal

Findings from this research will also refine standard operating procedures for effectively implementing DAKs to optimize outcomes related to quality of care, integration of services, and data quality and analysis. By leveraging SRH-HIV as a use case, this implementation research study will provide replicable models and findings that can be extended to additional health areas and offer a consistent methodology for digitizing services at the PHC level.

Intention to publish date
15/06/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date