Plan Overview

A Data Management Plan created using DMPonline

Title: Sexual and reproductive health and rights of young people: assessing the impact of digitalization in health care services. A mixed method approach to explore accessibility, content and quality of care

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Project abstract:

Digital transformation in healthcare has been accelerated by the covid-19 pandemic. Digitalization opens up for breakthroughs in care, but there are also challenges. This project aims to assess the impact of digitalization on healthcare services for sexual and reproductive health and rights (SRHR) of young people aged 16-29 years, by exploring the accessibility, content, and quality of digital SRHR care. The long-term goal is to improve SRHR in this age group. The project will be coordinated by the SRHR Unit within the Centre for epidemiology and community medicine, Region Stockholm, in collaboration with the Karolinska Institutet. By taking advantage of existing register linkages covering the whole population of Stockholm County and data from patients´ electronic health records, we will be able to compare young users and non-users of digital SRHR care during years 2020-2022, and how the content and quality of SRHR care may differ between digital consultations and consultations at the clinic. Additionally, we will use qualitative interviews to explore young people’s and healthcare providers’ perceptions of digital SRHR care. The timeline for the project is: register data will be analysed years 1-2, health records- and interview data will be collected and analysed years 1-3, drafting of papers will stretch over years 1-4. The project´s results will be used to optimize and expand digital SRHR care for young people so that SRHR can be improved and made more equitable.

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Sexual and reproductive health and rights of young people: assessing the impact of digitalization in health care services. A mixed method approach to explore accessibility, content and quality of care

Description of data

How will data be collected, created or reused?

The project will utilise data from primary care sexual and reproductive health (SRHR) clinics in Stockholm County, including approximately 31 youth clinics, 70 midwifery clinics, 4 sexual health clinics and one men's clinic. Registry data on healthcare visits within these clinics in years 2018-2024 will be used. We will also utilise registry data from all primary care settings in Stockholm County to follow sexual and reproductive health related healthcare visits and outcomes.

Study 1: We will use an existing register linkage within Region Stockholm´s Centre for epidemiology and community medicine (CES), SLSO, covering all residents in Stockholm
County since 2006, including a complete register of all publicly funded (both primary and
secondary/hospital) healthcare in Stockholm County (Region Stockholms´s VAL databases). The linkage has been created by CES for epidemiological surveillanance and public health research in Stockholm County. VAL contains data on patient age, sex, diagnoses, procedures, hospitalizations, consultations, prescription claims and codes for type of healthcare visits making it possible to stratify for digital care (e.g. remote, physical, home and team visits), type of remote visits (e.g. online video- or telephone consultations) and for personnel category for consultations (e.g. midwife). The data linkage also includes data on socioeconomic and demographic factors via the Longitudinal integration database for health insurance and labor market studies, the Longitudinal database for integration studies, the Cause of Death Register and the Total Population Register. First degree relatives to the linkage population are identified through the Multi-generation linkage and socioeconomic data are available also for them.

Study 2: We will use i) registry data from the linkage described above under Study 1 and ii) data from patients' medical records for the subsample of SRHR clinics for young people in Stockholm County (youth clinics, midwifery clinics, sexual health clinics and men's clinic) that are part of SLSO and use the same type of electronic patient records (Take Care). Take Care data from all publicly funded healthcare in Stockholm County is stored at a central database within Region Stockholm ('Intelligence' database) and available within the Public Healthcare Services
Administration in Region Stockholm (Hälso- och sjukvårds förvaltningen, HSF). Pseydoanonymized Take Care data for young (16-29 years) users of SRHR clinics for young people in SLSO for years 2020-2022 will be obtained from HSF.

Study 3: This study is based on qualitative interviews with young users of SRHR care and healthcare providers within SRHR clinics for your people in Stockholm County. Participants will be selected purposefully using heterogeneous sampling so that different gender and socioeconomic backgrounds are represented. Semi-structured interview guides with open ended questions will be used. Saturation of the data is usually reached after approximately 15 interviews per subgroup.

What types of data will be created and/or collected, in terms of data format? Include version numbers if applicable.

Study 1: registry data will be received in SAS format (.sas7bdat) and analyzed in STATA (file format .dta).
Study 2: pseydoanonymized patient records data will be received as Microsoft Excel Worksheet (.xlsx) and analyzed in STATA (file format .dta).
Study 3: interviews will be recorded and saved as M4A File (.m4a), transcripts will be saved as textfiles (Text Document (.txt)) and analyzed in OpenCode 4 Project (.opcx)

What volumes of data will be created and/or collected?

- < 1 TB

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and

format for descriptions of the content, collection method, file naming-format-versioning, etc

Documentation will include a standardized folder structure, codebooks (metadata about the data), logbooks (metadata about data processing), analysis plans, input and output files from databases and statistical software

Working files will be clearly labelled with a version suffix.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Study 1: For registry data included in the CES linkage, the respective register holders assure data quality in terms of completeness and correctness of registration.

Study 2: The patient record holder assures data quality in terms of completeness and correctness of registration. We will also try to quality-check the data at collection by validation against other available databases, for instance regarding the number of contraceptives prescription that we capture in Tace Care data, we will compare Take Care data to other available information for example from the VAL databases.

Study 3: The transcribed interview material will be coded independently by two researchers.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

- Other, please specify

The registry data that will be used for study 1 is already available within CES and working datasets for our analyses will be stored on a folder in the CES IT server, SLSO, Region Stockholm. The patients' records data that will be obtained will also be stored centrally at CES, and working datasets for our analyses will be stored and analysed on a folder at the CES IT server. The qualitative data that will be collected will be stored on a folder at the CES IT server.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

Access to the datasets stored within a folder at the CES IT server requires an SLSO/CES laptop and is restricted to group members. Data is backed up for one month.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

All data will be handled according to GDPR. (https://staff.ki.se/gdpr).

W will use de-identified registry- and patients' records data. Qualitative data that will be collected will also be de-identified.

The project will follow local regulation for data management and protection, the Swedish law, and the new General Data Protection Regulation (GDPR).

How is correct data handling according to ethical aspects safeguarded?

Patients record data will be pseudonymized by the HSF and the code is not accessible to researchers in our research group. The material will arrive to CES coded, and the original code will be saved by HSF.

The code key for pseudonymized registry data is kept by the holders of the original registers, i.e., by the Swedish National Board of Health and Welfare (https://www.socialstyrelsen.se/), Statistics Sweden (https://www.scb.se/), and Region Stockholm (https://www.sll.se/) and not available to us at any time.

Ethical approvals/amendments and informed consent forms for study 3 will be kept in project files.

Data Transfer/Processing agreements will be signed prior to any data sharing.

Results will only be presented on aggregated level without any possibility of backward identification.
The study will be performed in accordance with the ethical principles of the World Medical Association (WMA) Declaration of Helsinki and aims to follow Good Clinical Practice (GCP) guidelines.

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes, licenses and limitations on the access to and reuse of data?

Only metadata will be published openly, due to Swedish law and local procedures for data sharing, underlying data within Region Stockholm is not readily available upon request.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

Long-term storage will take place at the CES server. Data will be stored at least 10 years after publication. The data will include the final data analysis file. En copy of metadata will also be transferred and stored at a folder at KIs IT server after the end of the project.

Will specific systems, software, code or other types of services be necessary in order to open and use/analyse data in the long term?

The data can be read by any software compatible with .csv file

How will unique and persistent identifiers for the research data, such as a Digital Object Identifier (DOI), be obtained?

We will not obtain a persistent identifier.

Responsibility and resources

Who is responsible for data management while the research project is in progress?

Data management of our working datasets will be performed by a statistician within our research group who is employed within CES, Region Stockholm. Other statisticians within CES Region Stockholm regularly perform data management of the CES linkage that will provide registry data for our studies.

Who is responsible for data management, long-term storage after the research project has ended?

The PI is responsible for data management and long-term storage after the research project has ended.

What resources (costs, labour or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)?

The resources necessary for data management, back up, provision of access and processing for long-term storage are provided by CES, Region Stockholm.

What resources will be needed to ensure that data fulfil the FAIR principles?

No particular additional resources will be required.