

FULL/LONG TITLE OF THE STUDY	Antibiotic Prescribing in Primary Healthcare Point Prevalence Survey
SHORT STUDY TITLE / ACRONYM	Antibiotics in Primary Care PPS Acronym: APC-PPS
PROTOCOL VERSION NUMBER AND DATE	Version 2.0, 28 October 2022
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This protocol has regard for the HRA guidance and order of content	

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

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Date:

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Principal Investigator:

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Co-Investigator:

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STUDY SUMMARY	
Study Title	Antibiotic Prescribing in Primary Healthcare Point Prevalence Survey
Internal ref. no. (or short title)	Antibiotics in Primary Care PPS Acronym: APC-PPS
Study Design	Point prevalence survey
Study Participants	Patients presenting at primary health care clinics with acute infections <14 days duration
Planned Study Period	September 2022 – June 2025 Site set up: September 2022 – June 2024 Data collection at sites: January 2023- December 2024 Interim analyses: December 2023-December 2024 Final analyses: December 2024-June 2025
Research Question/Aim(s)	<ol style="list-style-type: none"> 1. To assess the feasibility of using a PPS methodology to collect data on clinical presentation and antibiotic prescribing in primary healthcare settings. 2. To determine the frequency of consultation for different clinical infections and diagnoses and the frequency and type of antibiotic prescribing associated with these infections in primary healthcare facilities.

ABBREVIATIONS	
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
REC	Research Ethics Committee
SGUL	St Georges, University of London
JRES	(St George's) Joint Research and Enterprise Services
PPS	Point Prevalence Survey
APC	Antibiotics in Primary Care
CNPI	Centre for Neonatal and Paediatric Infection
AWaRe	Access, Watch, Reserve classification for antibiotics
ADILA	AMR Data to Inform Local Action
WHO	World Health Organization
EML	Essential Medicines List
GLASS	Global Antimicrobial Resistance and Use Surveillance System
AMC	Antimicrobial consumption
LMIC	Low-and-middle income country
GBD	Global Burden of Disease
ODK	Open Data Kit
UTI	Urinary Tract Infection

1 BACKGROUND AND RATIONALE

The AMR Data to Inform Local Action (ADILA) project is a Wellcome Trust funded study that aims to use data on antimicrobial consumption, resistance, and clinical outcomes to derive novel frameworks that can inform the development of national and local policies to improve antibiotic prescribing. One of the key objectives focuses on developing a primary care clinical antibiotic prescribing framework that integrates clinical infection presentation/diagnoses with antibiotic prescribing.

The World Health Organization (WHO) will release the WHO Essential Medicines List (EML) AWaRe Antibiotic Book in 2022 (1,2), providing detailed guidance on the choice of antibiotic drug, dose and duration for 35 common infections in adults and children in primary care and hospital settings. The AWaRe Book is built around the AWaRe system (Access, Watch, Reserve), a classification for antibiotics related to their potential for selecting for resistance. Access antibiotics are the first choice for the most common infections and should be widely available and generally have a lower potential for selecting resistance; Watch antibiotics are broader spectrum antibiotics with higher potential for resistance so should be used only for specific indications; and Reserve antibiotics are important last line antibiotics, reserved for the management of multidrug-resistant pathogens.

The AWaRe Antibiotic Book recommends that 9 out of the 10 most common infections in primary care should be treated with Access antibiotics. The book also highlights that low-risk patients with mild infections may not need antibiotic treatment. There is very little data from the low and middle income (LMIC) setting describing the variation in the relative incidence of clinical infections presenting to different types of primary care/ambulatory care facilities.

Point prevalence surveys (PPS) are a simple method to measure antibiotic use (or other medicines use). They are generally implemented on a single day and capture anonymous data on patients receiving an antimicrobial on the given day including demographics, specific antibiotic and indication. These types of surveys have been used successfully globally to measure antibiotic use and indication for prescription in hospitals (3–14) and the WHO has a published methodology (3) for conducting these types of surveys in the hospital setting. These types of point prevalence surveys have not been widely adapted to capture antibiotic use in the primary healthcare setting (15) despite majority of antibiotic prescribing occurring in these settings compared to hospitals.

To inform and monitor local and national antibiotic use targets and quality indicators, understand the feasibility of collecting basic clinical and prescribing data in the primary healthcare settings using basic tools such as point prevalence surveys is necessary. This includes the sampling frame, costs and the minimum data required to provide reasonable levels of precision of estimates of antibiotic use accounting for variable clinical burden to allow comparison of actual use compared to local and global guidelines.

1.1 RATIONALE

Very little data is available from the primary healthcare setting in LMICs to describe the burden of clinical infections and antibiotic prescribing proportions for those infections. The few datasets available include data on (estimates of) infection and incidence by country alone (e.g. Global Burden of Disease (GBD); <https://www.healthdata.org/>), antibiotic prescriptions sometimes linked to diagnosis (16) or sales data without information on linked diagnoses (e.g. IQVIA MIDAS database, WHO GLASS Antimicrobial Consumption (AMC) module). However, there is currently insufficient data to compare observed prescribing patterns for common infections compared to local, national or WHO guidance.

2 RESEARCH QUESTION/AIM(S)

This project aims to understand the feasibility of using PPS methodology to collect data on patterns of clinical presentation and antibiotic prescribing / dispensing in primary healthcare.

The project also aims to determine the frequency of consultation for different clinical infection presentations/diagnoses together with the frequency of those prescribed and not prescribed and type of antibiotic prescribing (if prescribed) for these infections in primary healthcare facilities.

2.1 OBJECTIVES

1. Quantify the frequency of people presenting to primary healthcare facilities with an infection and the relative frequency of presentation of different clinical infections.
2. Quantify the proportion of those presenting with clinical infections that receive an antibiotic prescription
3. Of those who receive an antibiotic prescription, quantify the proportion of each AWaRe antibiotic prescribed
4. Inform the design of a future optimal sampling strategy to obtain a representative sample of sites within a region or country.

2.2 OUTCOME

To determine the feasibility of using PPS methodology for surveillance of antibiotic use and to inform the sampling strategy of future surveillance surveys.

To understand the relative presentation rates of clinical infections covered in the WHO EML AWaRe Antibiotic Book in different settings and to understand antibiotic prescribing rates for these infections.

Local data summaries and graphics will be shared with sites to inform local initiatives.

3 STUDY DESIGN

3.1 STUDY DESIGN AND SETTING

This is a multi-centre, multi-country series of point prevalence surveys (PPS) conducted in a range of primary healthcare settings that prescribe or dispense antibiotics (e.g., primary care facilities, community health centres, hospital outpatients/ambulatory care, pharmacies, etc.) in at least 10 countries globally (Appendix 2). Sites will predominantly be in Africa and Asia, although sites will be identified in other WHO regions globally from those who would like to participate through stakeholder engagements.

Study set up will commence in Autumn 2022 with outreach to country and site partners together with any required local ethical approvals. The first site will be opened in early 2023 with additional sites opening throughout 2023 and 2024 (dependent on local ethics timelines). Each site will conduct multiple PPS over 6 months from the first survey. The latest any site will be able to open in this phase is around mid 2024 to allow for all data collection to be completed during 2024. Full analyses will be completed 6 months after the last site finishes data collection. Interim analyses will be conducted by the end of 2023 and in 2024.

Each site will collect data over the course of a 6-month period to capture any seasonal differences in infection burden or antibiotic prescribing. Sites will conduct two surveys in a two-week period (a “set” of surveys) and repeat these sets every 4-6 weeks conducting where possible a total of six to eight surveys in 6 months (Figure 1).

APC-PPS Timeline

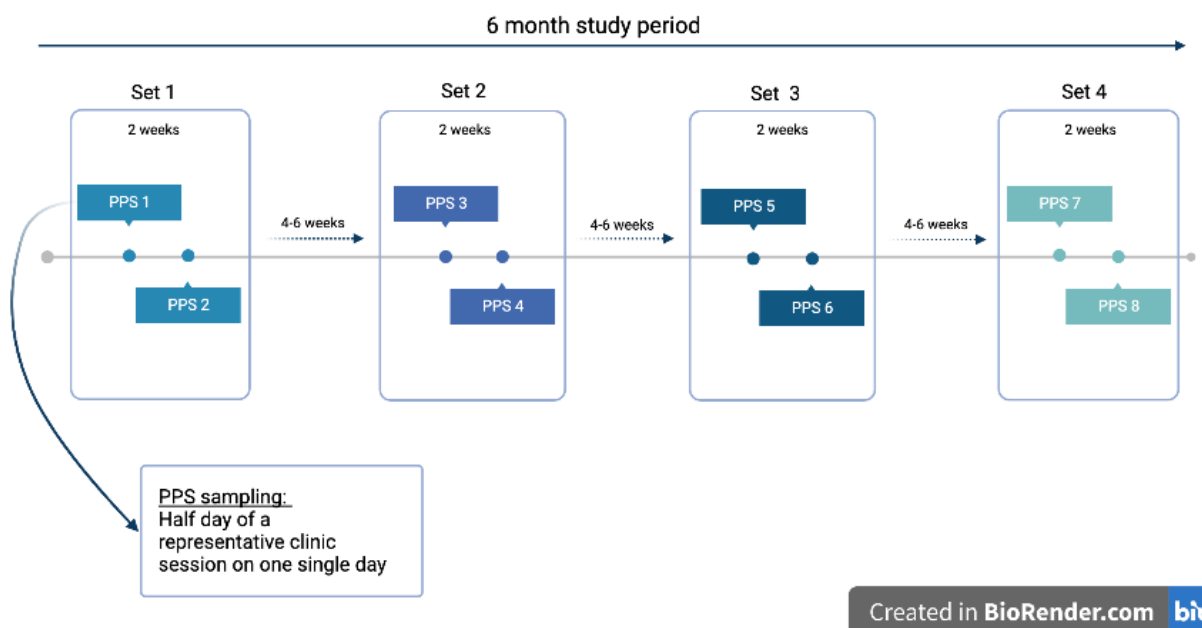


Figure 1. Study schematic timeline of APC-PPS for each site. Created with BioRender.com

3.2 SAMPLE RECRUITMENT

3.2.1 Country eligibility

Any country is eligible to participate in the point prevalence survey provided a country coordinator has been identified and the appropriate regulatory and ethical obligations are met.

3.2.2 Facility/site eligibility

Any facility within a country providing primary healthcare with staff (e.g. physician/doctor, medical officer, nurse, pharmacist, pharmacy technician, etc.) who can evaluate patient symptoms and then prescribe or dispense antibiotics are eligible to participate provided the site has identified a site point-of-contact and has met any regulatory and ethical obligations required. Sites will also need to ensure teams collecting data have access to Android phones to use the ODK Collect mobile app.

3.2.3 Patient Eligibility Criteria

This study will collect anonymous data on all eligible patients presenting to participating facilities on the day of the survey with acute infection symptoms. Data from each site will be grouped by a facility identifier to allow stratification by facility factors within a single country in order to assess heterogeneity.

Inclusion criteria

All children and adults presenting with acute infection symptoms on the day of the survey should be included. Acute is defined as symptom(s) occurring for less than 14 days.

Eligibility of patients presenting to the facility meeting these criteria will be determined by the local site team using the infection symptoms/diagnoses of interest outlined in table 1 as a guide. Local clinical discretion will be used to determine patients with acute infection symptoms. Patients with underlying chronic conditions presenting because they have acute infection symptoms should be included.

Exclusion criteria

Patients presenting to the facility seeking care for underlying chronic conditions as their primary reason for consultation will be excluded. Patients meeting the exclusion criteria will be determined by local clinical teams. Patients with chronic conditions (eg chronic obstructive pulmonary disease) who present with acute signs of infections should not be excluded.

3.3 SAMPLING STRATEGIES

3.3.1 Sampling strategy for site selection

Sites will be selected as a convenience sample based on the availability of a site team able to conduct data collection activities and for which they have met any local and/or national regulatory and ethics requirements.

As this study aims to determine the variability of clinical presentation and associated antibiotic prescribing rates there is no minimum number of sites per country defined. We aim to include a mix of private and public facilities and a mix of different types of outpatient and primary healthcare facilities and urban and rural facilities.

3.3.2 Sampling strategy for point prevalence surveys

Each primary care facility will conduct 2 single-day point prevalence surveys in a two-week period (a “set”) and repeat this every 4-6 weeks for 6 months in total. Each survey will be conducted for a half a day or approximately 4 hours of a **representative** standard clinic session on a single day. Surveys will be conducted over 6 months to capture any seasonal variation in clinical infections presenting to primary care (Figure 1).

Number of patients per facility:

As this is a point prevalence survey conducted within a specific period of time at different facilities, it is not possible to identify the specific size of the sample needed for each facility. The size of the facility and local population will influence the number of patients attending.

As presentation rates of different clinical infections will likely vary by country or facility it is difficult to determine the specific sample size of each type of infection at each facility. Some conditions are rarer than others and may not be captured on the specific day of the survey at each facility. In order to try to capture some of this variability in presentation we will conduct surveys in two half-days across different days in a two-week period.

This study will provide data on the number of patients with each diagnosis per time unit which will help to determine future sample size calculation for subsequent study designs aiming to define regional or country-level representativeness.

3.4 CONSENT

Data collected for this study will be fully anonymised at the time of data capture and will not contain any personal or identifiable information. In many settings, these types of data would be routinely collected as part of a clinical audit to assess adherence to local guidelines so we will not be obtaining individual informed consent from the patients for the purposes of this study. To understand prescribing practices in primary care, it is essential to capture as many patients presenting as possible to understand the true rates of different infections and true prescribing rates for each type of infection.

4 DATA COLLECTION

4.1 DATA COLLECTION PLATFORM

Data will be collected and managed using Open Data Kit (ODK; <https://getodk.org/>). ODK allows for offline data collection through a mobile app, ODK Collect, which improves the ease of implementation in global sites.

Data will be hosted using ODK Cloud, the hosting service provided by ODK. Data will be hosted on a private server, and only authorised project users will have access to the database. ODK Cloud is based in a secure GDPR-compliant EU data centre, all data is encrypted in transit and at rest in the ODK Cloud, and the database and data are backed up continuously.

Site data collectors will collect data using the ODK Collect app, an open-source Android application that supports offline data collection. Users will be allocated to country-specific forms using a site-specific QR code. If QR scanning does not work at a site, users can connect to the project on their computers or mobile phones using a URL and username/password. Data is synced automatically from the app to the central server when the device is connected to the internet/mobile network. Users can also submit records when they are not connected to the internet/mobile network, all data will be synced with the central server when the device is next connected to the internet/mobile network.

ODK Collect allows for an anonymous device-ID to be collected to distinguish users at each site assuming each data collector uses a unique device. In cases where one device may be used by multiple data collectors, data collectors will be prompted to enter an anonymous user ID to distinguish users where needed. To understand the feasibility of data collection of this type, the amount of time it takes for each record to be collected will be captured using ODK Collect app's metadata features. This will capture the elapsed time from when the data collector started data entry for that record to when they submitted that record.

Data in the ODK Cloud server will only be accessible to the core project team based at SGUL and University of Oxford. Sites will not have access to view or edit their data or data from other sites after it has been submitted to the central server from the mobile app (ODK Collect). At the end of the project, each site will receive a copy of their raw data in CSV format. This will be sent from the core project team at SGUL via SGUL iDrop a secure, encrypted, file transfer system. Sites will also receive summaries of their data which is outlined further in section 6.2 ("Site data at end of study").

4.1.1 Training

Country coordinators will be trained in the protocol and data collection processes by the central Project Team at SGUL. Site leaders will be trained by both the country coordinators and through online videos and documents. Data collectors at each site will be trained in ODK Collect and to understand the inclusion criteria by site leaders and online videos produced by the central Project Team. Site leaders are responsible for ensuring appropriate training of site teams to adequately implement the project. Country coordinators and site leaders will sign training logs confirming receipt of training and agreement for training those they are coordinating.

4.2 DATA COLLECTION WORKFLOW

4.2.1 Facility-level data

On the day of each PPS, data collectors will complete a form about the facility and the PPS time slot. These data will include:

Overall facility information	PPS-specific information
<ul style="list-style-type: none"> • Facility name • Facility location (city, country) • Type of primary healthcare facility • Public (e.g. government) or private • How patients pay for visits and medications • If there is a pharmacy onsite <ul style="list-style-type: none"> ○ List of antibiotics available at the facility ○ Cost of antibiotics available 	<ul style="list-style-type: none"> • Date of survey • Time slot for the PPS (e.g. start and end time indicating morning, afternoon or evening) • Total number of attenders (for all conditions) on the day of the PPS – split by number of adults (≥ 18 years) and children/babies (< 18 years) • Qualification(s) of prescribers/dispensers on day of survey (e.g. nurse, doctor, pharmacist, medical officer, etc) • Number of prescribers/dispensers during the survey time period • Antibiotics in stock on day of survey (if pharmacy is onsite)

4.2.2 Patient-level data

Fully anonymous data will be collected on the day of the PPS for all patients who present with acute (present for < 14 days) infection symptoms. Each record (patient encounter) collected is linked with a site/facility identifier based on the QR code/login used by each user at that facility which will enable analysis to account for facility differences in prescribing. The data collector will record the necessary clinical data about the patient's presentation (including patient / parent (or guardian) reported symptoms) and whether they were prescribed an antibiotic at this visit (as described in section 4.3).

Once data have been entered on the form in the ODK Collect app, the data collector will save/submit the finalised form at which point ODK will generate a unique ID number for that record. If the mobile device has internet access at the time, the data will be automatically uploaded to the server. If the mobile device is not connected to the internet, all data will be uploaded to the server when the device is next connected. Figure 2 illustrates the data collection flow.

4.2.3 Consultation data collected

No personal or identifiable data about patients will be collected. Age (years for patients ≥ 2 years; months for < 2 years) and sex of the patient will be collected to allow for reporting clinical presentation and prescribing rates adjusted for different patient populations. Certain diagnoses are more common in children (e.g. ear infections) or in women (e.g. UTI) so these data are necessary to appropriately adjust to wider populations. Time (in minutes) of travel from the patient's home to the facility will be collected for each patient to understand if there are any prescribing differences based on how far the patient had to travel to the facility. Information will also be collected as to whether the patient had previously sought medical care / medication for this infection episode.

Any relevant comorbidities that may influence antibiotic prescribing practices or clinical severity of infections will be collected as below with additional free text provision to specify any not included in this list:

- HIV
- Malnutrition
- Diabetes
- Chronic obstructive pulmonary disease (COPD)

- Asthma
- Other chronic lung problems
- Chronic heart problems

4.2.3.1 Common infection symptoms and linked clinical diagnoses

Key infections symptoms / diagnoses are based around clinical presentations described in the WHO EML Antibiotic Book. As this book provides model global guidance on prescribing for 35 common infections in adults and children, including the choice of drug, dose and duration, collecting infections and symptoms that can be mapped back to the Antibiotic Book and other guidelines is important to standardise data collection and allow for observed prescribing to be compared to guidelines.

For all primary presentations, additional symptoms are also identified including the presence of fever to assess severity of infection based around indications for antibiotic prescribing. The full list of primary infection symptoms / clinical diagnoses and additional symptom questions for each infection presentation can be found in table 1.

Table 1. List of presenting infection symptoms / diagnosis and additional symptoms questions for each infection presentation.

Presenting infection symptoms / diagnosis	Additional symptoms queried
<ul style="list-style-type: none"> • Does the patient have / report having a fever? 	<ul style="list-style-type: none"> O Persistent fever lasting 7 days or longer O Suspected enteric fever O Patient received anti-malarial prescription for this fever episode
<ul style="list-style-type: none"> • Acute cough 	<ul style="list-style-type: none"> O Cough >5 days O Shortness of breath/ difficulty breathing O Chest pain
<ul style="list-style-type: none"> • Sore throat/ pharyngitis/ tonsillitis 	
<ul style="list-style-type: none"> • Facial pain or pressure/ sinusitis 	
<ul style="list-style-type: none"> • Runny nose/ nasal congestion / coryza 	
<ul style="list-style-type: none"> • Ear pain/ acute otitis media 	<ul style="list-style-type: none"> O Uni-lateral ear pain O Bi-lateral ear pain O Otorrhoea/ ear discharge
<ul style="list-style-type: none"> • Toothache/ tooth abscess 	
<ul style="list-style-type: none"> • Acute diarrhoea / gastroenteritis 	<ul style="list-style-type: none"> O Bloody diarrhoea
<ul style="list-style-type: none"> • Increased urgency or frequency of urination / urinary tract infection (UTI) 	<ul style="list-style-type: none"> O Blood in urine
<ul style="list-style-type: none"> • Painful urination 	
<ul style="list-style-type: none"> • Genital discharge / sexually transmitted infection (STI) 	
<ul style="list-style-type: none"> • Wound/ burn/ bite infection 	
<ul style="list-style-type: none"> • Skin rash / spots – without swelling 	
<ul style="list-style-type: none"> • Skin swelling / redness / warmth / pain 	<ul style="list-style-type: none"> O Swollen lymph nodes
<ul style="list-style-type: none"> • Other primary presentation/ diagnosis 	<ul style="list-style-type: none"> Please specify other symptoms/ diagnosis:

4.2.3.2 Antibiotics of interest

We are interested in capturing all systemic antibiotics (e.g oral, intramuscular, intravenous) and topical antibiotics prescribed in primary healthcare for a given infection episode after consultation. All antivirals,

antifungals, anthelmintics, antimalarials, medicines for HIV, and any antibiotics eye drops are excluded. Generic name of antibiotic, prescribed dose and prescribed duration will be collected.

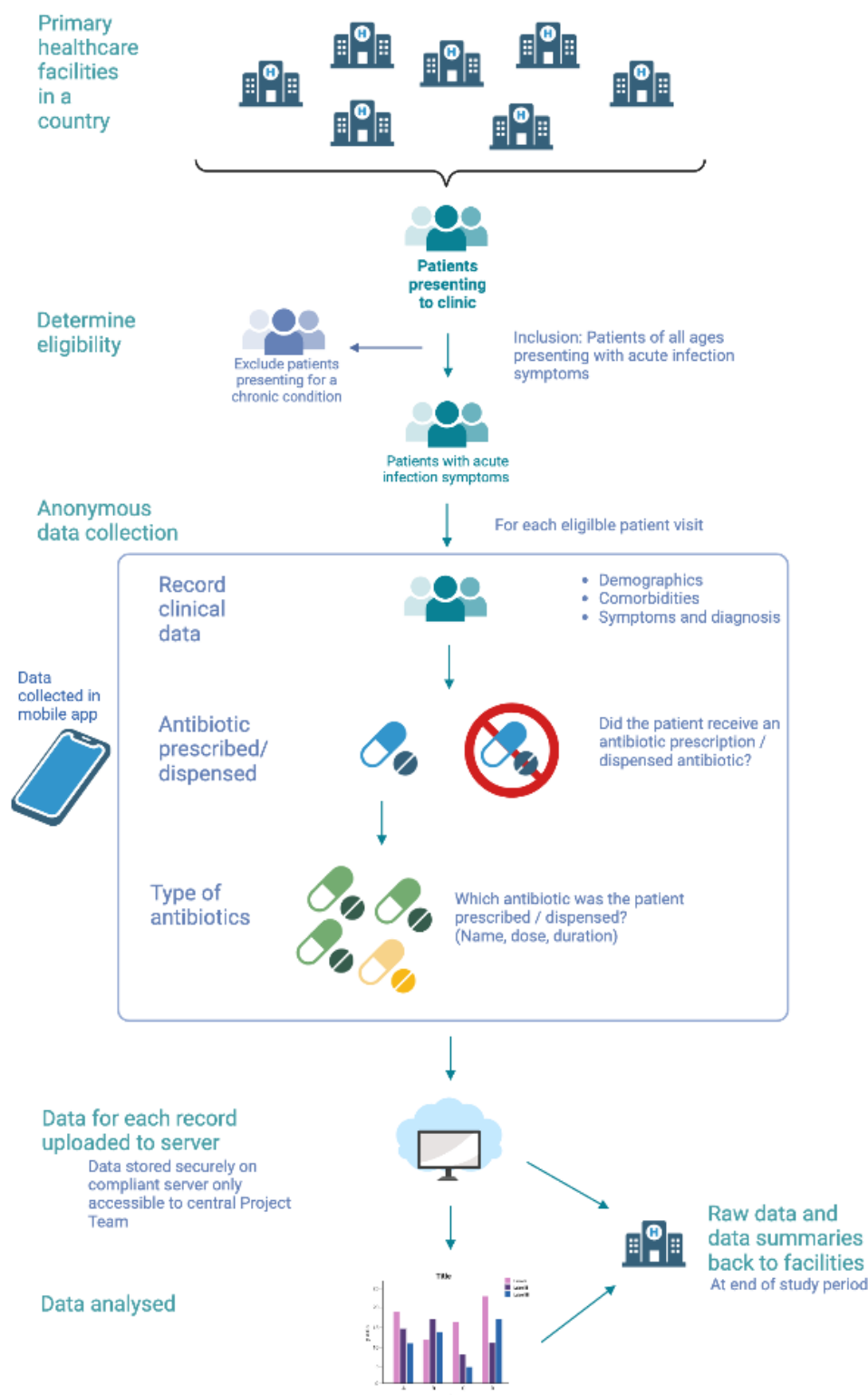


Figure 2. Data collection workflow diagram for the APC-PPS study. (created with BioRender.com)

4.3 DATA MANAGEMENT, PROTECTION AND SECURITY

Data will be collected on devices using the ODK Collect app. Only users at sites authorised by the central Project Team at SGUL, who have been allocated a QR code for the study and will be able to use the application and collect data. All patient data collected will be completely anonymous and there will be no unique identifiable patient data captured for any participant.

Data is encrypted in ODK Collect app and is sent encrypted to the ODK Cloud server. Data collected by sites will be stored centrally on ODK Cloud server based in an EU data centre, hosted by ODK. The server will be private to the central Project Team members based at SGUL and University of Oxford, and no unauthorised users will have access to the central server. The server is GDPR compliant and ISO27K, CSA STAR and SOC 2 certified. The server is backed up continuously and each back up is stored for 30 days. Data are encrypted on the ODK Central server at rest.

The data will also be downloaded from ODK Cloud monthly to a secure server based at St. George's, University of London, and there will be encrypted back up tapes, with 24-hour security. SGUL servers which are backed up overnight, every night, to hard disk and then cloned to tape storage. Full backups of all the data are carried out monthly. The cloned tapes are stored separately in a fireproof and bombproof safe off-site.

4.4 DATA ANALYSIS

Data will be analysed descriptively in the first instance. Rates of presentation for each clinical infection will be calculated. Overall antibiotic prescribing proportion and overall proportions by AWaRe categories will be summarised. The antibiotic prescribing proportion and AWaRe categories will be summarised for each clinical infection and be compared with the new WHO AWaRe Antibiotic Book prescribing guidelines, peers, and ideal prescribing proportions. Factors including demographics, comorbidities and infection severity will be explored to understand how they relate to an antibiotic prescription for an encounter, where sufficient data exists.

These data will also be used in simulations to explore the ideal sample size and sampling frame that would be needed for surveillance of antibiotic use in primary healthcare including the number and type of sites in a country, number of patients per site and frequency of sampling to inform future surveillance using PPS. We will aim to use these data to inform sample size calculations, understand co-efficients of variation and how to extrapolate from the number of patients per PPS time unit.

5 ETHICAL AND REGULATORY CONSIDERATIONS

5.1 RESEARCH ETHICS COMMITTEE (REC) AND OTHER REGULATORY REVIEW & REPORTS

Before the start of the study, an opinion will be sought from SGUL REC for the study protocol. Individual sites are responsible for ensuring relevant local and national ethics and regulatory approvals are in place prior to starting the study. The Project Team at SGUL will support sites in preparation of documents required to meet these obligations.

5.2 AMENDMENTS

For any amendment to the study, the Chief Investigator or delegated personnel, in agreement with the sponsor will submit information to the appropriate body to issue approval for the amendment. The Chief Investigator or delegated personnel will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

5.3 PROTOCOL COMPLIANCE

Protocol deviations, or data breaches are departures from the approved protocol. Any protocol deviations and data breaches must be adequately documented on the relevant forms and reported to the Chief Investigator

and Sponsor in a timely manner. However, overall risk of deviations and data breaches are low given the study design and risk to participants is negligible as there is no identifiable or personal data collected.

5.4 ARCHIVING ARRANGEMENTS

The full dataset will be downloaded from ODK Cloud at the end of data collection and the final dataset will be deposited on the St. George's Research Data Repository within one month of study completion. Analysis code and reports will also be archived on the APC-PPS Project space on the St. George's Research Data Repository. Access to the raw, unaggregated data on the repository will be restricted to only the central Project Team members at SGUL and University of Oxford. Sites will not be able to view/access raw data on the repository. Data will not be used for any purposes beyond the current described APC-PPS project and the ADILA project, without explicit permission and data sharing agreements in place with each individual site. Any aggregate datasets, code used for summary analyses and data visualisations / dashboards will be available to view on the repository Project space by collaborators at site teams 6-12 months after study completion after summary data has been returned to sites and the main paper(s) submitted for publication.

Datasets will be retained on the repository for the duration of the data retention period of 5 years. Any aggregated datasets that have been made publicly available will be published with a DOI and retained in perpetuity. All datasets archived on the repository will be accompanied by corresponding metadata in the study's documentation and cataloguing standards.

The project coordinator as SGUL will be responsible for uploading the final datasets, reports and code to the repository. The project coordinator will also be responsible for maintaining accuracy, completeness, relevance and timelines of all data archived on the repository. The St George's Research Data Service will support the project coordinator where required and ensure the data is preserved to the highest available standards. The Chief Investigator will have overall responsibility for the data archived in the repository. For corporate information governance purposes, the PI will be considered the data owner and will be the main contact for the data for the duration of the retention period. If the PI leaves St George's his/her institute manager will be responsible for the archived data.

6 DISSEMINATION AND PUBLICATION POLICY

6.1 GUIDING PRINCIPLES

The results of this study will be published in scientific and academic peer-reviewed journals and submitted as abstracts and presentations to relevant international conferences. The site and country collaborators will be involved in developing and reviewing drafts of manuscripts, abstracts and other publications and presentations arising from the results of this project.

The dissemination and publication policy for the APC-PPS project is guided by two overarching principles:

1. Transparency – All sites contributing data to the project will be informed as to the use of their data. We will ensure a process is in place for sites and collaborators to access data from the APC-PPS project for the purpose of generating local abstracts, reports, presentations and publications and the process of project approval for subsequent work are clear and agreed by all participating members of the project.
2. Quality – We will maintain a centralised publication and abstract discussion and approval process within the APC-PPS project to maintain a high quality of overall scientific output.

6.2 SITE DATA AT THE END OF STUDY

Individual sites will receive access to a summary report of their data and their raw data within 6-12 months of the end of the project (defined as end of data collection activities for all sites). Per individual agreements with each site, summary data will be shared separated by (anonymised) site, country and overall which will be

published on the APC-PPS Project space of the St. George's Research Data Repository at the end of the project and included in the analyses for the wider ADILA project. Access to raw individual site data by the country coordinator(s) will only be with explicit permission from each site in that country. Publications and other outputs from the wider ADILA project that use data contributed by collaborators from the APC-PPS will be governed by the ADILA project publication policy (separate attachment). Sites will have an opportunity to opt out of their data being used in the wider ADILA project for analyses beyond those described in the APC-PPS protocol.

6.3 ABSTRACTS AND PAPERS AUTHORSHIP

In general, all authors publishing abstracts and papers using data from the APC-PPS project are expected to adhere to the ICMJE authorship guidelines which includes:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The full dissemination and publication policy for APC-PPS is described in Appendix 3.

7 REFERENCES

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8 APPENDICIES

8.1 APPENDIX 1

Amendment Log				
Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

8.2 APPENDIX 2 – PARTICIPATING COUNTRIES

Below is a list of countries we are in discussion with as of the date of writing this protocol. Country participation will depend on meeting country and individual site ethics and regulatory requirements, thus this list remains in draft format until all of those requirements are met. Additional countries and sites will be sought throughout the study period to participate as long as all ethics and regulatory requirements are met.

- Tanzania
- Ghana
- Malawi
- Nigeria
- Kenya
- South Africa
- Botswana
- Namibia
- Uganda
- Zambia
- Pakistan
- India
- Bangladesh
- Vietnam
- Bhutan
- Malaysia
- Thailand

8.3 APPENDIX 3 – DISSEMINATION AND PUBLICATION POLICY

8.3.1 Guiding principles

The results of this study will be published in scientific and academic peer-reviewed journals and submitted as abstracts and presentations to relevant international conferences. The site and country collaborators will be involved in developing and reviewing drafts of manuscripts, abstracts and other publications and presentations arising from the results of this project.

The dissemination and publication policy for the APC-PPS project is guided by two overarching principles:

1. **Transparency** – All sites contributing data to the project will be informed as to the use of their data. We will ensure a process is in place for sites and collaborators to access data from the APC-PPS project for the purpose of generating abstracts, reports, presentations and publications and the process of project approval for subsequent work are clear and agreed by all participating members of the project.
2. **Quality** – We will maintain a centralised publication and abstract discussion and approval process within the APC-PPS project to maintain a high quality of overall scientific output.

8.3.2 Site data at the end of study

Individual sites will receive access to a summary report of their data and their raw data within 6-12 months of the end of the project (defined as end of data collection activities for all sites). Per individual agreements with each site, summary data will be shared separated by (anonymised) site, country and overall which will be published on the APC-PPS Project space of the St. George's Research Data Repository at the end of the project and included in the analyses for the wider ADILA project. Access to raw individual site data by the country coordinator(s) will only be with explicit permission from each site in that country. Publications and other outputs from the wider ADILA project that use data contributed by collaborators from the APC-PPS will be governed by the ADILA project publication policy (separate attachment). Sites will have an opportunity to opt out of their data being used in the wider ADILA project for analyses beyond those described in the APC-PPS protocol.

8.3.3 Abstracts and papers authorship

In general, all authors publishing abstracts and papers using data from the APC-PPS project are expected to adhere to the ICMJE authorship guidelines which includes:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

8.3.3.1 Main abstracts and papers

The central Project Team based at SGUL, and the University of Oxford will be responsible for overall analyses and writing of the main paper(s) which would expect to include data from all sites in all countries.

For the main papers of the project, two authors from each participating site and a country coordinator (based in the country, taking an active leadership role in identifying and coordinating sites) from each country will aim to be included. If the team is larger than 2 people at each site and more than 1 country coordinator, there will be the opportunity to include different authors on different papers. We aim to acknowledge all project contributors not listed as authors on each paper in the acknowledgements section.

8.3.3.2 Abstracts and papers using data from a single site

Sites will be provided with a summary and raw data at the end of the project. Use of summary data should acknowledge the project and funder as advised by the central Project Team.

Authors leading further analyses of single site data are recommended to but are not required to discuss and agree these with the Project Team before commencing analysis. Papers presenting data from a single site should not be submitted prior to publication of the main project paper(s).

Support for these analyses will be provided by the central Project Team where needed. Authorship for abstracts and publications arising from these analyses should comply with ICMJE criteria and all contributors from the project should be acknowledged. Authors will be expected to share any accepted abstracts and publications with the entire project network.

8.3.3.3 Abstracts and papers using data from multiple sites in the same country

Country-level analyses of data from sites is encouraged. These will be led by country coordinators (based in-country, coordinating local sites) and site teams, and raw data will be shared between sites and with the country coordinator only after explicit permission from each site. Proposed analyses should be discussed and agreed with the central Project Team before commencing analysis. The central Project Team will provide support on analyses and drafting of publications. Final abstracts and papers will be reviewed by the central Project Team at the Sponsor organisation prior to submission. Papers presenting data from multiple sites in the same country should not be submitted prior to publication of the main study paper(s).

The project and funder should be acknowledged as advised by the central Project Team. All contributing sites and researchers to these outputs should be listed as contributors/authors on each published paper and should comply with ICMJE guidelines. Authors will be expected to share any accepted abstracts and publications with the entire project network.

8.3.3.4 Abstracts and papers using data from regional analyses (e.g. multiple countries in a region)

Proposals for analyses using data from sites in multiple countries should be discussed and agreed with the Project Team. Once agreed, data will be shared with the authorship teams only after agreement from all sites in all proposed countries. Final abstracts and papers will be reviewed by the central Project Team at the Sponsor organisation prior to submission. Papers presenting data from a region or multiple countries should not be submitted prior to publication of the main study paper(s).

The project and funder should be acknowledged as advised by the central Project Team. All contributing centres and researchers to these outputs should be listed as contributors/authors on each published paper and authorship should comply with ICMJE guidelines. Authors will be expected to share any accepted abstracts and publications with the entire project network.

8.3.4 Other types of outputs

Other outputs from this project beyond conference abstracts and papers, although not exhaustive, includes presentations, dashboards, reports, and policy documents. The results of this study will also be reported in the PhD dissertation of the lead research fellow at the University of Oxford. All external communication relevant to the project should acknowledge the project and funder as advised by the central Project Team.

8.4 APPENDIX 4 – RESEARCH DATA PROTECTION IMPACT ASSESSMENT (DPIA)

Complete the form below. It will require review and sign-off by the Institute Director (SGUL) or the Care Group Lead (SGHFT).

Research Data Protection Impact Assessment (DPIA)

Data Protection Impact Assessments (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations under the Data Protection Act 2018 (DPA 18) and meet individuals' expectations of privacy.

A DPIA helps identify data privacy risks when planning new, or revising existing, projects and to identify actions to mitigate these risks. In the rare cases where risks cannot be mitigated at all it may be necessary to consult with the Information Commissioner's Office (ICO). Under data protection legislation it is a legal requirement to complete a DPIA in the following circumstances:

- where data processing is likely to result in a high risk of harm to individuals, e.g. new, invasive technology is proposed
- when large volumes of personal data are processed, e.g. use of behavioural profiles based on website usage
- when processing special category personal data on a large scale, e.g. healthcare data, genetic tests to assess and predict the disease/health risks
- where publicly accessible areas are monitored, e.g. CCTV or when filming public areas

Therefore a DPIA will be carried out for both internal and partnership projects which require the collection/processing of personal data in any format for the purpose of research.

The DPIA should be carried out towards the start of the project, in order to identify any associated information risks and mitigate in the early stages, before you start processing.

Study Title/Acronym:	Antibiotic Prescribing in Primary Care Point Prevalence Survey (APC-PPS): a Pilot Study
JRES Reference Number:	
Chief Investigator Name:	Chief Investigator: Prof. Mike Sharland
Chief Investigator Email Address:	msharland@sgul.ac.uk

PROJECT DETAILS
Project / process description: - include / attach processing operations (include a flow diagram or another way of explaining data flows), the purpose and, where applicable, what St George's lawful basis is for the processing of the information.
The APC-PPS project is a series of point prevalence surveys conducted at primary healthcare facilities to capture the types of clinical infections patients present with together with antibiotic prescribing practices. Completely anonymous data on age, sex, relevant comorbidities, infection symptoms and diagnoses and antibiotic prescription will be collected for patients of all ages who present to the facility on the day of the survey with acute infection symptoms (up to 14 days of symptoms). No personal or identifiable data will be collected from individuals. Data will be collected on ODK Collect, a mobile app designed for simple, offline data collection. Data from the app will be uploaded securely to a

private server for this project hosted by ODK Cloud. Data will only be accessible to researchers based at St. George's, University of London (sponsor) and University of Oxford as part of the ADILA project.

What personal data do you intend to use, and why? (List all categories)

No personal identifiable data will be collected.

Data on age of the patient (in months if <2 years; in years if ≥ 2 years), sex and presence of comorbidities will be collected. These are collected because risk of different clinical infections varies by demographics and the prescriber propensity to prescribe antibiotics can depend on patient comorbidities/severity of symptoms. These data are essential to interpret the presentation of clinical infections and associated prescribing proportions correctly.

Will the personal data be identifiable, pseudonymised or anonymised (if a mix tick accordingly)

Identifiable		
*Pseudonymised		
Anonymised	X	

**Confirm that the key to this data is kept securely away from the used data with strict controlled access*

List all organisations / agencies which will have access to the personal data collection used for this project / process

N/A as there is no personal data collected.

Researchers at SGUL and University of Oxford who are part of the ADILA project collaboration agreement will have access to the fully anonymised data.

Length of the study – include an assessment of the necessity and proportionality of the processing in relation to the purpose. Also include who, internally & externally, has been consulted in the preparation of this DPIA.

The study will run for 2 years total starting in January 2023. Each site will collect data for 12 months. Each site will conduct 6-8 point prevalence surveys over the course of these 12 months.

The data being processed are completely anonymous. The data collected are necessary to be able to summarise relative rates of presentation of different clinical infections and antibiotic prescribing practices to inform global estimates of antibiotic use and inform the development of surveillance methods.

If external organisations / agencies are involved, is there a contract or information sharing agreement in place with suitable clauses for data protection and data incident reporting,? If not why not?

A grant collaboration agreement is in place for the ADILA project between SGUL and University of Oxford, which outlines the Data sharing aspects of this project.

The sites will have a data sharing agreement with the sponsor before any data is shared.

RISK

Can you achieve your objectives using anonymised data? – see ICO Code of Practice on Anonymisation

Yes	X	
No		Why not?

What are the benefits to the individual of their personal data being used for this purpose?

There is no personal data being collected. Individuals will not receive any individual benefits for their data being collected. All clinical decisions are determined by local staff at the point of care; this project is only collecting information on the prescribing decisions made after the fact.			
What are the organisational benefits of the individual's personal data being used for this purpose?			
There is no personal data being collected. Data from this study will be sent back to individual sites along with summaries of their data which may allow sites to assess their prescribing practices and case burden.			
What are potential negative impacts to the individual of their personal data being used for this purpose in the event of a Data Breach occurring?			
Data are completely anonymous so there are no negative impacts to the individual in case of a data breach.			
How will you avoid causing unwarranted or substantial damage/distress to the individual when using their personal data for this purpose?			
The individual is not contributing personal data.			
Is the data already held by St George's?			
Yes			
No	X		
Is it held by one of the partner organisations / agencies involved in this process/project?			
Yes			
No	X	Which agency will be collecting the data	Local site teams
Have you told the individuals whose personal data you want to use for this purpose, how and why you intend to use their data?			
Yes			
No	X		
If not, are you intending to tell them?			
Yes			
No	X	Why not?	No personal data is being collected.
Do you already have the individual's consent to use their data for this purpose?			
Yes			
No	X	Why not?	No personal data is being collected.
If not, are you going to ask for their permission?			
Yes			
No	X	Why not?	No personal data is being collected.
Have individuals been given the opportunity to refuse us permission to use their data for this purpose?			
Yes			
No	X		
How will you make sure that the personal data you are using is kept accurate and up to date?			
N/A – no personal data is being collected.			
What steps or controls are you taking to minimise risks to privacy?			
Please tick those which apply and provide details of how each is ensured			
<ul style="list-style-type: none"> Risks to individual privacy are minimal Personal data is not collected Encryption of data at rest, i.e. when stored 		X – all data are anonymous. X – no personal data is collected. X – data is encrypted at transfer and at rest. X – IG training completed for all SGUL team members.	

<ul style="list-style-type: none"> • Information compliance training for staff has been completed - data protection, information security, FOI • Adherence to privacy by design principles • Special category personal data is not used • Research is not used to make decisions directly affecting individuals • Restricted access controls • Other (please specify) 	<p>X – data is anonymous and local clinicians are responsible for all clinical decisions regarding patients.</p> <p>X – only specific project members at SGUL and University of Oxford will have access to the data and this will be through secure and private logins.</p>
How long will you need to hold the personal data for after the study has completed?	
<p>N/A – no personal data is collected.</p> <p>Anonymised study data will be archived and retained per SGUL policies.</p>	
How will you make sure that you are holding data for the appropriate length of time and no longer?	
<p>No personal data is held.</p>	
How will the data be held /stored?	
<p>Data will be stored on a secure server hosted by ODK Cloud and the SGUL server. Only researchers from SGUL and University of Oxford who are a part of the ADILA project will be able to access the data.</p> <p>Data will be archived on the St. George's Research Data Repository and held for 5 years after the completion of the project. Access to any raw / unaggregated data on the repository will be limited to researchers who are members of the project team at SGUL and University of Oxford.</p>	
Will you be using any electronic and/or paper Case Report Forms (CRFs) to collect data? If so what are these and how will they be held securely and managed at the end of the project?	
<p>Data will be entered directly into a mobile app and uploaded to the server. No data is stored on the mobile device and data collectors will not be able to review the individual data once it has been submitted.</p>	
Will personal data be transferred/shared between the organisations involved in this project? If so how?	
<p>N/A – no personal data is collected.</p>	
Will you be transferring personal data to a country or territory outside of the UK? If yes, name countries and receiving parties.	
Yes – within EEA	
Yes – outside of EEA	
No	X No personal data is collected or held
How will you ensure that third parties will comply with data protection obligations?	
<p>No personal data is collected. Site partners will not have access to the main data server and will not be able to see data from other sites or amend their own data.</p>	
What measures are in place to ensure only appropriate and authorised access to and use of, personal data?	
<p>No personal data will be collected.</p>	
How will technical and organisational security be monitored/audited?	
<p>Data is encrypted in ODK Collect app and is sent encrypted to the ODK Cloud server. Data collected by sites will be stored centrally on ODK Cloud server based in an EU data centre, hosted by ODK. The server will be private to the central Project Team members based at SGUL and University of Oxford, and no unauthorised users will have access to the central server. The server is GDPR compliant and ISO27K, CSA STAR and SOC 2 certified. The server is backed up continuously and each back up is stored for 30 days. Data are encrypted on the ODK Central server at rest.</p>	

The data will also be downloaded from ODK Cloud monthly to a secure server based at St. George's, University of London, and there will be encrypted back up tapes, with 24-hour security. SGUL servers which are backed up overnight, every night, to hard disk and then cloned to tape storage. Full backups of all the data are carried out monthly. The cloned tapes are stored separately in a fireproof and bombproof safe off-site.

The CNPI data manager will check the audit trail on ODK Cloud server monthly to confirm user access remains secure and only those authorised have accessed the central server. The CNPI data manager will also confirm quarterly that data back ups from ODK Cloud to the SGUL server have occurred monthly and are stored securely only accessible to authorised users.

Declaration

I confirm that the information recorded on this form is, to the best of my knowledge, an accurate and complete assessment of the potential privacy impacts of this study.

Name:

Signature:

Date:

Institute Director (SGUL) or Care Group Lead (SGHFT)

Name:

Signature:

Date:

JRES Reviewer

Name:

Signature:

Date: