

Schools Transmission Study (COVID-19 and scarlet fever)

Submission date 02/10/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/03/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Prior to the COVID-19 pandemic this study focused on scarlet fever outbreaks amongst school children. In March 2020 schools and nurseries were closed due to the pandemic which demonstrated an abrupt decline in scarlet fever notifications. Now that schools and nurseries are reopening, this study has added a COVID-19 arm to monitor the spread in children. This will help us better understand the role of children in the transmission of COVID-19 and help modelling for better public health interventions. Therefore the purpose of this study is to gather much-needed information about the transmission of notifiable infectious diseases in children within nursery and school settings. The study currently focuses on two infections (scarlet fever and COVID-19). In both cases, there may be asymptomatic or mild infection in children, however if transmitted to a susceptible person these pathogens can result in more serious disease. It is therefore important to determine to what extent transmission occurs from an infected child, and to determine if there are interventions required to reduce transmission.

Who can participate?

Confirmed scarlet fever or COVID-19 Cases in a local community that trigger the study will be identified via voluntary or statutory notification to PHE. Cases to be recruited for this study will be school children aged 2 - 11 years (scarlet fever) or 2 - 14 years (COVID-19). Eligible Contacts will be invited to participate based on their membership of a nursery or school affected by scarlet fever (2 cases within the same class) or by COVID-19 (1 case within the same school or 2 cases in the local community), or by membership of the same household as a case. Contacts to be recruited for this study will be school children aged 2 - 11 years (scarlet fever) or 2 - 14 years (COVID-19) attending the school affected by the Case(s) or school staff or members of Household (any age) affected by Case(s).

What does the study involve?

The study will collect multiple different samples from an infected case, and also collect samples from the environment around the child and the school of air and surfaces over a period of 4 weeks. Household and classroom contacts will be followed up for 4 weeks. Samples collected will be tested for the pathogens (live group A streptococcus in the case of scarlet fever or live SARS-CoV-2 in the case of COVID-19).

What are the possible benefits and risks of participating?

Possible benefits of this study are an understanding of how scarlet fever and COVID-19 may or may not be transmitted amongst children in order to determine if there are interventions required to reduce transmission. The possible risks include mild discomfort from sample collection (throat swabs), and unintended consequences may include perceived stigma around sampled children, worry and mental wellbeing.

Where is the study run from?

The study will take place in schools or nurseries within the Greater London area as well as in homes of children who are infected or have been exposed to COVID-19 or scarlet fever.

When is the study starting and how long is it expected to run for?

September 2017 to March 2025

Who is funding the study?

1. Action Medical Research (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Prof. Shiranee Sriskandan (scientific), s.sriskandan@imperial.ac.uk
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

225006

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 225006, CPMS 37059

Study information

Scientific Title

Schools Transmission Study - COVID-19 and Scarlet Fever

Study objectives

The overall burden of human infectious diseases including scarlet fever and COVID-19 can be reduced by interruption of transmission; this will reduce the reservoir of such infections in the community that might otherwise infect susceptible people leading to more serious COVID-19 or iGAS disease. Understanding the burden and transmission of COVID-19 in schools should inform community control measures and vaccination strategies going forward.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/06/2020, London – Chelsea Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2561; Chelsea.rec@hra.nhs.uk), ref: 18/LO/0025

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection), Scarlet fever

Interventions

Scarlet fever arm:

At the time an outbreak of scarlet fever is reported to PHE (and there are at least 2 cases in a cluster):

1. HPT will offer the usual advice to the school/nursery about scarlet fever (written document) but also ask the school or nursery if it is interested in participating in a study about scarlet fever (additional information leaflet about the study)
2. The usual standard PHE letter about scarlet fever will be sent to the home of all classroom contacts via the school/nursery (letter sent with children or by email depending on school preference) PLUS a request to participate in study; an information leaflet and consent form will be supplied, with a request to bring signed form back to school/nursery next day. Age-appropriate leaflets and assent forms for children will also be sent home. Option to consent by email will also be possible via the school
3. HPT nurse will take environmental swabs (surfaces, toys etc) and issue standard guidance on hygiene to school
4. Next day: HPT nurse will visit school/nursery and, guided by the school/nursery, will take throat swabs from each child with completed consent and assent forms. The location where swabbing takes place will be advised by the school and will preferentially take place before eating. Each swab will be labelled with linked unique identifier and date. If a child reports sore throat or visible tonsillitis this will also be recorded and the advice from the routinely provided information leaflet will be reiterated via school to parents
5. One week later, the HPT nurse will visit school/nursery again: environmental swabs will be repeated and throat swabs from each child with a completed signed consent form will be taken. This will be repeated weekly until the end of a four week period (maximum four throat swabs per 'well' child)
6. In the event that a group A streptococcus is identified on throat swab, no action will be taken if the child was asymptomatic. If the child has symptoms of pharyngitis, the HPT nurse will advise that the child should be taken to their GP which is already advised on the routine leaflet.

At the time of notification of an individual case (aged 2-8) of suspected scarlet fever from within a cluster

1. HPT nurse will make contact with child's primary guardian and routine PHE information leaflet will be provided PLUS a request to participate in study (information leaflet and consent form, along with age appropriate leaflet and assent form)
2. Day 1: HPT nurse will visit household/child with agreement of carer and obtain informed consent for swabbing of case of scarlet fever and questionnaire. First swabs will be taken (throat and hand) and cough plate taken (child coughs directly onto a blood agar plate which is subsequently incubated for quantitative culture). Samples will be labelled with study unique identifier and sample type
3. Questionnaire administered - can be left with parents if requested. This will be labelled with unique study identifier and not any other identifier. HPT will ascertain if child has seen GP and is commencing antibiotics or that this is planned. HPT will ascertain if child is likely to be in school on day 2 or still at home
4. Consent will be sought for swabbing of other household contacts (adults and children) by providing information leaflet for household contacts including age-appropriate leaflet and assent forms for children in the household
5. Day 2: HPT will visit child with agreement of carer/school. Second swabs will be taken (throat and hand) and cough plate taken (child coughs directly onto a blood agar plate which is subsequently incubated for quantitative culture). Samples labelled as above
6. HPT nurse will visit child daily with agreement of carer/school to continue daily swabs and cough plate for a maximum of 7 consecutive days

7. Thereafter the HPT nurse will visit at day 14, day 21, day 28 to repeat the swabs and cough plates
8. The HPT nurse will obtain throat swabs from consenting household contacts (adults and other children) at any convenient time during week 1 and then again on day 14, day 21, and day 28
9. HPT nurse will complete the questionnaire in collaboration with the carer; this can be in person, by post, or by telephone
10. Sample timing will be flexible to accommodate participants' other activities and duties however the maximum number of samples will not exceed 4 timepoints for any classroom or household contact and will not exceed 10 timepoints for scarlet fever cases
11. Given that there will be far more notifications of scarlet fever cases than can be visited and swabbed, there will be an option to contact a child's guardian by post (in the case of notified cases) to request that a simplified questionnaire be completed on line, or the questionnaire will be mailed with a stamped addressed envelope. In the case of the on line survey, a unique link will be provided to ensure that the survey can only be completed once but this would be anonymised; consent for the survey alone would not be sought

COVID-19 arm:

Similar to the above with the following changes:

1. Trigger to recruitment in will be one case of SARS-CoV2 in the school or two cases of SARS-CoV2 in postcodes served by the school (adult or child cases)
2. Age range of Child Cases and Contacts 2 - 14 years
3. School Staff will be recruited as Contacts
4. Collect saliva rather than cough plates
5. Collect stool sample from Cases if available
6. Collect air samples rather than settle plates in school environment and home
7. Disclosure of SARS-CoV2 results to participants will be necessary because there is government guidance on actions to be taken in the event of a positive result. This is different from the scarlet fever arm of the study, where detection of streptococcus in asymptomatic children does not trigger any treatment or specific action

Intervention Type

Other

Primary outcome(s)

Measured at the time of outbreak:

Scarlet fever arm:

1. Detection of viable group A streptococcus measured by conventional bacterial culture
2. Longevity of group A streptococcal infection/shedding using bacterial culture on repeated days/weeks
3. Genomic evidence confirming or refuting transmission ascertained using genome sequencing and comparative phylogenetic analysis of bacteria identified

COVID-19 arm:

1. Detection of SARS-CoV2 RNA measured using quantitative rtPCR; result: Yes or No
2. Viral load of RNA measured by qRTPCR
3. Viability of viral RNA after viral culture measured using Vero Cell culture and assay of RNA increase; result: Yes or No
4. The longevity of SARS-CoV2 infection/RNA shedding measured using quantitative rtPCR and viral culture on repeated days/weeks
5. Total number of contacts (Contacts are school children 2 - 14 years attending the school affected by the Case(s) or school staff or members of Household (any age) affected by Case(s))

5. Number of contacts with a positive swab
6. Genomic evidence refuting transmission ascertained using genome sequencing and comparative phylogenetic analysis of viruses identified; result: Yes or No

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/03/2025

Eligibility

Key inclusion criteria

1. School children aged 2y - 11y (scarlet fever) or 2y - 14y (COVID-19)
2. Notified cases or contacts of cases attending the same school affected by case(s) or school staff or members of Households (any age) affected by case(s) provided consent is obtained

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

2 years

Upper age limit

14 years

Sex

All

Key exclusion criteria

1. Children who express a strong desire not to participate despite parental consent
2. Those who lack capacity to consent
3. Children aged under 1

Date of first enrolment

01/03/2018

Date of final enrolment

31/03/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Public Health England

South London Health Protection Team

Public Health England

Zone C, 3rd Floor, Skipton House

80 London Road

London

United Kingdom

SE1 6LH

Sponsor information

Organisation

Imperial College London

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Government

Funder Name

Action Medical Research; Grant Codes: GN2596

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

National Institute for Health Research; Grant Codes: COV0332

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Preprint results	non-peer-reviewed results in preprint	09/03/2021	17/03/2021	No	No
Protocol file	version v5	01/05/2020	22/10/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes