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Schools Transmission Study (COVID-19 and scarlet fever)

Submission date
02/10/2020

Recruitment status
No longer recruiting

Registration date
22/10/2020

Overall study status
Completed

Last Edited
17/03/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Kerri Hill-Cawthorne (public), k.hill-cawthorne@imperial.ac.uk

Study website
https://www.imperial.ac.uk/medicine/hpru-amr/patient-and-public-information/schools-transmission/

Contact information

Type(s)
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
225006

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)
School

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2017

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

Age group
Mixed

Lower age limit
2 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
Planned Sample Size: 344; UK Sample Size: 344

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
England

United Kingdom

Study participating centre
Public Health England
South London Health Protection Team
Public Health England
Zone C, 3rd Floor, Skipton House
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SE1 6LH

Sponsor information

Organisation
Imperial College London

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Sponsor type
University/education

Website
http://www.imperial.edu/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Action Medical Research; Grant Codes: GN2596

Alternative Name(s)
actionmedres, action medical research for children, 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

Publication and dissemination plan
Interim reports where appropriate will be posted to an open access site such as BioRXiv. Planned publication in a high-impact peer-reviewed journal at the end of the first year of study (Sept 2021) and each year thereafter until the study ends (March 2025).

Intention to publish date
30/09/2021

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?
Protocol file	version v5	01/05/2020	22/10/2020	No	No
Preprint results	non-peer-reviewed results in preprint	09/03/2021	17/03/2021	No	No
HRA research summary			28/06/2023	No	No