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Peru respiratory and enteric infection survey of incidence over time

Submission date
19/03/2025

Recruitment status
No longer recruiting

Registration date
28/03/2025

Overall study status
Ongoing

Last Edited
28/03/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol
Background and study aims
Acute respiratory infections (ARI), resulting from infection with viral and/or bacterial pathogens, are a major source of morbidity and mortality globally, and in Peru, lower respiratory infections are a leading cause of death. Moderna Therapeutics Inc. (the funder) is currently developing several mono- and multi-valent mRNA vaccines targeting a variety of ARI pathogens. They are also developing mRNA vaccines for the prevention of acute gastroenteritis (AGE) caused by the most prevalent norovirus genotypes in young children and older adults. This study aims to update the epidemiology, natural history and impact of ARIs and AGE.

Who can participate?
Residents in a randomly selected household within the participating communities in Callao, Peru

What does the study involve?
24 blocks will be randomly selected from a total of 8,382 blocks identified. Approximately 11 households in each block will be recruited to reach the required sample size. Characteristics of participants and their households will be recorded at recruitment and then updated approximately every 12 weeks.

Daily syndromic surveillance will identify episodes of ARI and AGE. When a participant develops such an episode, samples will be collected once, depending on ARI or AGE including some respiratory swab(s), saliva, and/or stool. For ARI episodes, a single point-of-care test will be performed on a respiratory swab specimen for two primary ARI pathogens combined (SARS-CoV-2 and Flu), usually in the participant's residence. All fieldwork will be carried out by the team at the NGO Prisma. Whilst, additional pathogen testing on respiratory and stool specimens using multiplex PCR-based assays will be conducted at the Laboratory of Investigation and Development (LID) - Universidad Peruana Cayetano Heredia (UPCH). The saliva specimens will be collected from individuals with AGE for immunologic analyses at Moderna. All specimens collected will be de-identified, processed, and stored as a biorepository. Stored specimens will be selected for whole genome sequencing. Questionnaires will be administered daily to collect data on self-reported symptoms and impact until resolution. Illness impact will be quantified as healthcare required and using a questionnaire. Regular control specimens will also be collected from a random set of participants. Lastly, wastewater specimens will be collected weekly from

community outlets for pathogen detection and sequencing using metagenomic methods at Johns Hopkins University, USA.

The investigators also partner with local health personnel to share study characterization of current infection epidemiology and to record weekly numbers and ages of patients seeking care in health centers for acute illnesses.

What are the possible benefits and risks of participating?
To reduce the risk of loss to follow-up, and to ensure that participating in the study is affordable, study participants will be reimbursed for their costs of participation. The details of this reimbursement can evolve over the study timeline, but initially are (1) phone credit for at least one member of each household to pay for the cost of and ensure the ability to use cell phones daily for the daily syndrome surveillance; (2) locally appropriate food baskets provided at recruitment and each 3-monthly interview (3) during an episode of ARI/AGE, for those who are recommended to seek medical attention their transport costs will be supported to the local health post to ensure access to care is affordable. The reimbursements outlined above are also considered as benefits to enter the study. No adverse events are anticipated to occur as a direct consequence of participating in this observational study, especially since the samples are being collected in a non-invasive manner.

Where is the study run from?
Prisma

When is the study starting and how long is it expected to run for?
April 2024 to April 2026

Who is funding the study?
Moderna TX Inc

Who is the main contact?
Dr Sumona Datta, sumona.datta@ifhad.org
Prof Carlton Evans, carlton.evans@ifhad.org

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
mRNA-IDOB-P906

Study information

Scientific Title
Peru Respiratory and Enteric infection Survey of IncidENce over TimE (PRESIENTE)

Acronym
PRESIENTE

Study objectives
The study rationale is to update the epidemiology and natural history of acute respiratory infections (ARI) and acute gastroenteritis (AGE) from routine collection of specimens from individuals with laboratory confirmed ARIs and AGE in urban poor communities in Peru.

Ethics approval required

Ethics approval required

Ethics approval(s)
1. Approved 19/12/2024, Institutional Ethics Committee of Research of Prisma (Santo Toribio 115 Office 701, Lima, 15306, Peru; +51 2090400; mmateo@prisma.org.pe), ref: CE0552.24

2. Approved 02/12/2024, Comité Institucional de Ética en Investigación (CIEI), Universidad Peruana Cayetano Heredia (Av Honorio Delgado 430, San Martin de Porres, Lima, 4314, Peru; +511 3190000; orvei.ciei@oficinas-upch.pe), ref: SIDISI 214969

3. Approved 10/06/2024, Comité de Ética para la Investigación de la DIRESA Callao (Jr, Colina #879, Bellavista, Lima, 07016, Peru; +51 1 4651801; faguilar@diresacallao.gob.pe), ref: CONSTANCIA N0 014-2024 – COMITÉ DE ÉTICA/UI/DIRESACALLAO

Study design
Community-based prospective syndromic surveillance study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community, Home, Internet/virtual, Laboratory, Telephone

Study type(s)
Other, Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Acute respiratory infections and gastroenteritis

Interventions
This is a longitudinal observational study. At recruitment, participants will undergo a face-to-face interview carried out by study staff; data from this interview will be updated in a follow-up interview every 3 months. After recruitment, and every day, for 18 months, participants will be surveyed about their ability to carry out their activities of daily living and symptoms with the use of a hybrid chatbot/interview system monitored and managed by study staff.

This daily syndromic surveillance aims to identify episodes of ARI and AGE. When a participant develops such an episode, samples including respiratory swab(s), saliva, and/or stool will be collected once, depending on whether ARI or AGE. For ARI episodes, a single point of care test will be performed on a respiratory swab specimen for two primary ARI pathogens combined (SARS-CoV-2 and Flu), usually in the participant's residence. All fieldwork will be carried out by the team at the NGO Asociacíon Benefica Prisma. Additional pathogen testing on respiratory and stool specimens using multiplex PCR-based assays will be conducted at the Laboratory of Investigation and Development (LID) - Universidad Peruana Cayetano Heredia (UPCH). Whilst saliva specimens will be collected from individuals with AGE for immunologic analyses at

Moderna. All specimens collected will be de-identified, processed, and stored as a biorepository, so that selected stored specimens can be processed later for testing such as whole genome sequencing. During an episode, ARI/AGE episodes data will be collected from face-to-face /telephone interviews until participants self-report no more impact on their activities of daily living. Illness impact will be quantified as healthcare required and using the EuroQol 5 Dimension 5 Level (EQ-5D-5L) questionnaire. Regular control specimens will also be collected from a random set of participants.

Lastly, wastewater specimens will be collected weekly from community outlets for pathogen detection and sequencing using metagenomic methods at Johns Hopkins University, USA.

Intervention Type
Other

Primary outcome measure
From individuals identified to have a new episode of acute respiratory infections (ARI) and/or acute gastroenteritis (AGE) from the daily symptoms surveillance, we will report the:
1. The frequency and incidence rate of specific infections measured using the rapid point-of-care test or multiplex PCR-based assay of the sample collected within 24 hours of identifying a new ARI/AGE episode
2. The frequency of symptoms by specific pathogens measured using the rapid point-of-care tests or multiplex PCR-based assays of the sample collected within 24 hours of identifying a new ARI/AGE episode
3. Genetic diversity of SARS-CoV-2, RSV, influenza and norovirus measured using sequencing of samples collected within 24 hours of identifying a new ARI/AGE episode

Secondary outcome measures
1. Measure the association between the incidence rate of overall and pathogen-specific ARI and AGE episodes as described in the primary outcome measures with individual/household level factors recorded in a locally validated questionnaire at recruitment and updated every 3 months.
2. Describe the secondary attack rate of ARI and AGE within household contacts of ARI/AGE overall and by pathogen by ARI and AGE episodes as described in the primary outcome measures.
3. Measure and describe the frequency of detection and genetic diversity of ARI and AGE-associated pathogens by multiplex PCR-based assays and metagenomics analysis from wastewater specimens collected weekly from participating communities' wastewater outlets.

Overall study start date
19/04/2024

Completion date
19/04/2026

Eligibility

Key inclusion criteria
1. Living in a randomly selected household in the study setting
2. Provision of informed written consent

Participant type(s)
Healthy volunteer, Resident

Age group
All

Sex
Both

Target number of participants
1056

Key exclusion criteria
1. Individuals expected to move out of the selected address during the study period
2. Adults without legal capacity
3. Illiteracy

Date of first enrolment
31/12/2024

Date of final enrolment
01/04/2025

Locations

Countries of recruitment
Peru

Study participating centre
Callao
Any residence within the following 32 communities:
C.S.Alta Mar
C.S.La Perla
C.S. Base Perú - Korea
C.S.Manuel Bonilla
C.S.Barton
C.S.Santa Fe
C.S.José Boterin
C.S.Callao
C.S.Nestor Gambetta
C.S. V. Sr. De Los Milagros
C.S. Acapulco
C.S. Bocanegra
P.S. Polígono IV
C.S.Previ
C.S.Sesquicentenario
C.S. EL Alamo
P.S. Oquendo
C.S.Marquez
C.S. Ventanilla Baja
C.S. Ventanilla Este
C.S. Angamos

C.S. Hijos del Almirante Grau
P.S. Defensores de la Patria
C.S. Ventanilla Alta
C.S. Ciudad Pachacútec
C.S. Bahía Blanca
C.S. 03 de Febrero
C.S. Materno Koika
C.S. Mi Perú
C.S. Sta. Rosa de Pachacútec
C.S. Villa de los Reyes
C.S. Luis Felipe de las Casas
Callao
Peru
07001

Sponsor information

Organisation
Prisma

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Sponsor type
Charity

Website
https://www.prisma.org.pe/

ROR
https://ror.org/011y8cj77

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan

The results of each objective of this study will be disseminated through the submission of scientific abstracts for presentation at domestic and international conferences as well as several manuscripts. Authorship of abstracts and manuscripts will follow ICJME guidelines for defining roles of authors and contributors.

Intention to publish date

19/04/2027

Individual participant data (IPD) sharing plan

The anonymised epidemiological data generated will be published as a supplement to the results publications

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	17/07/2024	28/03/2025	No	Yes