ISARIC

International Severe Acute Respiratory and emerging Infection Consortium

CCP Global

Case Study, Malawi

Name of network:	Malawi-Liverpool Wellcome Trust Clinical Research Programme.
Brief aim of the network:	Support the Malawi Ministry of Health in diagnostic, secondary care and public health delivery during the COVID-19 pandemic.
ISARIC resources being used/adapted e.g. CRFs, REDCap Data Platform:	Protocol, ICFs and LMIC eCRF platform. We developed the LMIC eCRF platform and have shared this for wider use in Africa context.
Brief overview of amendments to templates:	In general, amendments to the Participant Information Sheets and Informed Consent Forms were as follows: 1. Inserted local contact details 2. (if unable to take blood from a vein) specified finger or heel prick 3. Explained what DNA is 4. Inserted paragraph about withdrawing from the study 5. Inserted thumbprints to confirm signature, along with witnessed consent. Adult Participant Information Sheet: 1. IRB requires compensation to participants – paragraph inserted. 12-18 years old, Participant Information Sheet: 1. Increased age to 17 years old. Under 12 years old, Participant Information Sheet: 1. Blood sample - added finger/or vein. Consultee guidance: Added to the introduction “Once your relative / friend is well enough, we will ask them for their consent to be involved in this study (called ‘retrospective consent). They can withdraw from the study if they want to then, even if you have already given consent and signed this form. If they do not regain capacity for any reason then your assent will be used as evidence for involvement in the study.”
Brief description of the clinical infrastructure, resources and capacity at your network/site:	Our site is adjacent to Queen Elizabeth Central Hospital, the largest tertiary care centre in Malawi. We have excellent molecular and immunology laboratory facilities on site and are one of the four currently recognised COVID diagnostic testing centres in Malawi. We aim to leverage these facilities under the ISARIC protocol to understand how COVID-19 impacts on hospitalised patients in Malawi.
Which Tier are you operationalising?	We aim to operationalise Tiers 0, 1 and 2.
What sampling strategy are you using?	We are aiming to use the priority three sampling strategy, *[from Tier 2, with samples being taken at days 1, 3 and 9]*.

<table>
<tr>
<td>Focus for operationalising CCP?</td>
<td>First priority was staff safety and the difficulty in taking samples and collecting data per patient.

We established a team of three per patient – overview given in table below:

<table>
<tr><th>Team Member</th><th>PPE Context</th><th>Role</th></tr>
<tr><td>1</td><td>1 – full (single use)</td><td>Measures physiological observations and collects samples.</td></tr>
<tr><td>2</td><td>2 – less restrictive (sessional use)</td><td>Collects data from notes and witnesses Informed Consent.</td></tr>
<tr><td>3</td><td>2 – less restrictive (sessional use)</td><td>Supports Team Member 1 (double bagging and packing of samples; Runner – in case of unforeseen circumstances; Delivers samples to specimen collection reception before transfer to lab.</td></tr>
</table>

PPE guidance taken from the UK Governments' Public Health England Guide 'Recommended PPE for healthcare workers by secondary care inpatient clinical setting, NHS and independent sector'. Link below:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879107/T1_poster_Recommended_PPE_for_healthcare_workers_by_secondary_care_clinical_context.pdf</td>
</tr>
</table>