ALERRT Clinical Characterization Protocol (CCP): multinational research response to a global health emergency; the African Story

Dr. Joseph Bonney
Emergency Medicine Specialist, Komfo Anokye Teaching Hospital
Research Fellow, Global Health and Infectious Diseases Research Group, Kumasi
Collaborative Centre for Research in Tropical Medicine
21 partner organizations from 13 countries (9 African and 4 European)
ALERRT is part of the EDCTP2 Programme supported by the European Union under grant agreement RIA2016E-1612.

ALERRT is also supported by the United Kingdom National Institute for Health Research.
What is the Clinical Characterisation Protocol (CCP) ?

The Clinical Characterisation Protocol (CCP) is designed for any severe or potentially severe acute infection of public health interest.

• It is a standardised protocol that enables data and biological samples to be collected rapidly in a globally-harmonised manner.

• The Clinical Characterisation Protocol (CCP) can be used for the rapid, coordinated clinical investigation of confirmed cases of COVID-19.
Why is Clinical Characterisation Protocol (CCP) important?
Why is Clinical Characterisation Protocol (CCP) important?
Why is Clinical Characterisation Protocol (CCP) important?

Solution

Comparable Results
Large Data Sets
Increased Impact
Clinical Characterisation Protocol (ALERRT CCP)

ISARIC, the International Severe Acute Respiratory and emerging Infection Consortium has developed a clinical characterisation protocol for COVID-19. This protocol has been endorsed by the WHO.

Adaptation of the protocols based on the local capacity, resources and specific local context

ALERRT Africa Ready Documents
STEP 1- STEP 6
Development of XML files

ALERRT is part of the EDCTP2 Programme supported by the European Union under grant agreement RIA2016E-1612
ALERRT is also supported by the United Kingdom National Institute for Health Research
Clinical Characterisation Protocol (ALERRT CCP)

ALERRT will work closely with the WHO/AFRO, Africa CDC and existing networks and structures across Africa and globally to adapt the CCP for implementation in Africa.
Clinical Characterisation Protocol (ALERRT CCP)

- **Ethics and Consent**: inclusion of thumb printing and photography of consent forms
- **Data Collector’s Details**
- **Employment**:
- **Co-Morbidities and Risk Factors**: Addition of alcohol consumption with detail in consumption pattern and addition of details of smoking
- **Imaging**: Increased details on CXR and other images
- **Mental Assessment**: Kessler Psychological Distress Scale (K10)
- **Data Collection vs. EMR**: The electronic version of the CRF was adopted to enable the use of the REDCap as an electronic medical record
  - Identifiable data
  - Doctors and nurses notes

Adaptation of the protocols based on the local capacity, resources and specific local context.
Clinical Characterisation Protocol
### Clinical Characterisation Protocol

**Ghana COVID-19**

#### Background

**Adding new Record ID 2**

<table>
<thead>
<tr>
<th>Record ID</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PARTICIPANT IDENTIFICATION</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Date of birth</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Month</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Telephone Number</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Email</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Address with landmarkrs</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>Ghana Post GPS</strong></td>
<td></td>
</tr>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td><strong>National Identification Card Number</strong></td>
<td></td>
</tr>
<tr>
<td>Consent and Patient Categorization</td>
<td></td>
</tr>
<tr>
<td>Demography</td>
<td></td>
</tr>
<tr>
<td>Case Pathway</td>
<td></td>
</tr>
<tr>
<td>Epidemiological Factors</td>
<td></td>
</tr>
<tr>
<td>Animal Contact</td>
<td></td>
</tr>
<tr>
<td>Pregnancy and Postpartum</td>
<td></td>
</tr>
<tr>
<td>Infants and Children Under 5 Years</td>
<td></td>
</tr>
<tr>
<td>Vaccination Information</td>
<td></td>
</tr>
<tr>
<td>Signs and Symptoms Preadmission</td>
<td></td>
</tr>
<tr>
<td>Pre-Admission Medication</td>
<td></td>
</tr>
<tr>
<td>Comorbidities And Risk Factors</td>
<td></td>
</tr>
<tr>
<td>Vital Signs At Hospital Or Isolation Center Admiss</td>
<td></td>
</tr>
<tr>
<td>Oxygen Saturation And Oxygen Therapy On Admission</td>
<td></td>
</tr>
</tbody>
</table>

**These forms should be completed on Day 1 only**

| Daily Signs And Symptoms          |
| Recurrent Daily Vital Records     |
| Recurrent ICU ICU IMC HHD Records |
| Daily Medication                  |
| Daily Complications               |

**These are to be completed everyday**

| Doctors’ Notes (not required)     |
| Nurses’ Notes (not required)      |

**These are not required**

| Laboratory Results                |
| Imaging                           |
| Pathogen                          |
| Kessler Psychological Distress Scale K10 |

**These should be filled on any day the information is available and can be filled multiple times during admission**

| Overall Supportive Care           |
| Overall Medications               |
| Outcome                           |

**These are to be completed on outcome day only**
Clinical Characterisation Protocol

Cloud data management

Coordination

COVID-19 Case Management

Data capture tools

Facility

Health Facilities

Facility
Senegal: 260 participant have been recruited with follow up visits have commenced (1, 3, 6 months post-discharge)

Cameroon: Ethical clearance obtained. Preparation for training for data entry and recruitment to start in December

Ghana: 1157 records entered so far. Dynamic dashboard is fully operational. 2 sites are open but plan to add another 2 site far ahead.

Kenya: Database set up and awaiting final stage of Ethical Approval

Uganda: Database set up and awaiting final stage of Ethical Approval
AIM: describe the clinical features of COVID-19 and monitor the progress of all hospitalized patients including what is working and what is not

1263 records

697 records

565 records

NEW SITES:
- Kintampo Health Research Center
- St. Michael's Hospital
Challenges

- Ethical clearance delays
- Implementation and training
- Politics
- Monitoring
- Collaboration and Resource mobilization
- Tools and technology
- Quick and relevant output
- Race against time

ALERRT is part of the EDCTP2 Programme supported by the European Union under grant agreement RIA2016E-1612

ALERRT is also supported by the United Kingdom National Institute for Health Research
Practical Solutions

- Predesigned Protocols
- Discussion for an expedited review

- Use local Staff
- Apply for collaborative funding
- Use the science as the incentive and not money
Practical Solutions

- Open discussions with the leaders at the site on implementation plans that will work for this institution.
- Training on site.
- Use local leaders at the site.

- Use offline options if possible.
- Will the App work? Or use basic apps.
- Using technology to keep the devices safe.
Practical Solutions

- Keep all the authorities involved at the start
- Regular updates to all political leaders
- Be aware of the local politics

- Implantation papers
- Dashboards
- Media output: regular media and social media
Practical Solutions

- Setup systems at all levels: local, coordination and national
- Regular re-training and physical reviews

- Use pre-set protocols
- Work fast and collaboratively
- Be ready
Co-Morbidities presented at the time of admission

Correlation of symptoms

Top 3 comorbidities

ALERRT is part of the EDCTP2 Programme supported by the European Union under grant agreement RIA2016E-1612
ALERRT is also supported by the United Kingdom National Institute for Health Research
Conclusion

Global health emergency

Research and output

 Improved health care

Treatment and vaccines

ALERTT is part of the EDCTP2 Programme supported by the European Union under grant agreement RIA2016E-1612

ALERTT is also supported by the United Kingdom National Institute for Health Research
ALERRT Clinical Characterization Protocol (CCP): multinational research response to a global health emergency; the African Story

Dr. Joseph Bonney
Emergency Medicine Specialist, Komfo Anokye Teaching Hospital
Research Fellow, Global Health and Infectious Diseases Research Group, Kumasi
Collaborative Centre for Research in Tropical Medicine