

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

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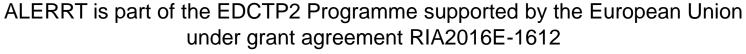


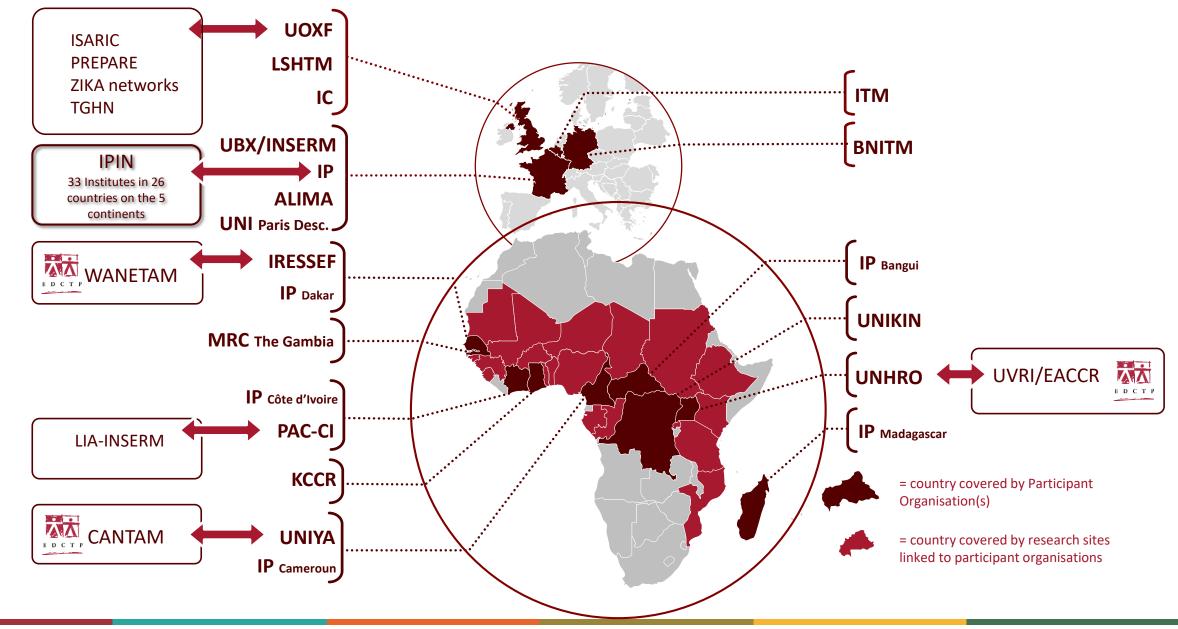
















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NHS
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# What is the Clinical Characterisation Protocol (CCP)?

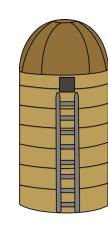
# The Clinical Characterisation Protocol (CCP) is designed for any severe or potentially severe acute infection of public health interest.

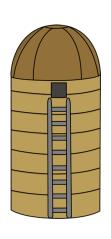
- It is a standardised protocol that enables data and biological samples to be collected rapidly in a globally-harmonised manner.
- The Clinical Characterisation Protocol (CCP) can be used for the rapid, coordinated clinical investigation of confirmed cases of COVID-19.

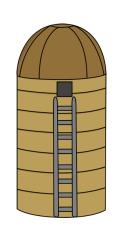


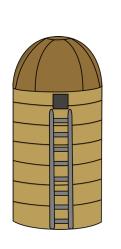


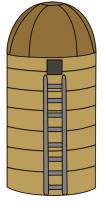
# Why is Clinical Characterisation Protocol (CCP) important?

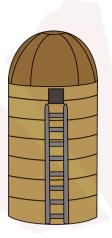


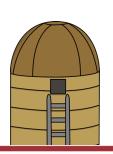


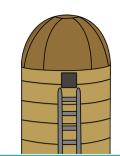


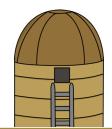


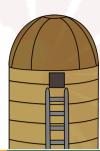






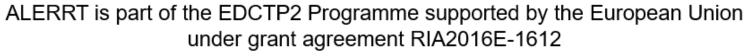








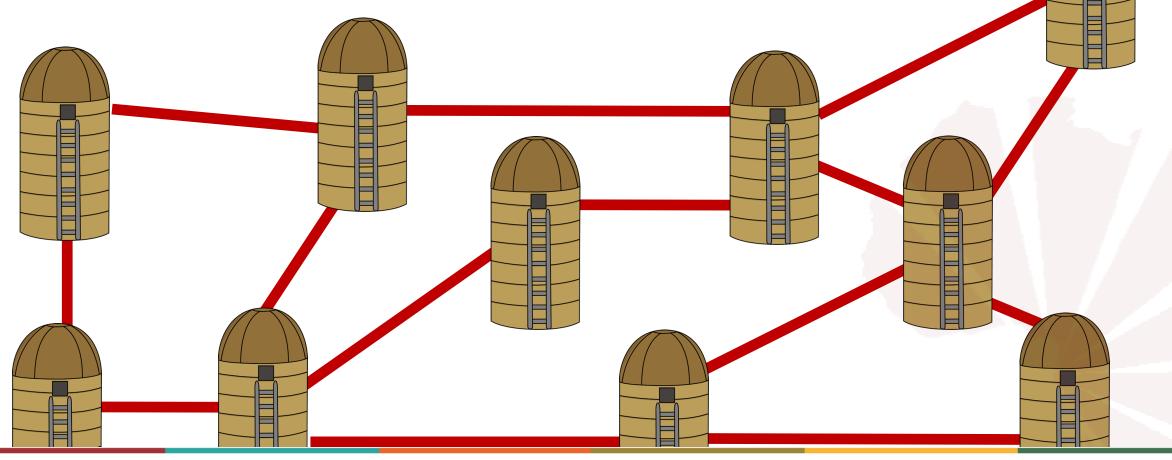




ALERRT is also supported by the United Kingdom National Institute for Health Research

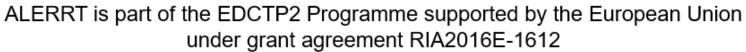




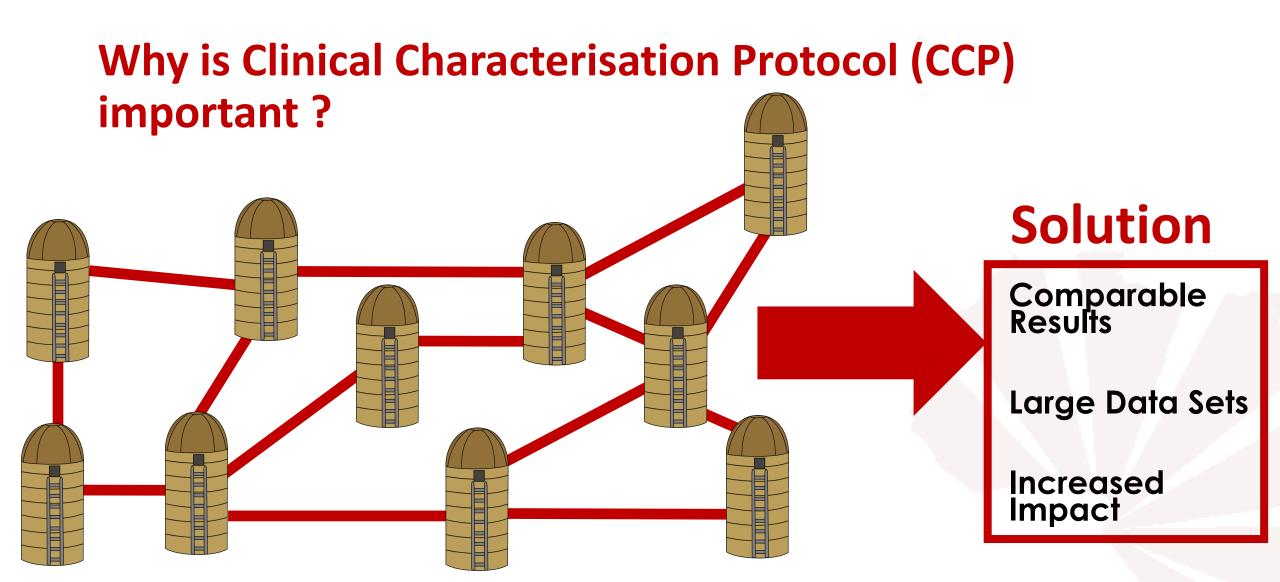






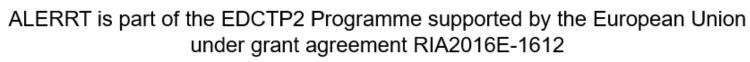
















# Clinical Characterisation Protocol (ALERRT CCP)



**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











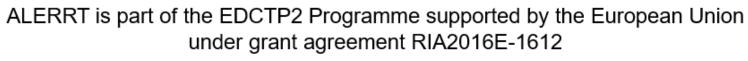


**ALERRT Africa Ready Documents** STEP 1- STEP 6

**Development of XML files** 











# 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)



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





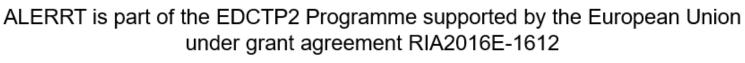




- Ethics and Consent: inclusion of thumb printing and photography of consent forms
- Data Collector's Details
- Employment:
- Co-Morbidities and Risk Factors: Addition of alcohol consumption with detail in consumption pattern and addition of details of smoking
- Imaging: Increased details on CXR and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











#### PATIENTNT IDENTIFICATION #: [ ][ ][ ]-- [ ][ ][ ][ ]

#### **COVID-19 CASE REPORT FORM**

This Case Report Form (CRF) has been adapted from the ISARIC/WHO COVID-19 Case Report Form. Available from https://media.tghn.org/medialibrary/2020/05/ISARIC\_WHO\_nCOV\_CORE\_CRF\_23APR20.pdf

The CRF collects basic sociodemographic and clinical data from suspected and confirmed cases of COVID-19. Refer to the data management document for further information.

#### GENERAL GUIDANCE:

- The CRF is designed to collect data obtained through interview, examination, review of patients and hospital notes.
   Data may be collected retrospectively.
- · Participant Identification Numbers consist of a 3-digit site code and a 4-digit participant number.
- Data should be entered to the prepared electronic REDCap database (preferred). Although not intended presently, printed paper CRFs may be used for later transfer of the data onto the electronic database. If using paper CRFs, we recommend writing clearly in ink, using BLOCK-CAPITAL LETTERS.
- In the case of a participant transferring between sites, it is recommended to maintain the same Participant Identification Number.
- Complete every line of every section, except for where the instructions say to skip a section based on certain
- Selections with circles (O) are single selection answers (choose one answer only). Selections with square boxes (LI)
  are multiple selection answers (choose as many answers as are applicable).
- . Mark 'N/A' for any results of laboratory values that are not available, not applicable or unknown.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- Place an (X) when you choose the corresponding answer. To make corrections, strike through (------) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
- · Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
- Please transfer all paper CRF data to the electronic database. All paper CRFs needs to be stored locally, do not send
  any forms with patient identifiable information via e-mail or post except authorized by the Moth/GHS and
  authorized persons.





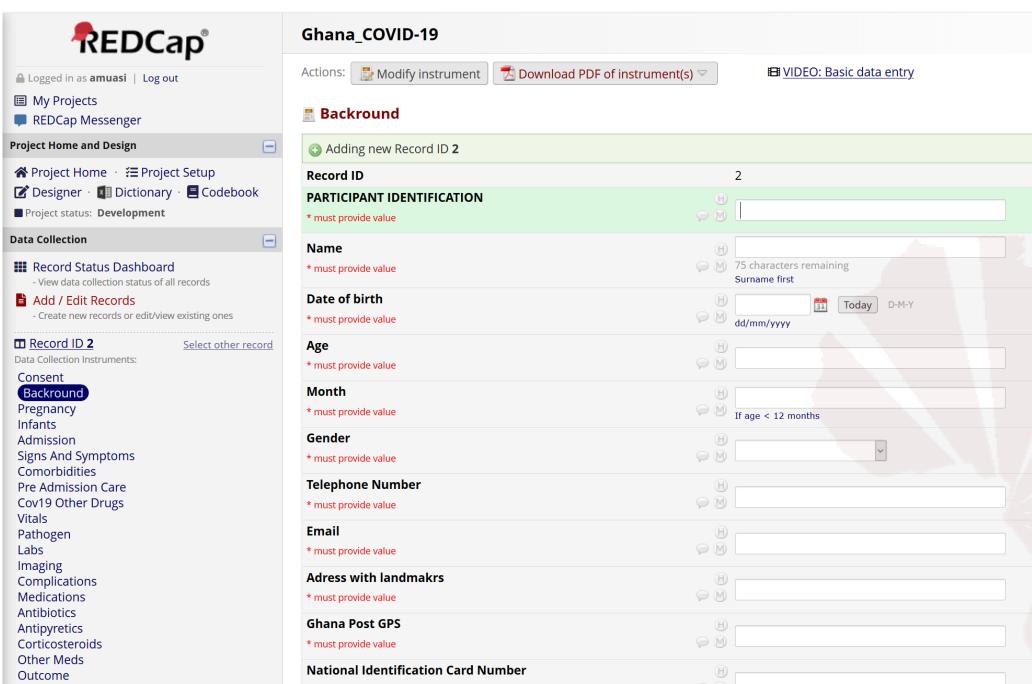
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#### COVID-19 CASE REPORT FORM

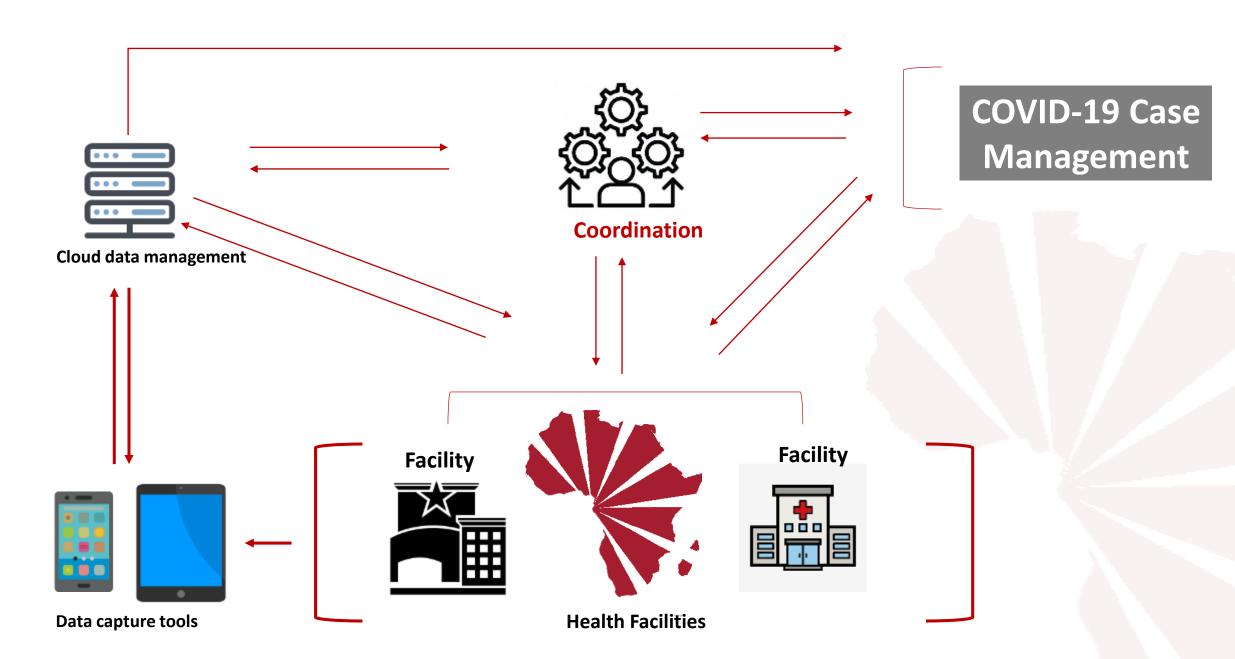
Visit to healthcare facility	y or treatment resource OY	ES O NO		
Name of healthcare facility or treatment resource:		Location (Region/Province etc.):		
Type: O Hospital/Clinic	OPharmacy OMaternity hom	<ul> <li>OHealthcare professional out of facility</li> <li>ON/A</li> </ul>		
Date of visit [_D_]/[_	M_][_M_]/[_2_][_0_][_Y_][_Y_]	O Unknown		
Admission and Referral				
Contact with emergency nu	mber/ hotline O YES O NO			
Date of emergency contact: [ D ] [ D ] / [ M ] [ M ] / [ 2 ] [ 0 ] [ Y ] [ Y ] O N/A				
Admission date at this facility: [D][D][M][M][Z][O][Y][Y]				
Time of admission (24-hr fo	ormat):[ H ][ H ]/[ M ][ M ] Ou	nknown		
Transfer from other facility	OYES ONO ON/A			
If YES: Facility name:		Location (Region/Province etc.):		
If YES: Reporting date at tra	ensferring facility (DD/MM/YYYY): [	D_[_D_]/[_M_](_M_]/[_2_][_0_][_Y_][_Y_]		
	ansferring facility: OSame as currer			

Epidemiological Factors			
In the 14 days before onset of illness had the patient any of the following:			
Travel (out of town/city) in the 14 days prior to first symptom onset? (capture all travel exents).  If Yes, specify location:  Location (Region/Province etc.)	OYE	s <b>O</b> NO	OUnknown
Return Date: [ D_] [ D ] / [ M ] [ M ] / [ 2 ] [ 0 ] [ Y ] [ Y ] O N/A			
Close contact* with a confirmed or probable case of COVID-19 infection,			
while that patient was symptomatic	O YES	<b>O</b> NO	O Unknown
Presence in a healthcare facility where COVID-19 infections have been managed	O YES	<b>0</b> NO	O Unknown
Presence in a laboratory handling suspected or confirmed COVID-19 samples	O YES	<b>O</b> NO	O Unknown
Direct contact with animals, raw meat or insect bites in the 14 days prior to sympt	om onse	t?	
******			O Unknown
If YES con	nnlete th	e ANIM	AL EXPOSURE section
* Close contact' is defined as:	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	_ /	in an oboling section
<ul> <li>Health care associated exposure, including providing direct care for novel coronavirus patients, e.g. care workers infected with novel coronavirus, visiting patients or staying in the same close envira</li> </ul>			
direct exposure to body fluids or specimens including aerosols.			
<ul> <li>Working together in close proximity or sharing the same classroom environment with a novel cord</li> </ul>	navirus pa	tient.	
Traveling together with novel coronavirus patient in any kind of conveyance.      Living in the same household as a novel coronavirus patient.			

Pregnancy and Postpartum	
Pregnant? O YES O NO O Unknown O N/A if YES: Gestational weeks assessment: [ I] weeks POST PARTUM? O YES O NO O N/A (if NO or N/A skip this section - go to INFANT) Pregnancy Outcome: O Live birth O Still birth Delivery date: [] [] /_[/]/	
Infants and Children under 5 years of age only	
Infected infant i.e. Less than 1 year old? OYES ONO (If NO skip this section) Birth weight:i[] Okg or Olbs ON/A Gestational outcome: O Term birth (≥37wk GA) OP/A Breastfed? OYES ONO ON/A If YES: O Currently breastfed OBreastfeeding discontinued at [i]]weeks□N/A Appropriate development for age? OYES ONO OUNknown Vaccinations appropriate for age/country? OYES ONO OUNknown ON/A	



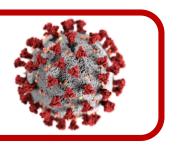
Consent and Patient Categorization			
Demography			
Case Pathway			
Epidemiological Factors			
Animal Contact			
Pregnancy and Postpartum	These forms should be		
Infants and Children Under 5 Years	completed on Day 1 only		
Vaccination Information			
Signs and Symptoms Preadmission			
Pre-Admission Medication			
Comorbidities And Risk Factors			
Vital Signs At Hospital Or Isolation Center Admiss			
Oxygen Saturation And Oxygen Therapy On Admission			
Daily Signs And Symptoms			
Recurrent Daily Vital Records	These are to be completed		
Recurrent Icu Itu Imc Hdu Records	everyday		
Daily Medication	cveryady		
Daily Complications			
Doctors' Notes (not required)	These are not required		
Nurses' Notes (not required)	These are not required		
Laboratory Results	There should be filled an annual analysis		
Imaging	These should be filled on any day the information is available and can be		
Pathogen	filled multiple times during admission		
Kessler Psychological Distress Scale K10			
Overall Supportive Care	These are to be completed on		
Overall Medications	outcome day only		
Outcome	outcome day only		





















#### **CLINICAL CHARACTERIZATION PROTOCOL**

**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



**GA East** 

#### **NEW SITES:**

- Kintampo Health Research Center
- St. Michael's Hospital





# Challenges



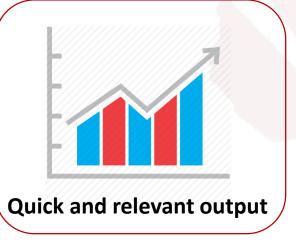






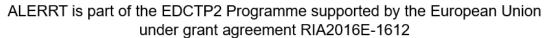


















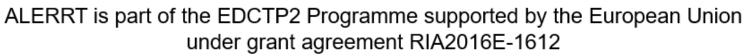
- Predesigned Protocols
- Discussion for an expedited review



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











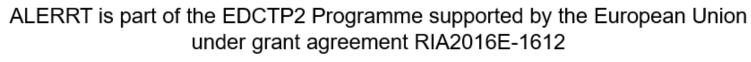
- Open discussions with the leaders at the site on implementation plans that will work for this institutions
- Training on site
- Use local leaders at the site



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



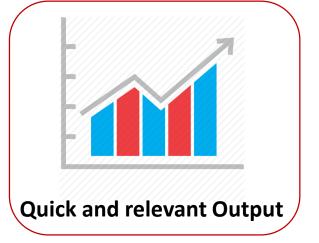








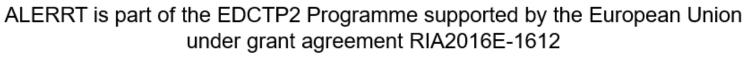
- Keep all the authorities involved at the start
- Regular updates to all political leaders
- Be aware of the local politics



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











- 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







National Institute for Health Research

#### Prevalence of comordities Co-Morbidites presented at the time of admission Proportion of patients with co-morbidities Correlation of symptoms Smoking Alcohol Sickle Cell Disease Obesity (as defined by clinical staff) Chronic neurological impairment/disease 0.5 Diabetes with complications Diabetes without complications Chronic pulmonary disease (not asthma) Chronic kidney disease Asthma AIDS / HIV Yes No 40-Top 3 comorbidities 30-Number of cases 17 Hypertension 10-





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Diabetes without complications

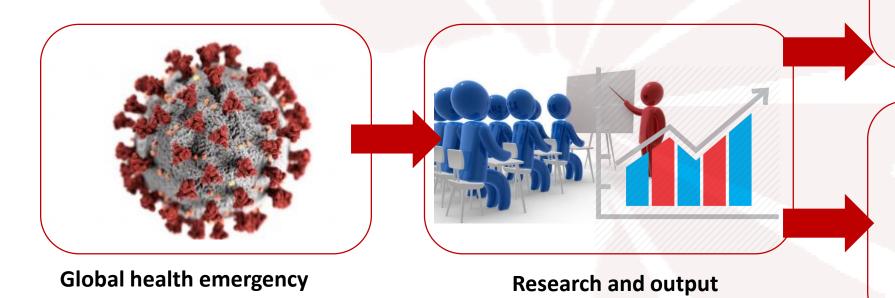
Alcohol

28



30

# Conclusion





Improved health care



**Treatment and vaccines** 





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