

COVID-19 Data Platform - Data Access Application Form

SECTION A: RESEARCHER / RESEARCH TEAM INFORMATION	
Lead Applicant Details	
Title	Dr
First name (given name)	Tim
Surname (family name)	Baker
Gender	M
Position at employing organisation/ institution	Associate Professor
ORCID ID (https://orcid.org) or URL to academic profile	0000-0001-8727-7018 <i>(if no ORCID or URL, please attach a short academic CV)</i>
Email	
Employing Organisation/Institution	
<i>Institution with a remit including health, research or academic pursuit, and with legal status which includes the scope to sign the Data Transfer Agreement.</i>	
Institution name	LSHTM
City, Country	London, UK
Does your institution agree to execute the Data Transfer Agreement? (if your application is approved)	YES (delete as appropriate)
Co-applicants	
<i>ALL individuals accessing the data must be listed. Any additions must be notified to the COVID-19 Data Access Committee. Add rows as necessary.</i>	
1. Name	Lorna Guinness
1. Position / Role in analysis	Lead Economist
1. Organisation/Institution	Centre for Global Development, UK
2. Name	Hiral Shah
2. Position / Role in analysis	Policy Analyst
2. Organisation/Institution	Centre for Global Development, UK
3. Name	August Joachim
3. Position / Role in analysis	Economist
3. Organisation/Institution	Ifakara Health Institute, Tanzania
4. Name	Dr Carl Otto Schell
4. Position / Role in analysis	Researcher
4. Organisation/Institution	Karolinska Institute/ Centre for Clinical Research Sörmland, Sweden
Conflicts of Interest	
<i>List details of any existing or perceived conflicts of interest (financial or non-financial) that exist relating to the use of the requested data by the data requestor and/or co-applicants (see ICMJE.org for the definition of conflicts of interest)</i>	
<i>No conflicts of interest declared</i>	

SECTION B: RESEARCH PLAN**Title of Proposed Research**

Avoiding preventable deaths through the Provision of Essential Treatment in Critical Illness in the COVID-19 pandemic.
Work Package 2: Estimating the cost-effectiveness of essential emergency critical care (EECC) and advanced critical care in low resource settings.

Is this a re-submission of a previous application to the COVID-19 DAC? If yes, provide the submission date of the previous application.

No

Summary of Research in Lay Language *(suggested ~ 100 words)*

Scaling-up critical care to meet the need of critically ill in the context of COVID-19 could follow alternative scenarios emphasising Essential Emergency Critical Care (EECC) – a low cost package of care feasible in all hospital settings - or advanced critical care. Domestic and international actors continue to lobby for a full range of services. However, budgets are limited so choices will be made between different types of care. To inform the choice of strategy and ensure the maximum benefit from any new investments, this research will model the costs and consequences of investing in basic provision of oxygen therapy and EECC relative to mechanical ventilators and advanced critical care.

Summary of Research Objectives and Scientific Value *(suggested maximum 400 words)*

The aim of the research is to explore the relative cost-effectiveness of different strategies to build critical care capacity, using COVID-19 as a tracer condition, through a strategy focusing on the provision of EECC and compare this to a strategy focusing on advanced critical care. The research questions addressed are: what are the costs and effects of EECC under different strategic scenarios? The analysis will use a simple decision analytic framework to model treatment costs and health outcomes over the time period of the local epidemic from a health systems perspective. It will estimate the cost per death averted and life-year saved for each scenario. Hospital admissions, clinical progression, mortality rates associated with each scenario will be based on the best data available at the time of the analysis or, if necessary, expert opinion. Sensitivity analyses will be run to address the likely uncertainty in all parameters. Building capacity for critical care will result in future health benefits and the need for continued funding for the new infrastructure and systems. The unit costs of EECC and advanced critical care will be made available for use for service design, budgeting and health technology appraisal, providing the first costs estimates of EECC and general advanced critical care for LMICs. The cost estimates and the frameworks developed for estimating the resource requirements and the cost-effectiveness analysis will be published and made available for adjustments for application to other country settings and further developments for the economic evaluation of EECC and advanced critical care post-pandemic.

Primary and Secondary Outcome Measures *(suggested maximum 200 words)*

Primary outcome measure: The relative costs and effects of EECC and advanced critical care in Tanzania and Kenya

Secondary measures:

- the cost per patient day of essential emergency critical care;
- the costs of scaling up to provide EECC in a low resource setting
- a recommended approach for a full economic evaluation of building capacity in critical care.

Proposed Methodology and Statistical Analysis Plan *(suggested maximum 400 words)*

The cost per patient day of EECC will be estimated from an EECC hospital requirement list derived from an international Delphi consensus on what constitutes EECC. This will be combined with local price data in Kenya and Tanzania, the case study countries. The cost of scaling up provision will be generated through primary and secondary data on the gap between current treatments and services, the defined EECC package and cost data collection. A decision analytic model will be developed to explore the relative costs and effects of different critical care strategies using COVID-19 as a tracer condition. We propose to use ISARIC data on hospital admissions (including length of stay), clinical events, clinical status and mortality rates to help populate the model as well as help generate a cost per admission.

Ethics *(suggested maximum 300 words)*

Provide details of any ethical considerations relating to the research proposal.

Additionally, list any approvals required by your institution to undertake this work, list reference numbers of any approved proposals, or explain why no approvals are required.

Primary cost data collection on costs of critical care are being collected in Tanzania. All work in Kenya is based on existing secondary data. Ethics clearance for the data collection in Tanzania has been obtained from National Institute for Medical Research, Dar-es-Salaam (NIMR/HQ/R.8a/Yol. IX/3537) and the London School of Hygiene and Tropical Medicine (Ref: 22866).

Publication and Dissemination Plan *(suggested maximum 300 words)*

Provide details of plans for authorship/acknowledgement of data contributors.

Provide details of timelines for publication and dissemination of research findings.

The following three publications are envisaged. Authorship will follow ICJME guidelines. Data contributors will be acknowledged and referenced appropriately. Data contributors will be acknowledged as authors in accordance with ICJME guidelines. We will seek guidance from the ISARIC group how to ensure that acknowledgement is appropriate.

- “The needs and costs of scaling up critical care at different levels of critical care provision in Kenya and Tanzania”.
- “The cost-effectiveness of COVID-19 care based on EECC and based on advanced critical care”.
- “The recommended approach for a full economic evaluation of building capacity for critical care”.

Online dissemination event and blogs facilitated by the Centre for Global Development to inform policy-makers, global funding agencies and other stakeholders are also planned in which data contributors can also be acknowledged.

Research Priorities Addressed *(suggested maximum 300 words)*

Provide details of how this research aligns with nationally or internationally set research priorities.

Understanding the role of low-cost treatment of critically ill patients is an urgent priority in the current pandemic. Providing evidence regarding the relative costs and effects of different critical care strategies will aid decision-makers at national and international levels in prioritising investments within limited budgets.

Collaboration and Knowledge Sharing *(suggested maximum 300 words)*

Provide details of how this research will collaborate, support and/or share knowledge with appropriate partners. The platform is particularly interested in research that builds capacity in low-resource settings.

The research programme is a multi-country collaboration involving partners in Kenya (KEMRI), Tanzania (Ifakara Health Institute), Sweden (Uppsala University) and the UK (LSTHM, CGD). Cross country collaboration is further supported by the collaborator networks with World Health Organisation, UNICEF, Muhimbili University of Health and Allied Sciences and College of Medicine in Malawi. The project is employing a PhD student in Tanzania, and a Master's student in Malawi. The research has its focus in Tanzania and Kenya, and aims to have direct policy impact in those and other low-income countries. All activities are conducted in partnership with researchers and teams in Tanzania and Kenya, with the goal of increasing research output, skills and capacities in local institutions.

Funding *(suggested maximum 100 words)*

Provide details of how this research will be funded/resourced. Please name the source of funding.

The research is funded under a Wellcome Trust Flagships Innovations Grant number 221571/Z/20/Z.

Scientific Review *(suggested maximum 200 words)*

If the project has been scientifically reviewed, please provide details. This could be by your institution, a funder/donor or review committee.

The research underwent scientific review by the Wellcome Trust proposal review committee as part of the grant submission process.

SECTION C: DATA

Data Variables

*Provide a list of the **data variables** required to achieve the research objectives.*

Note: Please go to www.iddo.cognitive.city to explore the interactive COVID-19 data inventory and to identify the variables, populations and data volumes required for your analysis. You can select the data variables from this inventory and copy it to this section.

In examining the CRF and the meta data we would like to apply for the following data variables. We have listed them as they appear in the CRF as well as in the inventory:

Demographics: Sex; DoB; Age

Admission vital signs:

Symptom onset; Admission data; prior collection of data; PIN; readmission; previous participant ID; number of readmissions; reason for readmission.

Temperature; HR; Resp rate; BP (both); dehydration; Sternal capillary refill; oxygen saturation; GCS; Malnutrition; arm circum; Height; Weight

Medication: IV fluids; Corticosteroid; Antibiotics

Module 1

Supportive care:All variables

Lab results: Haemoglobin, WBC count, Creatinine, CRP, D-dimer

Module 2

Vital signs: all variables

Lab results: Haemoglobin, WBC count, Creatinine, CRP, Lactate

Medication: IV fluids; Corticosteroid; Antibiotics

Supportive care: All variables

Module 3

Diagnostic/pathogen testing: Chest xray/CT performed; infiltrates; COVID test; If COVID =ve; HIV

Complications: All variables
Medication: IV fluids; Corticosteroid; Antibiotics
Supportive care: All variables
Outcome: All variables

Variables as listed under the inventory

Variable Group	Name
Clinical Classification (15256)	Glasgow Coma Score (GCS)
Demographics (127902)	AdmissionDate
Demographics (126825)	AGE
Demographics (129029)	COUNTRY
Demographics (129029)	SEX
Disposition (20357)	DEATH
Disposition (96136)	DISCHARGED
Disposition (5914)	STILL IN HOSPITAL
Disposition (4553)	TRANSFERRED
Disposition (786)	UNKNOWN
Healthcare Encounters (15118)	HOSPITAL
Healthcare Encounters (23149)	INTENSIVE CARE UNIT
Interventions (13690)	ANTIBACTERIALS FOR SYSTEMIC USE
Interventions (20288)	CORTICOSTEROIDS FOR SYSTEMIC USE
Interventions (2902)	INVASIVE VENTILATION
Interventions (8404)	MEDICATION
Interventions (2901)	NON-INVASIVE VENTILATION
Interventions (13541)	OTHER RESPIRATORY SYSTEM PRODUCTS
Interventions (19236)	OXYGEN
Interventions (2901)	PRONE POSITIONING
Interventions (13427)	SUPPORTIVE CARE
Laboratory Test Results (18358)	C Reactive Protein
Laboratory Test Results (21104)	Creatinine
Laboratory Test Results (5230)	D-Dimer
Laboratory Test Results (21525)	Hemoglobin
Laboratory Test Results (115)	Hemoglobin A1C
Laboratory Test Results (11279)	Lactate Dehydrogenase
Laboratory Test Results (3448)	Mean Corpuscular Haemoglobin Concentration (MCHC)
Laboratory Test Results (3448)	Mean Corpuscular Hemoglobin (MCH)
Laboratory Test Results (21439)	White blood cell (WBC) count
Vital Signs (3141)	Body Mass Index
Vital Signs (19309)	Diastolic Blood Pressure
Vital Signs (13342)	Heart Rate
Vital Signs (7126)	Height
Vital Signs (5732)	Mean Arterial Pressure

Vital Signs (64)	Mid-Upper Arm Circumference
Vital Signs (20522), Laboratory Test Results (223)	Oxygen Saturation
Vital Signs (6387)	Pulse Rate
Vital Signs (18365)	Respiratory Rate
Vital Signs (19322)	Systolic Blood Pressure
Vital Signs (22833)	Temperature
Vital Signs (7797)	Weight