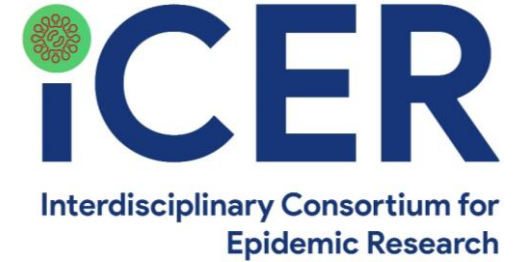


Research Ethics and Research in Emergency Situations

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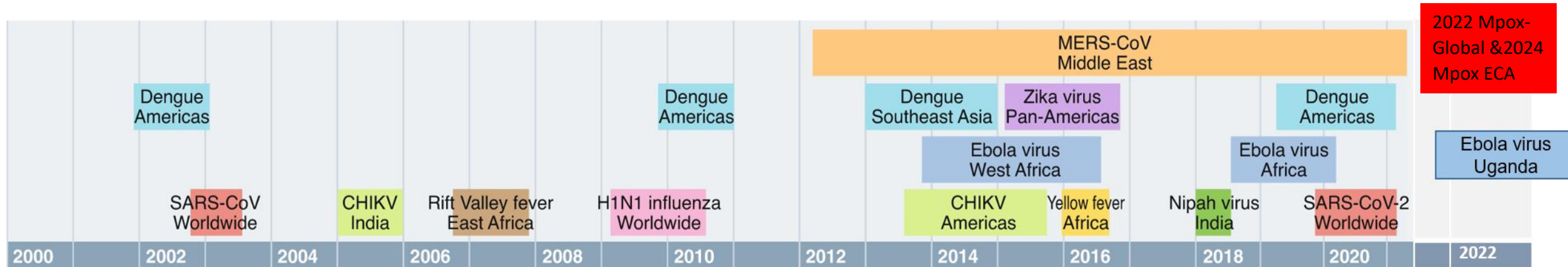
October 22 2025, Kampala, Uganda

Introduction



- An epidemic is “an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area.”
- Many conditions would therefore qualify as an epidemic, including both communicable and non-communicable diseases
- In many cases epidemics are considered in the context of an infectious disease outbreak
- Research brings evidence based tools to prevent and control epidemics
 - Diagnostics, treatments, and vaccines
 - Public health interventions e.g. lockdowns
- Epidemics occur and will occur, tools get obsolete, develop resistance, are ineffective calling for continued research to develop new ones

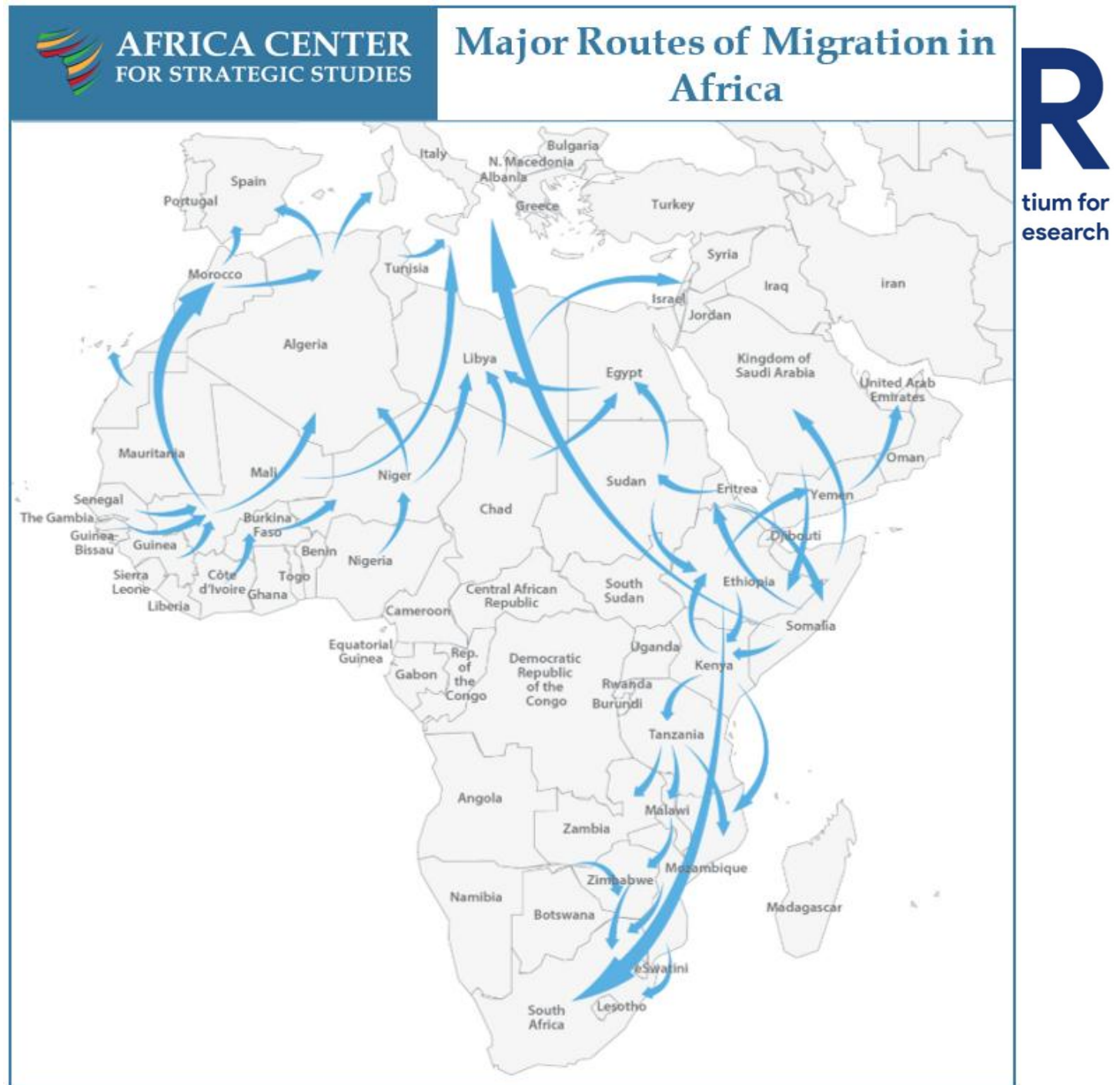
21st Century viral disease outbreaks



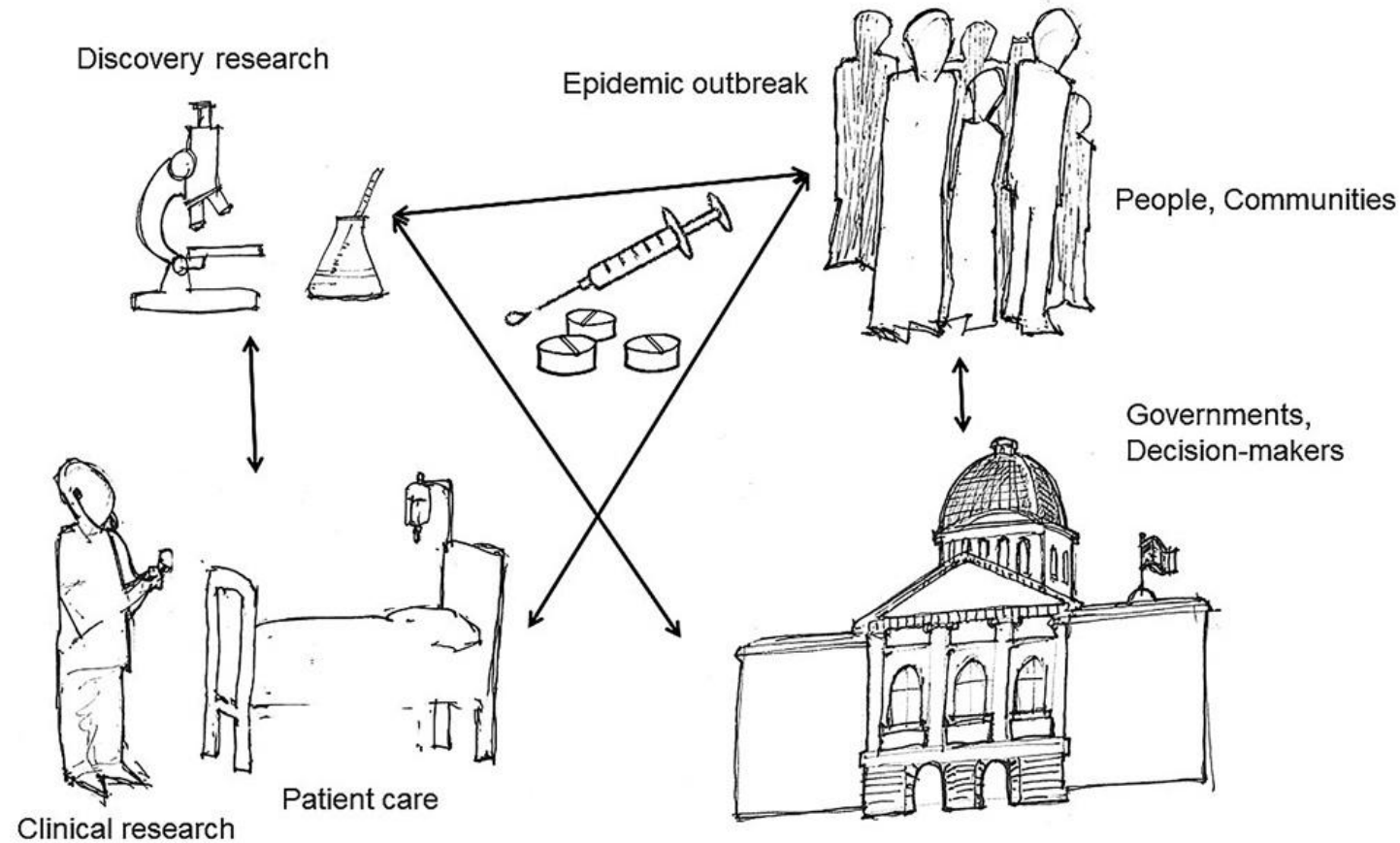
Modified from: Meganck, R.M., Baric, R.S. Developing therapeutic approaches for twenty-first-century emerging infectious viral diseases. *Nat Med* **27**, 401–410 (2021).

- **Why Africa**

1. **Conflict and displacement**
2. **Rich and preserved flora and fauna that foster wild-human life interactions**
3. **Weak public health systems**
4. **Poverty and limited access**
5. **Limited indigenous medical counter measures and science**
6. **Weak surveillance systems**
7. **Climate and environment**



Epidemics research, “multi-stakeholders endeavor”

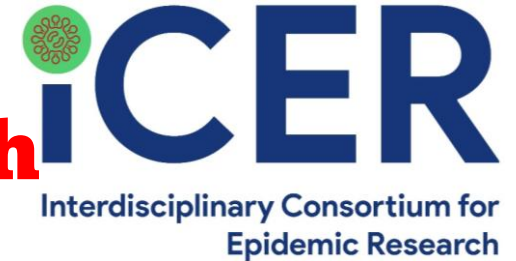


Challenges of epidemics research



- **Limited understanding of the disease:**
 - In the early stages of an epidemic, little may be known about the disease causing the outbreak
 - This can delay development of research protocols.
- **Rapidly evolving situation:**
 - Epidemics can spread quickly and change rapidly
 - This can complicate research due to rapidly changing information about the disease
 - Limited time for research
 - Usually intermittent, feasibility
- **Limited resources:**
 - Epidemic research often requires significant resources
 - Research funding mechanisms of most funding organizations follows a pre specified process- announcement, review award e.t.c
 - Epidemics will not fit in this framework.
- **Ethical considerations:**
 - Epidemic research by nature is conducted in situation of heightened psychological and physical distress
 - It must be done fast
 - It occurs in unusual settings such as community
 - Privacy may be compromised .
- **Access to research evidence and data:**
 - Researchers may face challenges in accessing data on an outbreak
 - Particularly if the data is controlled by government agencies or private organizations.
- **Communication challenges:**
 - Epidemic research often involves a large number of stakeholders
 - Government officials, healthcare providers, and the general public.
 - Effective communication is crucial to ensure that research findings are accurately conveyed and understood by all parties involved.
- **Access to investigational products**
 - IP R&D driven by profit oriented pharma
 - Competition may disrupt and delay trials
 - Interventions can only be tested clinically during an outbreak
- **Competition among academic and other public researchers**
 - For funding
 - Launch of many similar trials affecting accrual powered samples sizes
 - Community misinformation

International Health Regulation (IHR)'s Core Competencies for epidemic research



1. IHR (2005) mandates that when effective surveillance detects an outbreak in a Member State, WHO should be informed within 48 hours of that detection.
2. Trial planning for implementation of evidence driven countermeasures should commence at the same time as the outbreak is detected.
3. Core competencies for ensuring the capacity of Member States to detect pathogens with the potential to become outbreaks is the role of WHO.
4. It's anticipated that to facilitate effective clinical trials platforms deployable during outbreaks, critical expertise should be brought to bear on training of researchers and integration of research within the healthcare system, improving capacities for competent scientific ethical reviews, and strengthening abilities to negotiate complex legal agreements with trial sponsors.*
5. Effective and nimble regulatory capacities is a critical need.
6. Accommodate and integrate social science with clinical research is promoted.
7. Within country governance and political approval needs to be clarified.

*GT Keusch, KPWJ McAdam. Lancet 2017; 389; 2455-57

WHO. International Health Regulations (2005). Third edition. World Health Organization, Geneva 2016, <http://apps.who.int/iris/bitstream/10665/246107/1/9789241580496-eng.pdf?ua=1>

Case Study: Impact of epidemic research on Ebola



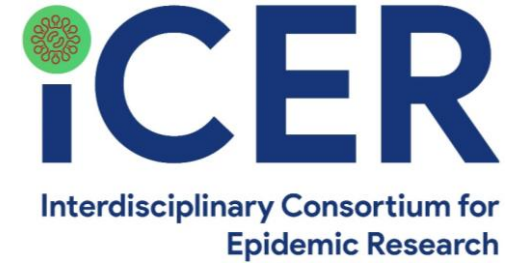
DRC

- **2018 – 2020 (702 Days)**
 - **2280 EBV Zaire deaths & 3470 cases**
 - Start: July 25, 2018
 - Detection: July 28, 2018
 - Verification: August 1, 2018
 - Control: June 25, 2020
- **2021 (103 Days)**
 - **09 EBV Zaire deaths & 20 cases**
 - Outbreak declared over in 3 months
 - Start: September 5, 2021
 - Detection: October 7, 2021
 - Verification: October 8, 2021
 - Control: December 16, 2021
- **Attributed causes were vaccine availability, improved health systems infrastructure, and workforce trained in surveillance and response.**

GUINEA

- **2014-16 (889 Days)**
 - **11,310 EBV Zaire deaths & 28,616 cases**
 - Start: December 26, 2013
 - Detected: March 10, 2014
 - Verification: March 22, 2014
 - Control: June 1, 2016
- **2021 (153 Days)**
 - **12 EBV Zaire deaths & 23 cases**
 - Epidemic declared over in 6 months
 - Start: January 18, 2021
 - Detected: February 11, 2021
 - Verification: February 13, 2021
 - Control: June 19, 2021
- **Attributed causes were deployment of experimental vaccines, clinical trials, multisectoral response team mechanism in place, and strengthening of healthcare infrastructure, including detection.**

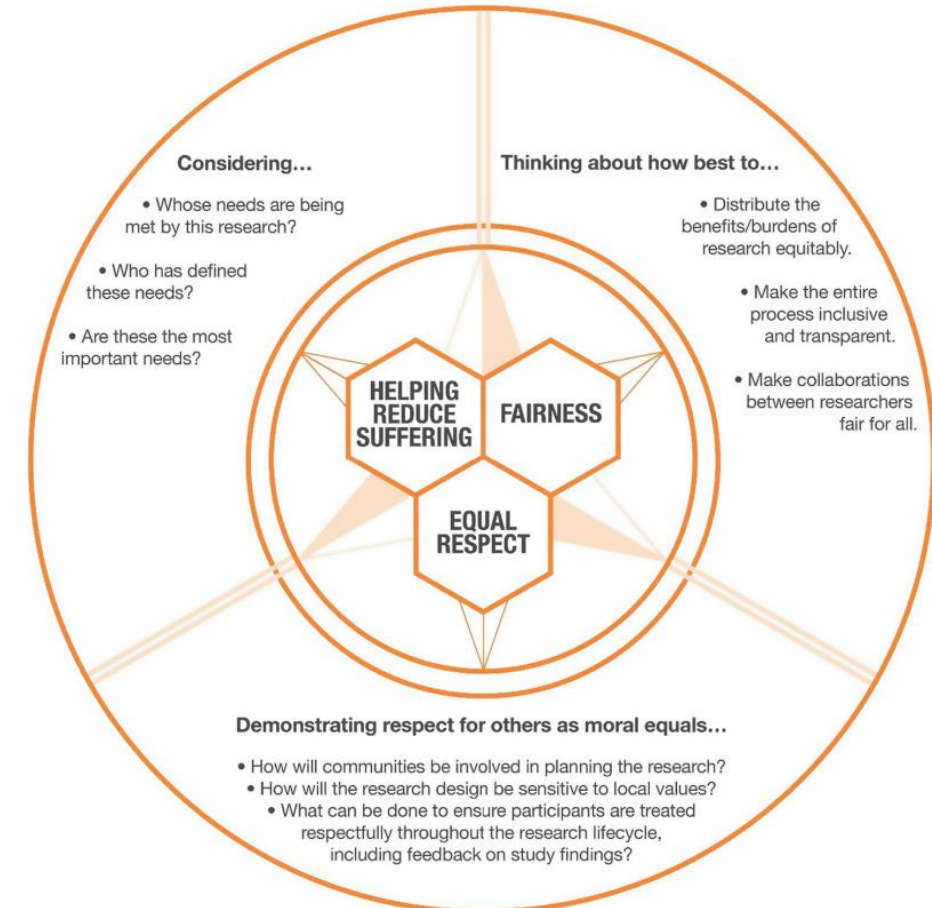
Epidemics research Ethics



- Research in emergency situations, outbreaks, epidemics and pandemics is no **longer a just nice to have activity** but an integral component of the epidemic response
- However like all research the need for regulation and subject protection is of paramount importance
- There several concerns about epidemic research e.g.
 - Distraction from epidemic response including taking away resources from the response
 - ethical standards will not be upheld
 - doubts about the interventions quality and effectiveness given the speed at which they are developed
 - its impact of research on distressed communities

Key ethical considerations on epidemic research

1. Do pandemics necessitate or justify deviations from ethical and scientific standards for research?
2. Do pandemics raise novel ethical questions for research?
3. How should research priorities be set during pandemics?
4. How should research be conducted in the context of other response efforts?
5. How should pandemic research be governed and coordinated?



- Article 33 of the Declaration of Helsinki, which states:

- Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or
- Where, for compelling and scientifically sound methodological reasons, the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option (WMA 2013).



Research priorities

- **Research is not a value-neutral enterprise:** Epidemics are more frequent in vulnerable resource poor settings. Research especially of medical countermeasures is most spearheaded by players from settings capable of developing these measures. This disconnect should be realized such that priorities take care of all stakeholders
- The following issues should be considered:
 1. Need
 2. Burden of disease
 3. Magnitude of benefits
 4. Equity
 5. The needs of vulnerable and disadvantaged groups
 6. Cost-effectiveness of research
 7. Cost-effectiveness of proposed interventions
 8. Likelihood of research success

Distribution of Covid-19 pandemic research

- The global h-index of COVID-19 publications is 260 (of all documents considered for the h-index, 260 have been cited at least 260 times), while the h-index for Africa is 42
- Sixty-five per cent of the published documents by Africans on COVID-19 were from just three countries: South Africa, Egypt and Nigeria
- A quarter of the COVID-19 publications by Africans stated a foreign funding sponsor.

Productivity of top 10 producers of COVID-19 research in 2020.



Interdisciplinary Consortium for
ch

		Share of total global articles		Share of total global internationally collaborative articles	
		2018–2019	2020	2018–2019	2020
Total number of global articles		5,175	92,008	1,628	20,203
1	USA	1741 (33.6%*)	26711 (29%)	856 (52.6%)	8544 (42.3%)
2	China	1240 (24%)	11591 (12.6%)	363 (22.3%)	3259 (16.1%)
3	UK	262 (5.1%)	10744 (11.7%)	213 (13.1%)	5164 (25.6%)
4	Italy	172 (3.3%)	8981 (9.8%)	85 (5.2%)	2976 (14.7%)
5	India	189 (3.7%)	5950 (6.5%)	87 (5.3%)	1684 (8.3%)
6	Germany	146 (2.8%)	4422 (4.8%)	105 (6.4%)	1442 (7.1%)
7	Canada	308 (6%)	4116 (4.5%)	204 (12.5%)	1990 (9.9%)
8	France	228 (4.4%)	4058 (4.4%)	134 (8.2%)	2250 (11.1%)
9	Spain	220 (4.3%)	4115 (4.5%)	154 (9.5%)	1629 (8.1%)
10	Australia	195 (3.8%)	3496 (3.8%)	123 (7.6%)	2132 (10.6%)
11	Brazil	127 (2.5%)	2736 (3%)	68 (4.2%)	919 (4.5%)

* Percentage share of articles with at least one article from the focal country in total global articles. Top 10 producers in pre-COVID-19 and COVID-19 (11 countries in total) are shown.

<https://doi.org/10.1371/journal.pone.0261624.t003>

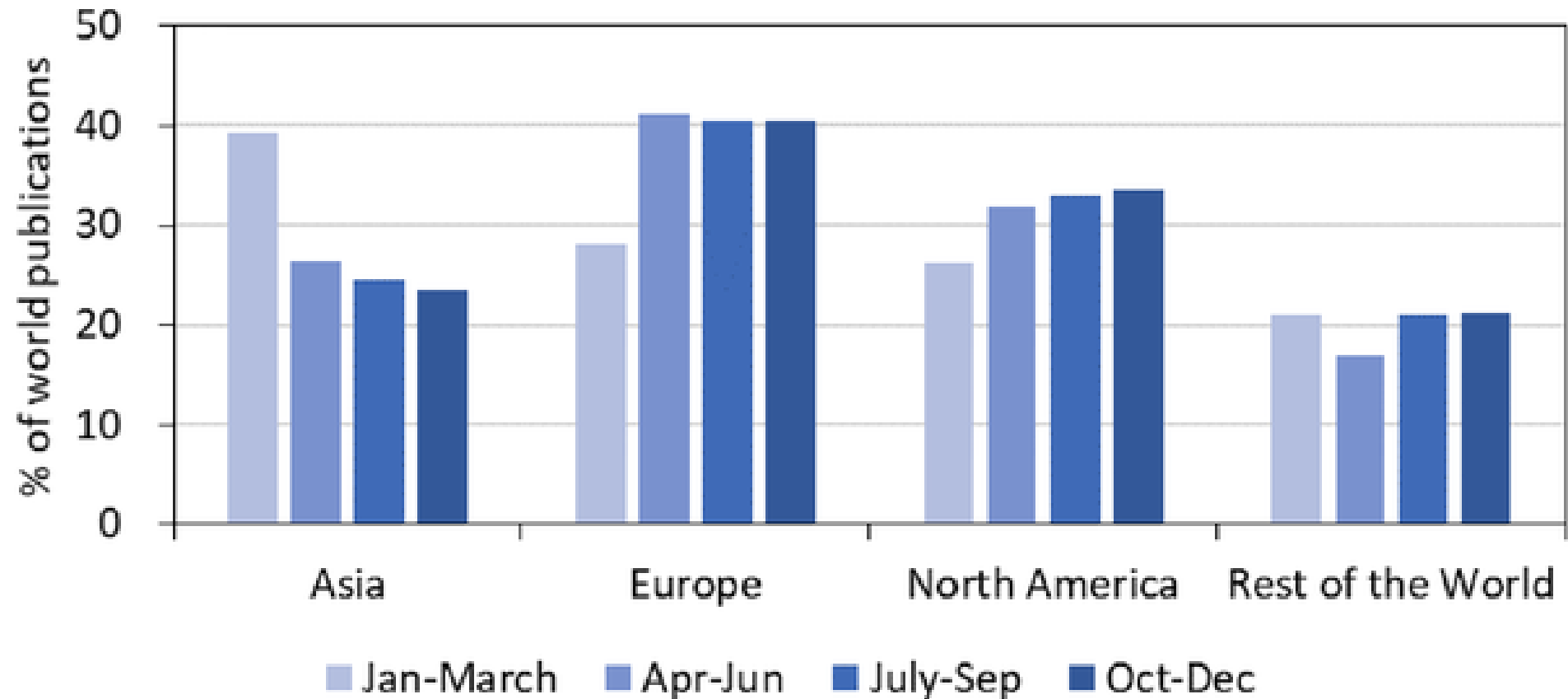
Wagner CS, Cai X, Zhang Y, Fry CV (2022) One-year in: COVID-19 research at the international level in CORD-19 data. PLOS ONE 17(5): e0261624.

<https://doi.org/10.1371/journal.pone.0261624>

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261624>

Author location by region based on 2020 coronavirus publications

Author location by Region



Ebola

Rank	Country	WoS	Single country papers	Country	Scopus	Single country papers
		Number of papers (%), N = 3865			Number of papers (%), N = 3848	
1	USA	1736 (44.9)	1189	USA	702 (18.3)	479
2	United Kingdom	352 (9.1)	180	United Kingdom	130 (3.4)	66
3	China	198 (5.1)	126	Canada	76 (2.0)	37
4	Canada	160 (4.1)	80	France	65 (1.7)	26
5	Germany	134 (3.5)	62	Germany	65 (1.7)	29
6	France	122 (3.2)	52	China	57 (1.5)	33
7	Australia	75 (1.9)	42	Italy	39 (1.0)	21
8	Switzerland	75 (1.9)	30	Japan	34 (0.9)	17
9	Italy	62 (1.6)	32	Switzerland	31 (0.8)	8
10	Japan	57 (1.5)	25	Georgia	23 (0.6)	14
11	Nigeria	52 (1.3)	30	India	23 (0.6)	21
12	Belgium	46 (1.2)	9	Spain	20 (0.5)	12
13	South Africa	42 (1.1)	18	Netherlands	19 (0.5)	10
14	India	41 (1.1)	36	Nigeria	17 (0.4)	10
15	Spain	41 (1.1)	23	Australia	16 (0.4)	6

Epidemic research funding

Top 10 funding agencies of EVD research (2010-2020).				
Rank	Funding agencies (WoS)	No. of papers (%), N=3865	Funding agencies (Scopus)	No. of papers (%) N=3848
1 st	US Dept. of Health Human Services	742 (19.2)	National Institutes of Health USA	422 (10.9)
2 nd	National Institutes of Health USA	691 (17.9)	NIAID	205 (5.3)
3 rd	NIAID	303 (7.8)	Defense Threat Reduction Agency	90 (2.3)
4 th	US Depart. of Defense	160 (4.1)	National Science Foundation NSF	82 (2.1)
5 th	Defense Threat Reduction Agency	124 (3.2)	National Natural Science Foundation of China	78 (2.0)
6 th	Wellcome Trust	106 (2.7)	Centers for Disease Control and Prevention	59 (1.5)
7 th	National Natural Science Foundation of China	100 (2.6)	Wellcome Trust	54 (1.4)
8 th	World Health Organization	97 (2.5)	Deutsche Forschungsgemeinschaft	45 (1.2)
9 th	National Science Foundation NSF	95 (2.5)	World Health Organization	45 (1.2)
10 th	European Union EU	84 (2.2)	National Institute of General Medical Sciences	44 (1.1)

Organizations working on epidemics

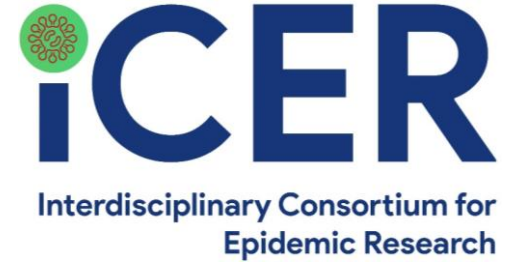


- There are many organizations working on epidemics around the world. Some of the major ones include:
 - World Health Organization (WHO) - The WHO is the leading international organization on public health, and is responsible for monitoring and responding to epidemics around the world.
 - Centers for Disease Control and Prevention (CDC) - The CDC is a national public health institute in the United States, and is responsible for preventing and controlling infectious diseases.
 - Médecins Sans Frontières (MSF) - MSF is an international humanitarian organization that provides medical aid to people affected by epidemics and other crises.
 - Global Health Security Agenda (GHSA) - GHSA is a partnership of countries, international organizations, and other stakeholders working to strengthen global health security and prevent epidemics.
 - Coalition for Epidemic Preparedness Innovations (CEPI) - CEPI is a global partnership that funds the development of vaccines against emerging infectious diseases.
 - The Bill and Melinda Gates Foundation - The foundation works to improve global health and reduce the burden of infectious diseases, including epidemics, through research and development of new tools and technologies.
 - UNICEF - The United Nations Children's Fund works to provide emergency support to children and families affected by epidemics.
 - The Red Cross - The International Committee of the Red Cross and Red Crescent provides assistance to people affected by epidemics and other emergencies.
 - The National Institutes of Health (NIH) - The NIH is a US government agency that conducts research on infectious diseases and develops new treatments and vaccines.
 - The Gavi Alliance - Gavi is an international organization that works to improve access to vaccines in low-income countries, including those affected by epidemics.

Landscape of epidemic research consortia



About ICER



- ICER= Interdisciplinary Consortium for Epidemic Research
- Conceived in Uganda during the 2022 SUDV outbreak
- ICER formally launched by Uganda Minister of Health at a breakfast meeting on 11th November 2022 at Serena International Conference centre
- Coordinated by Makerere University Lung Institute

African led consortium with representation in several African countries leveraging long standing collaborations from global north partners

Several scientists



Several research institutions

