ORIGINAL ARTICLE

WILEY

An ethics of anthropology-informed community engagement with COVID-19 clinical trials in Africa

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Abstract

The COVID-19 pandemic has reinforced the critical role of ethics and community engagement in designing and conducting clinical research during infectious disease outbreaks where no vaccine or treatment already exists. In reviewing current practices across Africa, we distinguish between three distinct roles for community engagement in clinical research that are often conflated: 1) the importance of community engagement for identifying and honouring cultural sensitivities; 2) the importance of recognising the socio-political context in which the research is proposed; and 3) the importance of understanding what is in the interest of communities recruited to research according to their own views and values. By making these distinctions, we show that current practice of clinical research could draw on anthropology in ways which are sometimes unnecessary to solicit local cultural values, overlook the importance of socio-political contexts and wider societal structures within which it works, potentially serving to reinforce unjust political or social regimes, and threaten to cast doubt on the trustworthiness of the research. We argue that more discerning anthropological engagement as well as wider collaboration with other social scientists and those working in the humanities is urgently needed to improve the ethics of current biomedical and pharmaceutical research practice in Africa.

KEYWORDS

Africa, anthropology, benefit sharing, bioethics, community engagement, research ethics

1 | INTRODUCTION

The COVID-19 pandemic has reinforced the critical role of ethics and community engagement in designing and conducting clinical research during infectious disease outbreaks where no vaccine or treatment already exists.[1] This includes the design and recruitment of participants in clinical trials and the equitable rollout of medical technologies, both vaccines and therapeutics, under emergency use

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[1]UNAIDS, AVAC. (2011). *Good Participatory Practice guidelines for biomedical HIV prevention trials.* Geneva: UNAIDS.

regulatory approvals. Past experiences with developing therapeutics during pandemics, including the 2009 H1N1 pandemic,[2,3] and the 1976 swine flu pandemic,[4] have shown that moments of emergency duress can suspend the usual ethical, scientific and regulatory frameworks whether sanctioned as official exceptional circumstances or not. The importance of assessing the social context of technological advance has resulted in the related broad integration of social sciences in outbreak response as outlined in the WHO R&D Blueprint for Covid-19,[5] and the African CDC's Covid-19 Research Priorities Taskforce.[6] In designing any specific response strategy, being able to assess the social context of an epidemic and the participation of affected communities in all scientific effort through meaningful community engagement is increasingly accepted or required by research ethics committees.[7] For this reason, the discipline of anthropology has increasingly become integrated with WHO's epidemic response strategies in Africa.[8,9,10]

Community suspicions and distrust of governments, medical authorities, and pharmaceutical companies have become a major focus during the COVID-19 pandemic, involving protests and civil society mobilization. One example highlights cultural and political insensitivities of two leading researchers at prominent medical institutes in France. They suggested, on television, that research should be conducted in Africa rather than in France simply because there were apparently fewer protective public health measures available in Africa at the time which would maximise the chances for natural exposure to the virus to better test clinical efficacy of the Bacille Calmette-Guérin (BCG) vaccine against COVID-19.[11] Rather than to consider helping to increase protective measures for vulnerable people, the objective was to benefit from the relative vulnerabilities of local communities for scientific advance. In South Africa, however, there were large scale protests at the early trials of the AstraZeneca COVID-19 vaccine which was developed with Oxford University and manufactured in Europe making recruitment of the most disadvantaged black populations difficult despite

maintaining culturally inclusive social media and marshaling intensive community engagement strategies.[12] That said, medical research involving vaccines and therapeutics in Africa remains a necessary way to gain knowledge of what works in a population with the oldest and most diverse genetics of the human race. With no patent waiver and no local manufacturing facilities to hand, the promise by a giant global pharmaceutical company to offer wide access to the vaccine on a not-for-profit basis after the trial for the period of the pandemic, we will argue, was morally and politically insufficient.

To illuminate the ethical issues in the above examples, we distinguish between three distinct roles for community engagement in clinical trial research that are often conflated: 1) the importance of community engagement for identifying and honouring cultural sensitivities; 2) the importance of recognising the socio-political context in which the research is proposed; and 3) the importance of understanding what is in the interest of communities recruited to research according to their own views and values. By making these distinctions, we show that current practices of clinical research may use anthropological expertise to solicit data on local cultural values which are of questionable value, and, in so doing, overlook the importance of socio-political contexts and wider societal structures within which clinical trials works. This may potentially serve to reinforce unjust political or social regimes, and threaten to cast doubt on the trustworthiness of anthropological and clinical research. We argue that more discerning anthropological engagement as well as wider collaboration with other social scientists and those working in the humanities is urgently needed to improve the ethics of current biomedical and pharmaceutical research practice in Africa.

To make progress in this area, we first evaluate the evolving role of anthropology in relation to community engagement with clinical trials across Africa, illustrating the valuable cross-fertilisation of anthropology with other disciplines in the social sciences and particularly with bioethics. We suggest that anthropology-informed community engagement with clinical trials is now less concerned with assessing cultural sensitivities than with social and political influence within communities, the larger structures through which they have little role in addressing, to advocate wholeheartedly for communities without potential conflicts of interests. Our main investigation is to determine whether there is a danger for practitioners of community engagement and any associated anthropologists to get swept up in the impetus to collaborate with clinical trialists, within dominant biomedical and technology development models, with the consequence of eroding their potential, actual and perceived psychological and moral independence from the research.

As a result, they may cease to remain trustworthy especially in the eyes of communities and participants. Researchers and social scientists could all too readily adopt the language of political persuasion to help increase recruitment and retention rates of

[2]Doshi, P. (2020). Covid-19: Do many people have pre-existing immunity? *BMJ*, 370. https://doi.org/10.1136/bmj.m3563

[3]Dyer, O. (2020). What did we learn from Tamiflu? *BMJ*, 368. https://doi.org/10.1136/bmj.m626

[4]Wecht, C. H. (1978). The swine flu immunization program: scientific venture or political folly? *American Journal of Law & Medicine, 3*(4), 425-445.

[5]WHO R&D Blueprint and COVID-19. Retrieved March 25, 2021, from https://www.who.int/teams/blueprint/covid-19

[6]African CDC Policy Paper: Research and Development Priorities for COVID-19 in Africa February 2021. Retrieved March 25, 2021, from https://africacdc.org/download/policy-paper-rsearch-and-development-priorities-for-covid-19-in-africa/

[7]AI, P. (2021). The value of communities and their consent: A communitarian justification of community consent in medical research. *Bioethics, 35*(3), 255-261. https://doi.org/10.1111/bioe.12820

[8]Carter, S. E., Gobat, N., Zambruni, J. P., Bedford, J., Van Kleef, E., Jombart, T. & Ahuka-Mundeke, S. (2020). What questions we should be asking about COVID-19 in humanitarian settings: perspectives from the social sciences analysis cell in the Democratic Republic of the Congo. *BMJ Global Health, 5*(9), e003607.

[9]Stellmach, D., Beshar, I., Bedford, J., du Cros, P., & Stringer, B. (2018). Anthropology in public health emergencies: what is anthropology good for? *BMJ Global Health, 3*(2), e000534.

[10]World Health Organization (2018). *Report of the informal consultation "Integrating social science interventions in epidemic, pandemic and health emergencies response"*. Geneva: World Health Organization, 2018.

[11]Thacker, P. D. (2021). Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. *BMJ, 375*.

[12]Reuters World News. (2020, July 1). 'We are not guinea pigs,' say South African anti-vaccine protesters. Retrieved August 3, 2020, from https://www.reuters.com/article/us-health-coronavirus-safrica-vaccine/we- are-not-guinea-pigs-say-south-african-anti-vaccine-protesters-idUSKBN2426RY

individuals within communities. It is not always easy to identify when one set of interests impinges another's so such approaches to communication could be unwitting. Community engagement practitioners must thus tread a tightrope between validating local voices and respecting their values, assessing and checking understanding of and dispelling misconceptions about clinical trials for local, national, regional and perhaps global reach.

Potential co-optation of community engagement practitioners may, we will argue, be compounded by new institutional efficiencies in administration and streamlined ethics approvals of scientific protocols to be implemented across multiple sites to increase recruitment rates and statistical comparisons as part of the pandemic response. Maintaining the integrity of community engagement is thus an increasingly important moral test against potential exploitation by scientific and pharmaceutical industries. To establish and care for the interests of the communities in question, the three roles above need to be disentangled and the potentially conflicting roles clarified.

2 | PURPOSE OF COMMUNITY ENGAGEMENT AND CLINICAL TRIALS

Community engagement is now widely recognized as an important ethical principle for global health research,[13] and for gaining rapport with and trust from local communities during humanitarian emergencies.[14,15] Community engagement, in this sense, was initially conceived in the conduct of clinical research, often designed by researchers and sponsors in developed countries, to be carried out in Africa and other low- and middle-income countries (LMICs). Sometimes, this meant consulting a traditional ruler as 'gatekeeper' and securing his/her consent to enter a village and to recruit its villagers with a communitarian rationale;[16] although never meaning "collective consent" (consent from each and every individual before anyone can participate). In theory, community engagement (like community or patient participation in health programmes) is supposed to ensure that the proposed research responds to genuine needs, if not the highest priorities, of the host community and that the methods planned by scientists are apparently morally acceptable to the community.[17] Occasionally, it is seen as a precursor to individual consent, by providing general information and answering specific questions usually in coordinated meetings, although the pre-existing consent from a community leader could put pressure on how autonomy is conceptualised in such circumstances.[18] Considerable

work on community engagement across LMICs and in Africa culminated in the WHO's *Good Participatory Practice* (GPP) guidance as part of its longstanding research in HIV/AIDS.[19,20,21,22]

As the above guidance recommends, early community consultations could help identify what sorts of intervention, if any, communities would accept before financial investment is made and there is a political commitment to a certain technology. Community engagement should solicit views and values before identifying barriers to recruitment rates to established research protocols and seek to ask participants to recommend compromises where needed. Engaging with community values should pervade the entire process of clinical research, actively seeking lay input, from conception through to design and dissemination of research findings.

This guidance has made the practice of participatory decision more common, especially following collaboration with bioethics.[23] But all too often, the practice of community engagement is still part of pre-determined and funded scientific or policy work with specific rationale defined by powerful scientific and pharmaceutical stakeholders.[24] Indeed, criticism about community engagement in clinical trials highlight the fact that scientific, corporate and funding networks, coalesced around specific technologies, have difficulties and clear conflicts of interest in adequately evaluating community voices and concerns. Arguably, technological "lock-in" coupled with the increasingly recognised 'saviour complex' is the more usual approach, making community engagement a piece-meal exercise that aims to simply validate predetermined plans, and can even involve the sidestepping of complaints and dissenting voices under the guise of education. In this way, "community engagement" as a concept and process is often depoliticized and co-opted by the biomedical establishment.[25]

3 | CULTURAL SENSITIVITY AND ANTHROPOLOGY

Since the West African Ebola epidemic, anthropology has assumed an increasingly important role in policy discourses about how to improve outbreak response.[26] In Africa, anthropological knowledge has

[13]Adhikari, B., Pell C., & Cheah P. Y. (2020). Community engagement and ethical global health research, *Global Bioethics*, 31, 1–12.

[14]Laverack, G., & Manoncourt, E. (2016). Key experiences of community engagement and social mobilization in the Ebola response. *Global Health Promotion*, 23(1), 79–82.

[15]Marcis, F., Enria, L., Abramowitz, S., Saez, M. A., & Faye, S. L. B. (2019). Three acts of resistance during the 2014-16 West Africa Ebola epidemic: A focus on community engagement. *Journal of Humanitarian Affairs*, 1(2), 23–31.

[16]Stellmach, et. al., op. cit. note 9.

[17]Marsh, V. M., Kamuya, D. K., Parker, M. J., & Molyneux, C. S. (2011). Working with concepts: The role of community in international collaborative biomedical research. *Public Health Ethics*, 4, 26–39.

[18]Stellmach, et. al., op. cit. note 9.

[19]UNAIDS, AVAC, op. cit. note 1.

[20]Marsh, V., Kamuya, D., Rowa, Y., Gikonyo, C., & Molyneux, S. (2008). Beginning community engagement at a busy biomedical research programme: Experiences from the KEMRI-Wellcome Trust Research Programme, Kilifi, Kenya. *Social Science & Medicine*, 67, 721–733.

[21]Tindana, P. O., Singh, J. A., Tracy, C. S., Upshur, R. E., Daar, A. S., Singer, P. A., et al. (2007). Grand challenges in global health: Community engagement in research in developing countries. *PLoS Medicine*, 4, e273.

[22]Workshop Report: Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises. 17-18 March 2017, Dakar, Senegal. Retrieved November 1, 2021, from https://www.nuffieldbioethics.org/assets/pdfs/Research-in-global-health-emergencies-Dakar-Workshop.pdf

[23]Ibid.

[24]Loewenson, R., Colvin, C.J., Szabzon, F., Das, S., Khanna, R., Coelho, V.P., Gansane, Z., Yao, S., Asibu, W.D., Rome, N., & Nolan, E. (2021) Beyond command and control: A rapid review of meaningful community-engaged responses to COVID-19. *Global Public Health*, 16, 1439-1453. https://doi.org/10.1080/17441692.2021.1900316

[25]Dumit, J. (2012). *Drugs for life: how pharmaceutical companies define our health*. Duke University Press.

[26]Stellmach, et. al., op. cit. note 9.

historically been linked to colonial regimes and outlooks. Even today those who do "anthropology" inherit various epistemological risks, one of which is the reducing and simplification of African values and philosophies to anthropological curiosities.[27,28] This means that anthropology is not a neutral field of knowledge creation but also comes with specific values and biases. Anthropology has also evolved with the world. Culture today is less definitive and more porous, and often related in various ways to "trans-national" and "global" forces, which has driven the need for "multi-sited" ethnography that relates particular observations in a specific place with networks around the world.[29] This means that anthropological engagement with clinical trials cannot, by definition, only focus on a geographically bounded location (eg the village) but must necessarily incorporate how local decisions and experiences are influenced by actors at a distance, including global pharmaceutical offices and public health agencies.

The results of the community engagement exercises at a local level can conversely inform wider policy making. For example, there is a danger that anthropological knowledge comes to over-generalize the motivation of people to participate in clinical trials in order to present simplistic or selective data that supports biomedical narratives about recruitment. For example, the data, presented in a paper by Tengbeh et al., provides an interesting insight into the clinical trial of EBOVAC, a vaccine against Ebola developed by Janssen and trialled in Sierra Leone.[30] This study reported that the dominant motivational factors behind participating in the trial was a prevailing narrative about solidarity and sacrifice. The following quotation was taken from the title of the paper and was recorded from an individual trial participant: *"We are the heroes because we are ready to die for this country"*. This denotes a tendency for people to assume a degree of risk from a clinical trial pharmaceutical drug (that may have major adverse side effects) due to the belief that the medical technology may end the crisis and save other peoples' lives. The data on why people would be willing to participate in the EBOVAC trial appears remarkably similar to results from qualitative or mixed methods research completed in Western contexts to accompany clinical trials.[31] However the narrative about sacrifice needs to be critically evaluated. From these results, it is not clear that sacrifice is the sole or predominant motivation for participation in a trial while more

discerning methods eg using forced choice or standard gamble techniques reveal that self-interest is often the predominant or decisively motivating force behind consenting to take part in trials.[32]

There is also often an unspoken assumption that such research must commence from scratch-*tabula rasa*. It is, therefore, worth distinguishing between the simple access to sources of cultural knowledge and the use of anthropological methods to study cultures and communities. Much preparatory work can be done without the need for further 'study' of people who may already be overburdened by disease, trauma and participation in other clinical or epidemiological research studies. An anthropologist in one area of expertise may be highly skilled in study methods yet be largely ignorant of a particular culture or place. Instead of studying a particular culture or community *de novo* during an outbreak, it may be possible to paint a picture of the philosophies of affected communities using existing general knowledge from which beliefs could be inferred about the case of infection and disease. General knowledge of culture may also be gathered between outbreaks particularly where infectious diseases are known to be endemic making the risk of another outbreak high. It can otherwise be directly and quickly accessed through other sources of cultural heritage and indigenous knowledge, which provides a check on the risk of appropriating community voices and projecting interpretations onto them, providing the opportunity for a 'triangulation' or pluralistic methodological approach. It is important to avoid "parachuting" anthropologists into a clinical trial situation, as a general rule. Indeed, we might expect that members of local ethics committees (which approve a clinical trial) would or should have some insight into the cultural context of the populations they serve. But this is sometimes not the case in practice. Collaboration with knowledgeable individuals, academics, health practitioners and cultural leaders may be enough to gather essential cultural information on which to base an intervention and prepare the way for sharing specific information about it for individual consent within what are often communitarian traditions.

There may be important limits to these methods for establishing the interests of communities. Beliefs and values, especially of those cultures with oral rather than written records, are often thought to reflect mere tradition and to be wholly accessible by anthropological techniques and hence themselves amenable to influence and change. The philosophies in which these traditions are rooted provide insight into the ways different cultures think. For example, the current outbreak of Chikungunya (an emerging mosquito- borne disease) in Congo-Brazzaville affects people living in what was the old Loango Kingdom, on which very little written record exists. Known to be a sub-group of the Bantu, the Vili peoples are thought to harness the power of their ancestors by collecting rainwater in vessels to be used as medicines.[33] Without fully understanding why standing water is

[27]Parker, M., Hanson, T. M., Vandi, A., Babawo, L. S., & Allen, T. (2019). Ebola, community engagement, and saving loved ones. *Lancet*, 393(10191), 2585. https://doi.org/10.1016/S0140-6736(19)31364-9

[28]Shelley-Egan, C., & Dratwa, J. (2019). Marginalisation, Ebola and Health for All: From outbreak to lessons learned. *International Journal of Environmental Research & Public Health*, 16(17), 3023.

[29]Marcus, G. E., & Fischer, M. M. J. (1999). Anthropology as cultural critique: An experimental moment in the human sciences. The University of Chicago Press. Second edition. Chicago and London.

[30]Tengbeh, A. F., Enria, L., Smout, E., Mooney, T., Callaghan, M., Ishola, D., Leigh, B., et al. (2018). We are the heroes because we are ready to die for this country: Participants' decision-making and grounded ethics in an Ebola vaccine clinical trial. *Social Science & Medicine*, 203, 35–42.

[31]For example, see Bidad, N., MacDonald, L., Winters, Z. E., Edwards, S. J., Emson, M., Griffin, C. L., Bliss, J., & Horne, R. (2016). How informed is declared altruism in clinical trials? A qualitative interview study of patient decision-making about the QUEST trials (Quality of Life after Mastectomy and Breast Reconstruction). *Trials*, 17(1), 431. https://doi.org/10.1186/s13063-016-1550-7. PMID: 27590594; PMCID: PMC5009536.

[32]Jansen, L. A. (2009). The Ethics of Altruism in Clinical Research. *The Hastings Center Report*, 39(4), 26-36.

[33]Hersak, D. (2001). There Are Many Kongo Worlds: Particularities of Magico-Religious Beliefs among the Vili and Yombe of Congo-Brazzaville. *Africa: Journal of the International African Institute*, 71(4), 614-640.

left near people's homes, it would be unwise to try to 'educate' them and simply to remove it. Alternative methods of controlling the mosquito population might be more sensitive to cultural norms leaving behaviour and practice intact. In this case, anthropological study of basic concepts is indeed important and a vital first step, if at least to document the oral tradition, from which methods for engaging communities can be derived, now and for future research. The attempt to change what could be risky behaviour simply by identifying and dismantling 'folk beliefs' which are presumed to lack all the sophistication and moral importance of scientific inquiry and logical reason could ultimately be morally and politically misguided or even counter-productive.

All of these efforts, however, take considerable time, coordination, and resource which may not be ready to deploy as ideally required. Methods for engaging with cultural beliefs and behaviours include drawing up dedicated codes of conduct such as the San Code of Research Ethics which was written with the San people of South Africa for all research involving them,[34] and deriving a cultural protocol for foreign researchers such as one developed for Pakistan.[35] In some cases, however, trust in researchers through community engagement is sufficiently strong for members regardless of any guide or protocol. In Bangladesh, another Muslim country, alcohol is prohibited and thus asking people about drinking alcohol is perceived to be a culturally very sensitive issue. However, social scientists on the investigation team of Nipah outbreaks explored the consumption of bat-contaminated raw date palm sap by keeping respondents completely anonymous throughout.[36] The fermented date palm wine did not contain enough alcohol to destroy the virus.[37] Furthermore, the investigation team found the presence of bat excreta inside date palm wine pots, the use of the same pot for several days without cleaning and the accumulation of sap from multiple pots into one pot suggesting that sap is probably contaminated with bat urine or saliva during collection and fermentation. While an important first step, a cultural protocol alone may be useful for first approaching some communities but may not be enough even when there is cultural knowledge from prior research.

Some host communities are, in any case, too diverse in significant respects and require more extensive political engagement to show how these cultural values co-exist or interact. The notion of community acknowledges that social diversity exists within communities so engagement needs also to be flexible enough to accommodate it.[38] In places with multiple ethnicities and different religions and outlooks, an anthropological approach to community engagement could thus be misleading by recording an unrepresentative sub-section of the host population as artificially homogenous.[39] Indeed, the very idea of 'community' could be imposed on residents by researchers wishing to engage with a convenient geographically contained population.[40]

Sadly, many of the general codes for conducting research, within which cultural protocols may be nested and with which they must be compatible, are written mainly by researchers in the West and are simply imported into other countries and cultures while few if any values travel in the other direction.[41] For example, substantive and procedural ideas about research ethics are becoming globally adopted to enable international research and to harmonise regulations. Thankfully, the International Conference on Harmonisation of Good Clinical Practice (ICH-GCP), from which most legally enforceable standards of clinical trials of vaccines and medicines across the World are now drawn, is currently being revised to endorse a more diverse toolkit of scientific methods and to be more acceptable to different communities especially from the Global South than has hitherto been the case. Cultural sensitivities are often regarded as important when they conflict with established Western norms or received scientific outlooks inviting intense philosophical debate over the moral universalism of respect for individual autonomy and the limits to political toleration of unusual beliefs or "practices", especially those regarded as religious or spiritual in nature. The liberal values which shape a society that comprises independent individuals each seeking to maximise their own interests along with the predominance of scientific methods and technological innovations is reflected in our own cultural philosophies and even the languages we use to express them. However, this approach is itself unusual when viewed from a global perspective.[42]

Community engagement is far from being a 'magic bullet'. Just as democratic processes can lead to apparently irrational preferences for incompatible options, the views and values of communities sought through engagement and the sophisticated social science methods can reveal inconsistent and incompatible preferences. Ultimately, good governance and law has to set the boundaries on liberty. The barriers to policies and ethical frameworks for outbreak prevention, preparedness, detection, and response management are often political in nature, with competing interests and social structures being difficult for first responders to navigate especially if they feel under-resourced and over-stretched.[43] Indeed, working within these established structures and piggybacking on existing procedures means potentially reinforcing unjust political regimes despite a commitment from major organisations to increase funding. Indeed, Transparency International

[34]San Code of Research Ethics. (2017). Retrieved January 15, 2020, from http://www.globalcodeofconduct.org/affiliated-codes/

[35]Memon, R., Asif, M., Khoso, A. B., et al. (2021). Recognising values and engaging communities across cultures: towards developing a cultural protocol for researchers. *BMC Med Ethics, 22*, 47. https://doi.org/10.1186/s12910-021-00608-4

[36]Islam, S. M., Sazzad, H. M. S., Satter, S. M., Sultana, S., Hossain, M. J., Hasan, M., et al. (2016). Nipah virus transmission from bats to humans associated with drinking traditional liquor made from date palm sap, Bangladesh, 2011–2014. *Emerging Infectious Diseases, 22*(4), 664– 670.

[37]Chandrasekhar, K., Sreevani, S., Seshapani, P., Pramodhakumari, J. (2012). A review on palm wine. *International Journal of Biological Sciences, 2*, 33–38.

[38]Loewenson, et.al,. op. cit. note 24.

[39]Molyneux, S., & Bull, S. (2013). Consent and Community Engagement in Diverse Research Contexts: Reviewing and Developing Research and Practice: Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya, March 2011. *Journal of Empirical Research on Human Research Ethics, 8*(4), 1-18. https://doi.org/10.1525/jer.2013.8.4.1

[40]Lignou, S., Das, S., Mistry, J., et al. (2016). Reconstructing communities in cluster trials? *Trials, 17*, 166. https://doi.org/10.1186/s13063-016-1284-6

[41]Baggini, J. (2019). How the world thinks: A global history of philosophy. Granta Books.

[42]Ibid.

[43]Wilkinson A., & Fairhead J. (2017). Comparison of social resistance to Ebola response in Sierra Leone and Guinea suggests explanations lie in political configurations not culture. *Critical Public Health, 27*(1), 14–27. https://doi.org/10.1080/09581596.2016.1252034. PMID: 28366999

released a report in 2021 showing that, of the 86 registered clinical trials, only 6 were being conducted by developers based in the countries hosting them.[44] To address the widely recognised structural inequalities between the global north and south over access to COVID-19 vaccines shown to be efficacious in reducing rates of severe disease, Moderna announced a patent waiver to allow local manufacture of the novel nRNA vaccine, now based at several sites across the African Continent.[45] Moreover, the Gates Foundation has recently announced that major funding in Global Health will in future be administered through the new coordinating African Centres for Disease Control (CDC) and other major centres in the Global South in an attempt to redress the imbalance of power associated with funding which will help focus local expertise and markedly increase research capacity and outbreak response. WHO has also helped coordinate vaccine hubs to facilitate these processes. Given that the ethics of research rests both on the macro- and the micro-environments, the global and local, the limitations to what community engagement can achieve becomes clearer.

We further suggest that the emphasis on using anthropology in epidemic response and community engagement may distract from politically unjust or socially unstable dynamics. The promise of 'learning about' and 'facilitating engagement' could generate blindspots and strategic ignorance.[46] Those communities thought to possess high social capital, a measure of trust, norms and networks, seem to have fared best against COVID-19.[47] Lack of trust in officials is often cited as the problem leading response workers to hope for some social intervention to make communities more trusting of them, through reframing information or through education. However, we need to be looking at ways to ensure that powerful officials are themselves trustworthy and accountable in demonstrable ways and how we might politically enfranchise those remote and underserved through fair negotiation and good governance.

While anthropology has long been recognized as important,[48,49,50,51,52] the current COVID-19 pandemic underlines a need to draw on a wide range of social science disciplines as well as the humanities.[53,54,55,56] For example, methods used in behavioural economics such as standard gambles (as used in expected utility theory) and scenario experiments could help to elucidate how people trade-off different values, for example, between different public health measures to elicit preferences in more formalised ways. There is though increasing recognition that behavioural science can be used to increase recruitment rates to clinical trials.[57] While it is not our aim to describe how each discipline could contribute in coordinated or integrated ways, there is much work needed to reconcile disciplinary differences and theoretical conflicts to achieve a more integrated and holistic approach to outbreak management. For example, behavioural change nudge theory has become a very popular technique in the COVID-19 pandemic to influence human behaviour, if not to increase recruitment rates to clinical trials. While largely compatible with autonomous choice, there are occasions where manipulating choices could systematically be achieved through deception, equivocation or misdirection, just as advertising departments and Personal Relations have sought to do for many years. On other occasions, anthropologists see behaviour change approaches appearing to blame individuals without recognising they can also pick up major structural barriers to opportunities for behaviour change. Using social sciences in coordinated and integrated ways needs ethical insights and independent judgements to mitigate such risks.

4 | THE AMBIGUOUS ROLE OF ANTHROPOLOGY IN COMMUNITY ENGAGEMENT

Community engagement is widely regarded as critical to implementing individual clinical research projects in Africa. With cross fertilization with bioethics, community engagement and the anthropological studies that inform them are now involving communities earlier on in the research process. However, an ethics of community engagement requires more careful justification when anthropological study is included. In particular, community engagement practitioners require a role as *either* community *or* research advocates especially when their interests pull apart. All engagement practitioners will thus need to reflect on their practice and independent checks sought

[44] See Transparency International Report. For Whose Benefit, 2021. http://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf

[45] For example, see announcement: Fourlong, A. (2022). Moderna to share vaccine tech, commits to never enforce COVID-19 jab patents. Politico; and Bill and Melinda Gates Foundation Explore Africa. Retrieved March 18, 2022, from https://www.gatesfoundation.org/our-work/places/africa

[46] Bovensiepen, J. (2020). On the banality of wilful blindness: Ignorance and affect in extractive encounters. *Critique of Anthropology*, 40(4), 490-507.

[47] Makridis, C. A., & Wu, C.(2021). How social capital helps communities weather the COVID-19 pandemic. *PLoS ONE*, 16(1), e0245135. https://doi.org/10.1371/journal.pone.0245135

[48] Brown, H., & Kelly, A. H. (2014). Material proximities and hotspots: Toward an anthropology of viral haemorrhagic fevers. *Medical Anthropology Quarterly*, 28(2), 280-303.

[49] Davidoff, V. (2016). The contribution of anthropology during the operational response to an Ebola outbreak: An analysis of the West African Ebola epidemic. Unpublished Masters Thesis: Geneva University. Retrieved January 16, 2020, from https://www.cerahgeneve.ch/files/2914/8163/3257/WP39-contribution-anthropology- during-operational-response-ebola-outbreak2.pdf

[50] Hewlett, B., & Amola, R. (2003). Cultural contexts of Ebola in Northern Uganda. *Emerging Infectious Diseases*, 9(10), 1242–1248.

[51] Hewlett. B., & Hewlett, B. (2008). Ebola, culture, and politics: The anthropology of an emerging disease. Belmont, CA: Thomson Wadsworth.

[52] Leach, M. (2008). Haemorrhagic fevers in Africa: Narratives, politics and pathways of disease and response, STEPS working paper 14, Brighton: STEPS Centre.

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when potential conflicting interests potentially threaten their integrity. Limitations to their abilities to advocate for communities beyond the immediate clinical research team need to be recognised to cultivate trustworthy institutions.

There may be considerable personal rapport and apparent trust in the community engagement team and associate researchers in some cases as can be seen from reports seeking to assess trust over COVID-19 vaccines in Uganda.[58] However, the role of social scientists and community engagement practitioners associated with and employed by clinical trial investigators may potentially be ambiguous-as advocates for the community or for the researchers-especially during epidemics of emerging and re-emerging infectious diseases for which little medical help is available. Such potential conflict could in turn cast some doubt on their trustworthiness, as they may not be seen to care for the community in a wholehearted sense. Onora O'Neill observed that trustworthiness and transparency is morally more important than gaining trust, defining the conditions for trustworthiness as to care and be competent.[59] The appearance of potential conflicts of interests are often enough to erode trust and, where not, there is usually some independent or third-party check to mitigate against it becoming problematic. The first challenge though is simply to recognise and acknowledge them where they exist especially where multiple strategies are used in an attempt to recruit participants.

The standard way to address potentially conflicting interests is to avoid them altogether or seek independent assessment. There is now a long history of running wholly independent social science projects on the back of clinical trials but historically and typically they have used quantitative methods and been led by psychologists or clinicians. As long ago as 1998, fifty-eight articles in a review paper provided data on how patients and the public view randomized clinical trials (RCTs), illuminating what motivates them to take part.[60] Fifty-one contained quantitative data while eight contained qualitative data (one study used both methods). The objectives and methods of such work have developed along with the technologies under evaluation with little theory-driven study from the point of view of advancing the disciplines in the social sciences themselves.

Methods for community engagement have largely been advanced by the study in the social sciences and the rise of specialist community engagement practitioners, working together with the research team or more independently. A social scientist may be enlisted merely to help a researcher with community engagement before any participants are enrolled. In this vein, the social scientist is an instrument and an intermediary or 'bridge' between the researcher and the community and is principally tasked with informing people,

allaying concerns as they arise, and correcting misconceptions before they take hold. Social science is, by contrast, the academic study of society. To neatly illustrate the tension, a team of anthropologists publishing the findings of the EBOVAC Salone trial of an Ebola vaccine developed by Janssen pharmaceuticals discusses one of the challenges thus:

> "The role of the social science team was to produce academic research on the acceptability of the vaccine trial; and to work in conjunction with a community engagement team to develop community-led approaches to participant recruitment…the social science team contended with the tension between ensuring independence and providing critique whilst also generating impactful findings that can support the intervention".[61]

In this case, the objectives behind community engagement to smooth the running of the trial, and the anthropological study to capture an accurate and complete picture of the community's views could easily diverge. While not necessarily a problematic conflict of interest, the objectives of engaging with communities could be clarified. The anthropological project Ebola Vaccine Deployment, Acceptance and Compliance (EBODAC) itself refers to both 'acceptance' and 'compliance' declaring its primary instrumental rationale. Anthropology, even as an academic study, is thus mainly a tool to ensure community acceptance of study design (here, randomised controlled trials of experimental Ebola vaccines) and sometimes explicitly to increase recruitment rates. While anthropological study can be separated from the practice of community engagement, as is the case with Covid vaccine trials,[62] a cycle of communication that continuously feeds results into the process of engaging communities is designed albeit indirectly to influence recruitment. Social study is in this case as much to gather what might be called 'intelligence' in other contexts as it is to conduct ethnography.[63]

While politics is all about persuasion and it is increasingly accepted that policy should be 'evidence-based', there are various sources of evidence which can make such political conversations and policy innovations more-or-less effective. For example, the results of social sciences may be put to several uses. An example of using qualitative research explicitly designed to inform recruitment strategies from the UK illustrates exactly how powerful a tool it can be. In 2002, a paper was published showing how recruitment rates to a clinical trial could be dramatically increased by investing in qualitative inquiry.[64] The ProtecT study was trialing the intervention of prostate

[58]Kasozi, K. I., Laudisoit, A., Osuwat, L. O., et al. (2021). A Descriptive-Multivariate Analysis of Community Knowledge, Confidence, and Trust in COVID-19 Clinical Trials among Healthcare Workers in Uganda. *Vaccines, 9*, 253. https://doi.org/10.3390/vaccines9030253

[59]O'Neill, O. (2018) Linking Trust to Trustworthiness. *International Journal of Philosophical Studies, 26*(2), 293-300. https://doi.org/10.1080/09672559.2018.1454637

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[61]Tengbeh, et al., op. cit. note 30.

[62]Stellmach, et al., op. cit. note 9.

[63]Social Science in Humanitarian Action Platform COVID-19: Using Social Science in Clinical and Vaccine Trials 2020. Retrieved March 25, 2021, from https://www.socialscienceinaction.org/resources/covid-19-using-social-science-in-clinical-and-vaccine-trials/

[64]Donovan, J., Mills, N., Smith, M., Brindle, L., Jacoby, A., Peters T., Frankel, S., Neal, D., & Hamdy, F. (2002). Quality improvement report: improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study commentary: presenting unbiased information to patients can be difficult. *BMJ, 325*, 766.

testing for cancer and treatment. On asking patients why they were not as a group consenting, it transpired that, amongst other things, the name of the control arm was putting them off. The description of the control arm was duly changed from 'watchful waiting' to 'active monitoring'. Without data on what people understood by the terms before and after the change in description, it is impossible to tell whether a stark increase in recruitment rates from 40 to 70% was not also associated with a corresponding decrease in understanding. The 'therapeutic misconception' in research is well documented,[65] but is more often associated with over-estimating the prospects of an experimental treatment than it is with misunderstanding the implications of a control arm. Nothing of substance in the control arm of ProtecT had changed. While the therapeutic misconception is a well-known difficulty with consent to research, the ability to influence people with style over substance is gaining ground in the public health world. The idea of Nudge as originally advocated by Thaler and Sunstein in their now influential book focuses largely on the use of incentives to motivate behaviour or changing the environment to make certain habits more convenient and more likely.[66]

While Nudge theory may appear relatively novel and especially helpfully in a historically under-resourced public health sector, the politics of language and the value of rhetorical devices was at once recognised and prized as far back as the ancient Greeks as it has been by contemporary political leaders during COVID-19.[67] The moral significance of informational manipulation is thought to turn on whether autonomy is compromised and, where it is compromised, for whose benefit.[68] To further the point, plans to pay a member of the community to recruit participants on behalf of trialists are based on the idea that community trust can sometimes be won simply by having someone from within the community advocate for it.[69] However, there is then no independent check to show that the community's interests are of primary importance given the existence of a pre-determined research project. In any case, manipulating and framing information to implement public health measures and to increase recruitment rates can go only so far. While community engagement practitioners should not be paid by the research team, a standard practice associated with clinical trial funding, and certainly not on commission in proportion to the numbers of people they introduce to the trial and recruit to it, there will be an implicit expectation for the community engagement practitioner to improve recruitment rates perhaps by periodically drawing on the results from

on-going social science study of the problems and processes. Studies need to reach a certain number of participants to win the game of statistical significance.

5 | MANAGING MISCONCEPTIONS AND VALIDATING VOICES: A DELICATE NEGOTIATION

During the 10th outbreak of Ebola in DRC, violence against outbreak response teams and refugees crossing borders with Uganda and Tanzania were reported. To enable an efficient and more comprehensive study, many interviews with members of the populations were conducted via WhatsApp rather than face-to-face ethnography with individual communities. The results emerged in an impressively systematic effort to collate community feedback on Ministry of Health initiatives in timely ways to continually inform outbreak response strategies. These data are publicly available as a briefing on the SSHAP platform; over 14, 143 comments were coded as rumours, observations or beliefs identifying problems and enabling more concentrated efforts.[70] Unsafe burials were for example again usefully identified in several remote places. While this study presented only retrospective data on a restricted number of public health initiatives, it gave a general picture within which further health interventions, specifically clinical trials, could be designed.

The word 'rumour' may, however, itself be seen as somewhat dismissive or pejorative as if it is not entirely rational and transmitted in the absence or against what officials or scientists regard as good evidence. Rumours can be true or carry some grain of truth that needs to be acknowledged. Beliefs that do not align with scientific ones are not *ipso facto* irrational. A major concern has been for exploitation and 'stealing blood' as only later evidenced by the row of ownership of thousands of 'lost' blood samples during the Ebola crisis of 2014-16.[71] Depending on the governance arrangements, and on the public-private commercialisation of any derived biological materials, such concerns may be justifiable.[72] Contrary to the pejorative characterization, rumours may be accurate accounts of some aspect of experience, or indicative of attitudes or relationships that are crucial to understand. Indeed, another recent SSHAP reported that many people in Africa believed they already have some immunity to COVID-19 and do not need to be vaccinated.[73] There could be some, albeit limited, evidence suggesting some cross-over immunity with other zoonotic coronaviruses but such evidence

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[66]Thaler, R. H., & Sunstein, C. R. (2008). *Nudge: Improving decisions about health, wealth, and happiness*. New Haven, CT: Yale University Press.

[67]Lilleker, D., Coman, I. A., Gregor, M., & Novelli, E. (2021). Political Communication and COVID-19: Governance and Rhetoric in Times of Crisis (1st ed.). Routledge. https://doi.org/10.4324/9781003120254.

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[72]Stokstad E. (2019) Genetics lab accused of misusing African DNA. *Science*, 366(6465), 555-556. https://doi.org/10.1126/science.366.6465.555

[73]Tulloch, O., Roldan de Jong, T., & Bardosh, K. (2021) Data Synthesis: COVID-19 Vaccine perceptions in Africa: Social and behavioural science data, March 2020-March 2021, Brighton: Social Science In Humanitarian Action (SSHAP). https://doi.org/10.19088/SSHAP.2028

is far from accepted scientific fact.[74] It is not only the legacy of past unethical research to overcome, but the immediate controversy is over vaccine nationalism with LMICs apparently left behind and strikingly low prevalence of COVID-19 in some African countries. But there is the growing recognition that humanity may have to, as they say, "learn to live with the virus".

One major difficulty has been mistrust in officials and, until recently, the lack of promising and clinically tested treatments for emerging and re-emerging infectious diseases. Patients and their families observed that people with Ebola would go to hospital only to die.[75] With case fatality rates high and 'supportive care' being the only real incentive to seek outside help, a reluctance to report possible cases seems understandable. The same can be seen with cases of COVID-19 across Africa where intensive care units are not as available as in more developed countries. The mainstay of outbreak response, contact tracing and isolating, is difficult to maintain. There needs to be some incentive to report suspected cases which can outweigh the longstanding mistrust in national authorities and international organisations. With successful treatments, an information campaign from trusted sources as well as officials may be critical. However, further evaluation is needed to monitor their use.

6 | CONCLUSION

Despite the availability of early vaccines and some therapies, there continues to be the need for on-going research. It is thus time we acknowledge the emerging role of community engagement as an increasingly important check on streamlining approvals of clinical trials across multiple sites due to time constraints of the pandemic, as the virus becomes endemic and for future outbreaks. As research ethics committees accept the social value of research prioritised by the governments that support them and are under political pressure to standardise review, local values are at stake. The rationale behind ethics review by committee–to reflect a diversity of value, knowledge and experience–could be recast in a coordinated global effort in support of science to resolve the pandemic. A public health crisis calls for a different balance of moral values. A test for ethics of research thus seems, somewhat alarmingly, to have shifted more onto the communities themselves and their advocates to voice their values and views. Risks associated with pre-existing imbalances of power between researchers (together with their often-funded teams of engagement practitioners) and the communities they should serve is even more important to illuminate and mitigate against. Clear unambiguous roles for community engagement practitioners as advocates is needed more than ever to ensure that research is coordinated and governed in the interests of the communities that participate in it.

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[74]Doshi, op. cit. note 2.
[75]Abramowitz, et al., op. cit. note 53.

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