CLINICAL AND VACCINE TRIALS FOR COVID-19: KEY CONSIDERATIONS FROM SOCIAL SCIENCE

Previous months have witnessed a growth of clinical research in response to the COVID-19 crisis. This brief sets out social science considerations that can inform clinical and vaccine trials for COVID-19.

It was developed for SSHAP by London School of Hygiene and Tropical Medicine (LSHTM) by Rose Burns, Alex Bowmer, Luisa Enria, Samantha Vanderslott (University of Oxford) and Shelley Lees in order to inform design, recruitment and community engagement, implementation and results dissemination for trials of emerging vaccine and therapeutic candidates for COVID-19. Colleagues from Dalhousie University and Kings College London reviewed it. The brief is the responsibility of the Social Science in Humanitarian Action Platform.

SUMMARY CONSIDERATIONS

The following brief outlines how, and in what ways, social science can contribute to ongoing/future COVID-19 clinical and vaccine trials. Considerations for such trials include:

- The need to carry out context specific research, engaging with prospective participants and communities around relevant ethical, political, economic, legal and religious dynamics, histories and experiences of clinical research, perceptions of COVID-19 and associated interventions, concerns and expectations of clinical research and potential facilitators and barriers to participation.
- The need to identify community dynamics and patterns of trust – this means understanding contextual determinants of (mis)information and (dis)information and identifying both formal authority structures and informal sources of information/influence – to be able to ensure different kinds of actors and groups are involved in discussions before, during and after trials are conducted.
- The need for engagement and trust underline the need to watchguard open data and ensure full transparency in clinical trial protocols

- The need to integrate participant and community perspectives in deliberations about aspects of trial design and procedures to ensure these take into account specific benefits, concerns and socio-cultural context.
- The need to maintain open dialogue with participants and relevant communities, e.g. through participant advisory groups and community consultations.
- The need to ensure that engagement does not focus simply on 'misinformation' or the need for more information but also identifies sources of mistrust and potentials for community dialogue and responds to them in dynamic ways.

BACKGROUND AND PURPOSE

As the COVID-19 pandemic continues, it is vital to engage deeply and systematically with social context and identify factors that may influence community responses to the outbreak, transmission patterns and response efforts.[1–7] Globally, COVID-19 continues to trigger non-medical crises including significant indirect social and economic impacts resulting both from the pandemic itself and control measures deployed to contain it. Apart from a limited number of therapeutics, methods of management have focussed on non-pharmaceutical interventions, including social/physical distancing, quarantining, contact tracing, and increased hygiene requirements. In this context, it has been recognised that detailed insights from social science disciplines are critical in managing the crisis.[8] This is because social science insights help to elucidate the complexities of the contexts in which outbreaks occur, and the diverse forms of public authority and power at play which are inherently dynamic, complex and uncertain. However, so far, there has been limited social science research within or alongside the clinical trials underway.[3,9] With promising new vaccine candidates in phase 2/3 clinical trials, it is important that social science inputs are recognised and employed in trial design and management during this pandemic.

As the COVID-19 pandemic has and will likely continue to threaten public health systems and their ability to effectively engage with affected populations, we must learn from recent emergent disease outbreaks including SARS, MERS, A (H1N1), Zika and Ebola to provide lessons for COVID-19 clinical trials. These outbreaks have demonstrated that social science informed interventions and engagement with communities is integral to the success of an outbreak response, including clinical and vaccine trials for emerging pathogens. Multiple studies have shown how community dynamics, local beliefs, local and global political economies, historical legacies of inequality, and marginalisation and mistrust in service providers, can inform medical interventions capable of establishing

positive and productive relations with local communities.[10–18] These insights have reinforced long-standing work in medical anthropology that has highlighted hesitancy, concerns and resistance to interventions such as immunisation and medical trials and tensions between biomedical and local knowledge.[19–22]

THE NEEDS OF RESEARCH PARTICIPANTS

Community engagement and patient and public involvement (PPI) in the design, conduct and dissemination of clinical trials is now understood as essential. This is in terms of both research ethics *and* positive impact on quality, uptake, and relevance of research that can contribute to an outbreak response, with recent evidence also revealing improved enrolment of trial participants.[23,24] There are specific challenges of conducting clinical trials during an outbreak including those related to trial design, community engagement during an outbreak, the regulatory environment around such trials and operational constraints.[25] Given these challenges there is a risk that the concerns and realities of potential trial participants and communities are neglected, rather than placed at the centre of such research. It is essential that research during the COVID-19 pandemic actively contributes to the response as well as long term system capacity for effective epidemic prevention and response. Good practice for this work has been defined in the WHO *Good Participatory Practice guidelines for trials of emerging (and re-emerging) pathogens* (GPP-EP). These outline the foundational principles underpinning partnerships among trial stakeholders in situations of crisis: respect, fairness, integrity, transparency, accountability, and autonomy. These guidelines also set benchmarks, including those for mutual understanding, complementarity, and efficiency.[26]

SOCIAL SCIENCE AND TRIALS: EXPERIENCES FROM PAST OUTBREAKS

There is a growing body of experience from clinical and vaccine trials that show how social science can inform community engagement and PPI efforts, as well as other broader aspects of clinical trials conducted during outbreaks and crises. Social science contributions include identifying key questions about: the outbreak; outbreak response; the social and political machinations involved in the development of vaccines for global health; collating applicable social science research tools (including rapid tools) for use in trials and developing of social science information delivery systems; providing surge capacity including mobilising local social science expertise and deployment of external

technical staff, and ultimately contribute to a vaccine or therapy that is better accepted.[27,28]

Work during recent Ebola outbreaks has provided understanding of how interdisciplinary community liaison and social science teams can work within a clinical trial. This research has highlighted the importance of using social science to inform trial set up, procedures and ethics, support community engagement to track and address rumours and concerns around the trial, and to engage with motivations for participating in a trial for an experimental product.[25,29–31] These reflections highlight the importance of understanding rumours through a contextual lens (for example as commentary on broader social and political dynamics). Identifying community dynamics, rather than treating them as homogenous, and recognising who has authority and influence in different communities, can help to identify pathways for meaningful community engagement. For example, trust has been built in communities around trials when local leaders are engaged, involved in communicating the purpose of research, and when they decide to take part in trials themselves.[29] Above all, engagement needs to be understood as an iterative exercise; publics are not static and are often brought together through the very process of research. It is critical to attend to the ways in which practices of inclusion and exclusion can be played out and amplified through the research process.[32]

Some of the key themes that emerge from existing social science research on and within clinical trials include:

- Political and economic contexts - different kinds of political systems and economies will raise different kinds of questions around the implementation of an emergency response, including clinical research. The role of national authorities; relationship with international organisations as well as norms and standards; different levels of preparedness and established systems (e.g. ethics boards); different relations between and within communities; past experiences of external or government-led interventions, including previous experience of research, will matter for developing effective trials.
- Engaging relevant communities and prospective participants - good community and participant engagement should be based on free flowing information from and to communities to sufficiently represent community dynamics and their needs, issues of (mis)trust, context-specific sources of anxiety and hesitancy, trauma and violence in conflict/post-conflict contexts, locally specific understanding of illness and disease, previous experiences of medical research and/or engagement with (different kinds of) health service providers.

- Perspectives on disease and illness - research has highlighted that individual and community perceptions and experiences of illness, disease and health frame their engagement with clinical research and can be important for understanding hesitancy, the acceptability of different kinds of messaging, and to consider participants' health-seeking behaviours whilst on the trial (e.g. formal and informal providers).
- Participant experience - social science research has highlighted the need to take seriously participants' hopes and expectations from their involvement in clinical research, as well as fears (and experiences) of stigma or marginalisation.
- Protocol design - concerns should be identified around how informed consent is designed and carried out to ensure engagement around specific procedures (e.g. blood taking or the use of contraception), the acceptability of various designs (including debates around randomisation in emergency contexts); the adequacy of reimbursement in different kinds of socio-economic contexts; the acceptability of different selection criteria (e.g. exclusion/ inclusion, the use of lotteries to select volunteers if demand is high etc).
- Infrastructure and resources - important considerations in trial design and implementation plans include the staffing of trials and local recruitment, expectations placed on trials by both participants and relevant communities; the impact of clinical trials on existing health services and the standard of care provided within those services.
- Operationalising social science during trials within emergencies - in these unique circumstances social scientists must engage with outbreak response structures themselves (district, national, global) including into the recovery period. Participants' expectations of an investigational product need to be considered given they face a high risk of infection, and research activities must adapt to movement and other restrictions. Below we outline considerations with regards to operationalising social science research during trials in emergency contexts.

OPERATIONALISING SOCIAL SCIENCE DURING TRIALS IN EMERGENCY CONTEXTS

Best practice on operationalising these insights is emerging, and we know that such work must include dynamic and rapid research (e.g. power mapping to identify trusted authorities, rumour tracking and the identification of relevant local knowledge), engagement of different groups and actors, participatory and deliberative discussions

around messaging and trial design and the establishment of participant representation groups.[33]

The role of social science to support community engagement is increasingly well defined. In the EBOVAC trials, for example, a social science team acts as investigators for the effects of trials on individual lives, listening to individuals, community concerns and expectations about the study, through ethnographic and other qualitative methods. They also deploy these methods to produce more contextualised recommendations for community engagement and the clinical teams to be able to tailor their operations in locally relevant ways. In a context of mistrust and crisis these social science teams have been able to provide feedback to community liaison teams, for example, to directly address rumours that the experimental vaccine was infecting participants with Ebola. In recent months, social scientists have also addressed similar rumours associated with COVID-19 in phase 2/3 vaccine trials. Similarly, prevalent fears around trial procedures such as blood taking, which have been identified in other kinds of clinical research for Ebola, were identified and formed the basis of community-led engagement strategies. The social science research also indicated a range of motivating factors behind participation in the early stages of the trial, including the notion of 'sacrifice' or duty as a citizen, and hope or belief in the power of the vaccine to prevent Ebola.[34,35] These insights can not only inform more nuanced messaging but can also enable clinicians to think about the framing of discussions around informed consent and to ensure that trial procedures are well understood.

Work around these trials indicates how social science insights can significantly influence operational decisions regarding tailoring messaging, ensuring the right people are involved in discussions and that there are opportunities for participants and communities to have a say in the running of clinical research throughout each stage of the trial.

STRATEGIES FOR ONGOING AND FUTURE COVID-19 TRIALS

Research on anthropology, human behaviour, socio-political contexts and implementation strategies must play a central role in the COVID-19 response and research efforts. They are essential when designing and implementing clinical trials that evaluate experimental treatments, vaccines, and other preventive measures for COVID-19. The findings of these trials will be enhanced when they integrate social science into their design. Examples of how this can be implemented in different areas include:

- Formative research - an initial phase of stakeholder outreach and engagement is needed to identify key stakeholders, understand accepted channels of communication, local power dynamics and how decisions are made in communities.
- Stakeholder engagement plans - a phase of discussions with the key stakeholders identified in the formative research should take place in order to discuss trial design (and where appropriate seek feedback), implementation planning, and setting out a place for community engagement activities that will vary across contexts and relevant communities of prospective participants. These discussions may need to occur at different levels (regional, national, local).
- Protocol development - deliberative engagement with communities should feed into protocol development and clinical trial design during epidemics. Methods are emerging for this work (for example those being developed under the AViD study and the ALERRT consortium) and these could be rapidly adapted for different contexts.
- Informed consent process - community groups and key stakeholders should be consulted to test informed consent language; to ensure that informed consent forms are translated into relevant languages; where necessary (e.g. low literacy contexts) to consider alternative approaches, including video and audio.[36]
- Standard of prevention and care - frameworks and guidelines of prevention and care should be developed with reference to a particular context and the constraints faced in that setting (e.g. of providing care during a pandemic). The standard of prevention and care for trials continues to evolve and communities are encouraged to define what is a locally relevant standard of care. A consensus should be reached by stakeholders on the standard of prevention and care to be provided.
- Payments – considerations should be taken about the recruitment of staff that might fuel local tensions in contexts of high poverty. Similarly, considerations about reimbursements should take into account local economies. Community dialogue is important to address these tensions
- Follow up and exit - considerations must be made with regard to the length of time for follow up and exit. There is a requirement to create reciprocal relationships with trial participants during and after trials have been conducted.
- Trial closure, results dissemination and access to trial products - trials should develop open access resources following the closure of a trial to disseminate results. Considerations should be made for clear and accessible communication following the publication of results, and trialists' expectations should be managed through continued communication during each phase of the study.

LIST OF RESOURCES

- SoNAR-Global - A social science platform composed of 11 institutions working to create regional hubs, to provide tested and evaluated tools and models, and strengthen capacity. Their scope of action includes preparedness and response to epidemics, vaccine hesitancy, and the prevention of antimicrobial resistance. https://www.sonar-global.eu/

- Wellcome online community - https://mesh.tghn.org/ Practical guides and tools: https://mesh.tghn.org/resources/guides-and-tools/, and resources for epidemics and outbreaks: https://mesh.tghn.org/themes/epidemic-preparedness-and-response/

- Good Participatory Practice (GPP) - Guidance for participant and community engagement developed for HIV treatment trials, but of relevance to all clinical research. https://www.avac.org/good-participatory-practice

- AViD Project - The Anthropological Exploration of Facilitators and Barriers to Vaccine Deployment and Administration During Disease Outbreaks (AViD) project works across DRC, Sierra Leone, Brazil, India and Uganda, adopting both a top-down and bottom-up approach to exploring vaccine acceptance. https://www.avidproject.co.uk/about

- ALERRT- The African Coalition for Epidemic Research, Response and Training (ALERRT) is a multi-disciplinary consortium building a patient-centered clinical research network to respond to epidemics across sub-Saharan Africa. https://www.alerrt.global/content/our-members

- EBOVAC - The EBOVAC vaccine trial and follow up studies aims to support the final preparatory activities required for the licensure of a two-dose vaccine for Ebola Virus Disease. In-depth social science research is being conducted alongside the vaccine trial to explore community experiences and perceptions of the trial, vaccine and EVD in order to garner recommendations for future vaccine delivery and preparedness efforts.

  https://www.ebovac.org/the-trials/the-trials-phase-3/ https://www.ebovac.org/ebovac-3/

- PREVAC –The PREVAC (Partnership for Research on Ebola Vaccination) trial and follow up studies aim to compare three Ebola Virus Disease vaccine strategies with placebo. Social science research is being carried out during the trial to examine perspectives on the role of the trial and the vaccines as well as rumours and concerns that may arise.

  https://clinicaltrials.gov/ct2/show/NCT02876328, https://eurekalert.org/pub_releases/2020-01/ind-ptp011320.php

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If you have a direct request concerning the response to COVID-19, regarding a brief, tools, additional technical expertise or remote analysis, or should you like to be considered for the network of advisers, please contact the Social Science in Humanitarian Action Platform by emailing Annie Lowden (a.lowden@ids.ac.uk) or (oliviatulloch@anthrologica.com). Key Platform liaison points include: UNICEF (nnaqvi@unicef.org); IFRC (ombretta.baggio@ifrc.org); and GOARN Research Social Science Group (nina.gobat@phc.ox.ac.uk).

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