**Supplementary Materials 4. Table of Findings**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Study data | | | | | | | | | | | | Engagement data | | | | |
|  | P | I/E | C | O | | T | | S | | S | | Where reported | | Engagement Activities | | Engagement Intensity (4Cs) | Engagement-related Findings and Recommendations |
| Anguzu | Youth with nodding syndrome | 100 mg oral doxycycline for six weeks | Placebo | | NR | | 2015-2016 | | Community settings in rural Northern Uganda | | T2, evidence generation | | Text | | “Stakeholder meetings were held with community, district and political leaders and their views and opinions documented in the proceedings... Discussions with the district and hospital leaders aimed to introduce the trial, seek collaboration and advocate for support for the study...Trial protocol development [included a] ... consultative and training process by study investigators to engage trial staff and other stakeholders for the development of essential trial documents. Brainstorming sessions with stakeholders were conducted to develop draft and final versions of standard operating procedures and case report forms (CRFs), and described in pre-visit activity reports.” | Consultation | POTENTIAL FINDING  “Potential solutions to the often very slow and multilevel processes for procurement and other trial related activities need to be explored or identified. Potential needs exist to: (1) provide information about research and progress (dissemination), (2) consult with members and leaders about their views (dialogue) and (3) collaborate with members and scientists to plan, implement and propose recommendations (partnerships).”  UNMEASURED FINDING  “A program of community engagement and local leader involvement that is culturally competent and gender-sensitive may be key to success and in reducing community opposition towards participation in research.”  RECOMMENDATION  “Formation of community advisory boards and engagement teams is recommended.” |
| Dawson | HIV uninfected adults at high risk for sexual transmission | Preventive DNA/rAd5 HIV vaccine regimen | NR | | NR (Assessment of safety and efficacy) | | 2008-2013 | | USA | | T2, evidence generation | | Text | | “Decisions made by the protocol team were informed by extensive stakeholder consultations.” | Consultation | UNMEASURED FINDING  “The team’s extensive consultations with community representatives and other parties facilitated full consideration of stakeholder views and transparent communication. These steps will be essential in all HIV vaccine and prevention efficacy trials.”  UNMEASURED FINDING  “The tradition of robust community engagement in HIV vaccine research has provided a good foundation for discussions of complex new issues involving emerging prevention methods, and the design and conduct of clinical trials. That said, diverse opinions may be expressed, and there will not always be consensus on the best way to move forward in a trial as stakeholders grapple with new evidence and policy changes in the field. In this case, consensus was reached on how to move forward. The question of how to design and conduct future HIV prevention trials will become increasingly complex as more partially effective prevention methods are developed.” |
| Dickert | Adults with acute traumatic brain injury | Progesterone (dosage and duration NR) | Placebo | | NR | | NR (pub. 2014) | | Atlanta, GA, USA | | T2, evidence generation | | Acknowledge-ments | | “The nested ProTECT community consultation ancillary study incorporated a standardized survey/assessment tool into community consultation efforts across ProTECT III sites. The instrument was developed in consultation with the NETT Human Subjects Protections Working Group... The study population thus represented the universe of participants at sites using this survey. The 12 participating sites represented all major U.S. geographic regions.” | Consultation | MEASURED FINDING:  “Overall acceptance of personal EFIC enrollment was 70.8% among community consultation participants, consistent with some other published reports. Interactive methods were associated with increased acceptance of EFIC and recall of relevant study details; however, acceptance within interactive methods was highly variable, and participants had lower recall of study risks. Choice of consultation method appears to impact both the nature of feedback and the extent to which participants understand study content.  RECOMMENDATION  “Our findings highlight the need for further research to refine and improve understanding of community consultation methods and facilitate advancement of care for critical illness.” |
| Ezran | Mouse lemurs | NA | NR | | NR | | 2009-2013 | | School and community-based settings in rural Madagascar | | T.5 Evidence synthesis | | Text | | “Biology education in Madagascar has the potential to become an active, hands-on discovery curriculum in which students are citizen scientists exploring the unique but largely uncharted biology around their schools. We are therefore designing lecture and laboratory units, each centered on a major biological concept, that use the surrounding environment as a living laboratory the students explore with frugal science tools.” | Collaboration | FINDING IS A RECITATION OF THE STUDY APPROACH AND OBJECTIVE:  “Students were an active part of the field work. This is part of a citizen science project in which students across Madagascar explore the remarkable biology around their schools, including longitudinal studies of the local mouse lemurs. The hope is to spawn a new model organism and cultivate a deep genetic understanding of primate biology and health.” |
| Galadanci | Children ages 5–12 years with sickle cell disease (elevated TCD measurements) | Low-dose hydroxyurea for 3 years | NA | | Feasibility of a hydroxyurea trial for children with SCD | | 2011-2013 | | Sub-Saharan Africa (Nigeria) | | T2, evidence generation | | Text | | Brought together a team of investigators to work on a common research question to establish feasibility to conduct a Phase III Clinical Trial on SCD in sub- Saharan Africa. | Co-production | STUDY FINDING  “A hydroxyurea trial for children with SCD is feasible  in sub-Saharan Africa;... “  ENGAGEMENT FINDING: ENGAGEMENT REQUIRES RESOURCES  “...however, extensive training and resources are needed to build a global patient oriented multi-disciplinary research team with a common purpose.” |
| Kuhlman | Adults working in research professions | NA | NA | | NA | | 2018 | | Newport Beach, California, USA | | Non-specific T-phase; Evidence synthesis | | Text | | “The panelists brought different perspectives from working, for example, in Latin American communities in the U.S., studying ethnically and racially diverse, and low-income samples across U.S. urban and rural areas, conducting research with families in their homes in Los Angeles, and LMIC collaborations.” | Collaboration | PANEL RECOMMENDATION WAS NOT FOCUSED SPECIFICALLY ON ENGAGEMENT BUT MIGHT INCLUDE ENGAGEMENT  “Biopsychosocial health researchers, and those with whom they collaborate, must meet the challenge of studying all people especially populations at the greatest risk of disease. The challenges are notable and, like most methodological challenges, may seem insurmountable at times. Yet science will only progress for the public good if these methodological challenges lead to new strategies, techniques, creative solutions, and efforts to surmount them.” |
| Nagpal | Adult survivors of stroke chronic ischaemic stroke | Autologous administration of adult dental pulp stem cells | NR | | NR | | 2016-2017 | | South Australia | | T2, evidence generation | | Text | | "The study aimed to explore [through in-depth qualitative interviews] the views of people with chronic stroke on:   * the relevance and importance of an early phase clinical study such as TOOTH, with adult human dental pulp stem cells in chronic ischaemic stroke * the relevance and acceptability of the planned outcome measures and study design of the TOOTH study and * issues with consent to participate in the TOOTH study.” | Consultation | study FINDING:  “Participants conveyed that the most relevant outcomes to them were regaining participation, decreased dependence on caregivers and improvement in cognition, memory, mood, pain and fatigue. The perception of risk vs. benefit was likely influenced by the time elapsed since stroke, with participants being more willing to accept a higher level of risk early in the post‐stroke disease course.”  STAKEHOLDER RECOMMENDATION  “They believed that all stroke survivors should be given an opportunity to participate in research, irrespective of their cognitive capacity.”  UNMEASURED FINDING  “Incorporation of outcomes relevant to patients' need within the study design is critical to generate data that will enable personalized application of regenerative medicine in stroke.” |
| Osterholm | trials, studies, expert opinion, vaccine case examples | NA  Review of research, expert opinion, and case studies related to Ebola vaccine development | NA | | NA | | 2014-2015 | | Africa | | T2, evidence synthesis | | Text | | “This ongoing initiative includes experts with global experience in various phases of bringing new vaccines to market, such as funding, research and development, manufacturing, determination of safety and efficacy, regulatory approval, and vaccination delivery. It also includes experts in community engagement strategies and ethical issues germane to vaccination policies, including eight African scientists with direct experience in developing and implementing vaccination policies in Africa.” | Co-production | EXPERT RECOMMENDATIONS MAY INCLUDE ENGAGEMENT OF INDUSTRY AND POLICYMAKERS  “Numerous crucial issues in the development of Ebola vaccines still remain: the limitations of single-source vaccine supplies and the need to keep multiple pharmaceutical companies engaged in the process; the need to pursue development of vaccines that can be used in larger inter-epidemic or endemic situations; the need for continued funding for development of other Ebola vaccine candidates until final products with appropriate risk-benefit profiles are available for use under different circumstances; the need to provide actionable information to African countries about Ebola vaccine availability and use in the future; and the need to derive benefit from the wide range of clinical trials that are currently ongoing or planned to start in the near future.”  . |
| Sahay | Adults at high risk of HIV infection | (1) AAV based HIV vaccine; (2) Modified Vaccinia Ankara (MVA) based HIV vaccine (3) prime-boost strategy using DNA-MVA candidates | NR | | NR | | 2003-2006 | | Pune and Chennai, India in community and clinical settings | | T2, evidence generation | | Acknowledge-ments | | “Major initiatives in community engagement for three HIV vaccine trials were implemented for the first time in India and included establishment and involvement of Community Advisory Board and capacity building and engagement of lay community-based volunteers called ‘peers’ using ‘lay health promotion’ model. Community education program designed for trial participants’ education, identification and enrollment was a three-tiered approach, moving from large community awareness meetings (first step) to facility-based small group meeting to provide trial specific information (second step); ending with one-to-one vaccine center-based meeting with the volunteers to clear doubts, myths, and misconceptions about HIV/AIDS, the experimental vaccine and HIV vaccine trials as well as to explain trial specific procedures (third step).” | Communication, Consultation, Collaboration | ENGAGEMENT FINDINGS – COMMUNITY BASED RECRUITMENT IS CAPABLE OF PROVIDING COMMITTED VOLUNTEERS TO RESEARCH  “The trials demonstrated that community engagement and ownership is possible even in resource-limited settings. Recruitment process was participatory and culturally relevant. Coordinated efforts of the medical, social science, and field teams helped to resolve participant’ problems and issues. Participants are a representative mix of both genders, different educational backgrounds as well as socio-economic strata. The gap between intention to participate and actual participation exists and to bridge that the reasons for stepping back need to be explored. Although the community-based recruitment approach is labor intensive, it is rewarding and capable of providing committed volunteers.” |
| Sankaranarayanan | Adult members of Cheyenne and Arapahoe Tribal communities | NA  Descriptive: the gut microbiome of two native American communities | NR | | Taxonomic profiles of: bacterial genera. Fecal metabolite profile. | | NR (pub. 2015) | | Western Oklahoma, Cheyenne and Arapaho Indian Tribal Communities  USA | | T1, evidence generation | | Text | | “This research is the product of 4 years of collaboration and engagement work with C&A tribal members representing five different towns in western Oklahoma...” | Collaboration | STUDY FINDINGS but not engagement findings  “American Indians are known to be at elevated risk for metabolic disorders. While many aspects of this health disparity remain poorly understood, our results support the need to further study the microbiome as a contributing factor. As the field of microbiome research transitions to therapeutic interventions, it raises concerns that the continued exclusion and lack of participation of American Indian communities in these studies will further exacerbate health disparities.  RECOMMENDATION – ENGAGEMENT IS NECESSARY  To increase momentum in fostering these much needed partnerships, it is essential that the scientific community actively engage in and recruit these vulnerable populations in basic research through a strategy that promotes mutual trust and understanding.” |
| Seifer | Adults living with cancer | NA  Recommendations of stakeholder advisors to employ CBPR in phase III cancer clinical trials | NA | | NA | | 2006 | | USA | | T2, dissemination and application | | Text | | “ENACCT and CCPH established a fourteen-member National Advisory Committee to guide the initiative, composed of national leaders from five key stakeholder groups:  (1) cancer clinical research investigators and their staff from both academic and community settings;  (2) cancer clinical research sponsors from both government and industry;  (3) cancer patient advocates and advocacy organizations;  (4) community-based organizations whose constituencies are disproportionately affected by cancer; and  (5) experts in CBPR.” | Collaboration, Co-production | Umeasured ENGAGEMENT FINDING – ENGAGEMENT IS CRITICAL TO THE SUCCESS OF CANCER CLINICAL RESEARCH  “For cancer clinical research to achieve its full potential in reducing cancer deaths and eliminating cancer disparities, it is imperative to foster greater community involvement in the design and implementation of CCTs.  ENGAGEMENT-RELATED RECOMMENDATIONS FOR COMMUNITY AND RESEARCHERS. THIS IS OVERSTATED AS A “PARADIGM SHIFT” IN CCTS.  “Communities must better understand how CCTs work, how members can be involved as participants and advisors, and how they can maximally benefit from the results. Similarly, researchers must better understand how communities are organized and function, how community involvement can benefit cancer research, and how to effectively engage communities in meaningful roles. The Communities as Partners report calls for nothing less than a paradigm shift in the way CCTs are conducted.” |
| Talebizadeh | Youth and adults affected by Autism | Phase I of a PCORI study to gather information from stakeholders about genetics research related to Autism | NR | | NA | | NR (pub. 2018) | | Kansas, Missouri, USA | | T2, evidence generation | | Text | | “...formed a community advisory board composed of 33 participants, including outcomes and genetics researchers, clinicians, healthcare providers, patients/family members, and community/industry representatives, and convened six sessions over the 12-month period. During the sessions, discussed topics pertaining to linking genetics and outcomes research and reviewed relevant materials, including patient stories, research projects, and existing resources.” | Consultation | No findings on engagement, but the rationale for engagement -- that it IS NECESSARY TO ADVANCE GO STUDIES – is reported in other work  “The principles of conducting outcomes studies, such as patient involvement in every aspect of the process, have been well defined elsewhere [[3](https://link.springer.com/article/10.1007/s40271-018-0302-z#ref-CR3), [15](https://link.springer.com/article/10.1007/s40271-018-0302-z#ref-CR15)] and are intrinsic elements of the AutGO project. However, a lack of communication between genetics and outcomes researchers is a unique gap pertaining to conducting GO projects; therefore, to address this gap, we are targeting the research community as a main audience for this paper.  Recommendations  To make a connection between genetic information and patient-centered studies, in addition to engaging patients in the process, the research community, particularly, the genetics research community needs to: (1) be aware of the communication gap and (2) dynamically participate in relevant dialogues to become an active partner in designing/conducting genetic (GO) outcomes projects. One effective method of stimulating interest in developing this type of unique collaborative effort is to educate stakeholders about why and how team members may work in synergy on developing GO projects. This process may involve (1) developing disease-specific educational protocols that integrate relevant concepts (e.g., patient centeredness and translational elements) and demonstrate their applicability at different stages of the study process, (2) identifying potential connections between outcomes research and genetic information, and (3) assessing the potential applicability of the existing phenotypic/genotypic data in this context.” |
| Wamwenje, S. A. O. | Smallholder farmers and agricultural stakeholders. | Use of smartphones for monitoring cattle trypanocide non-susceptibility. | NR | | Efficacy of community-led  data collection | | NR (pub. 2019) | | Rural farms in Shimba Hills, Kwale County, Kenya | | T.5, evidence generation | | Text | | “Community engagement when implementing mobile phone-based strategies is important for gaining trust, educating on use and importance of data collected, and easy reporting of feedback... We also examine whether this strategy of data collection was robust enough to collect information on inclusivity, since data on gender inequality are harder to collect and constitute the “silences” in smallholder farming in resource poor settings...This pilot study was part of a larger study evaluating evolutionary markers of trypanocide non-susceptibility conducted among two smallholder livestock farming communities of different ethnicities from Mbegani and Kizibe.” | Co-production | How to do engagement  Study provides proof of concept for the viability of using smartphone Apps to remotely collect reliable large-scale information from smallholder farmers and veterinary health care givers in resource poor settings. It is shown that these datasets can be reliably collated remotely, analysed, and the findings can inform policies that improve farming practices and economic wellbeing while restricting widespread multi-drug resistance. Moreover, this strategy can be used to monitor and manage other infectious diseases in other rural, resource poor settings. |

SOURCE: TUFTS analysis of included publications

NOTES: PI/ECOTSS is a common reporting format for study data. The 4C’s is a taxonomy of engagement intensity from lowest to highest intensity. NR = not reported; NA = not applicable; ProTECT = Progesterone for the Treatment of Traumatic Brain Injury; TCD = transcranial Doppler; EFIC = exception from informed consent; TOOTH = The Open study Of dental pulp stem cell (DPSC) Therapy in Humans; CCT = cancer clinical trials.