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Defining Health Research for Development: The perspective of stakeholders from an international health research partnership in Ghana and Tanzania

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Abstract

Objectives: The study uses a qualitative empirical method to define Health Research for Development. This project explores the perspectives of stakeholders in an international health research partnership operating in Ghana and Tanzania.

Methods: We conducted 52 key informant interviews with major stakeholders in an international multicenter partnership between GlaxoSmithKline (GSK, Vaccine Developer) and the global health nonprofit organisation PATH and its Malaria Vaccine Initiative program (PATH/MVI, Funder-Development Partner), (RTS,S) (NCT00866619). The respondents included teams from four clinical research centres (two centres in Ghana and two in Tanzania) and various collaborating partners. This paper analyses responses to the question: What is Health Research for Development?

Results: Based on the stakeholders' experience the respondents offered many ways of defining Health Research for Development. The responses fell into four broad themes: i) Equitable Partnerships; ii) System Sustainability; iii) Addressing Local Health Targets, and iv) Regional Commitment to Benefit Sharing.

Conclusion: Through defining Health Research for Development six key learning points were generated from the four result themes: 1) Ensure there is local research leadership working with the collaborative partnership, and local healthcare system, to align the project agenda and activities with local research and health priorities; 2) Know the country-specific context - map the social, health, legislative and political setting; 3) Define an explicit development component and plan of action in a research project; 4) Address the barriers and opportunities to sustain system capacity. 5) Support decentralised health system decision-making to facilitate the translation pathway; 6) Govern, monitor and evaluate the development components of health research partnerships. Overall, equity and unity between partners are required to deliver health research for development.

KEYWORDS

Collaboration, Development, Empirical, Equity, Health Research

1 | INTRODUCTION

The role of research in advancing robust, functional and equitable health systems has been recognised for some time,[1] and most recently in the UN Sustainable Development Goals.[2] This is a welcome reminder of the importance and urgency of finding methods and resources to overcome the barriers present in low-resource settings where research capacity is limited, and a country's ability to address global health challenges is significantly reduced.[3] Establishing health research systems and activities in a country is important for development because it enables "countries to capitalise more effectively on the supply of ideas, translate research into effective interventions and design resilient health strategies."[4] Moreover, the conduct of local research is critical for adapting approaches to specific settings and maximizing the success of health policies.[5] Overtime more and more funding initiatives have aimed to strengthen health research capacity in Low and Middle-Income Countries.[6] In this paper, we concentrate on one particular initiative construct, Product Development Partnerships (PDP). These partnerships form international collaboration between scientists in wider multi-stakeholder programmes of research. This approach has the potential to reduce global health disparities through developing cost effective solutions to disease along with offering complementary activities that contribute to country development.[7] In this instance, our paper is based on stakeholder views from one specific long-standing partnership, between GlaxoSmithKline (GSK, Vaccine Developer) and the global health nonprofit organisation PATH and its Malaria Vaccine Initiative program (PATH/MVI, Funder-Development Partner). Through partnership this collaboration has developed a malaria vaccine candidate (RTS, S), and has conducted PhaseII/III in-human paediatric trials across seven (with an eigth country included for a further lot-to-lot consistency and non-inferiority study) sub-Saharan African Countries (NCT00866619, NCT01323972).[8] This paper is based on interviews with stakeholders of the vaccine candidate trial from two of the countries, Ghana and Tanzania.

A collaborative partnership such as that between GSK and PATH/MVI is tasked with successfully developing a new health intervention for, and with, low resource countries. Over the course of the malaria vaccine candidate trial, the partnership has incorporated different ways to build up scientific research capacity in the countries (Ghana and Tanzania) where the intervention (RTS,S malaria vaccine candidate) has been tested. Through PATH/MVI (MVI) and with funding from the Bill & Melinda Gates Foundation, the GSK/MVI malaria vaccine trial worked with the INDEPTH Network, Malaria Clinical Trial Alliance (MCTA) "to facilitate site preparation for the effective conduct of (malaria vaccine) clinical trials and simultaneously promote the long-term development and sustainability of clinical trial sites in resource-constrained countries in the developing world."[9] The partnering of GSK/MVI with MCTA actively promoted the objective of constructing health research for development by both collecting data on the safety and efficacy of a potential new malaria vaccine candidate and; strengthening the research capacities of the countries in the locations where the research was being conducted.

Before the 1970s, the idea that scientists and researchers from institutions of advanced industrialised nations had a role in research capacity strengthening and health system development was very limited, and it was even rarer to find a programme of capacity strengthening accompanying clinical research.[10] It was the pioneering work of groups such as TDR (the Special Programme for Research and Training in Tropical Diseases of the World Health Organisation), the Commission for Research Partnerships with Developing Countries (KFPE) and the Commission on Health Research for Development (COHRED) that first assigned funding and implemented programmes to provide support to strengthen local tropical disease research capacity; recognition of the fact that health research has a critical role in the development of low-income and middle-income countries.[11] Over time, this work led to the evolution of the concept, Health Research for Development, a campaign for equitable research in low resource settings. The concept was formally established in a landmark paper in 1990s by the Commission on Health Research for Development.[12] Health Research for Development is an approach to international collaborative health research that was

[1]Nuyens Y, Global Forum for Health Research.2005. *No Development without Borders: A Challenge for Research Capacity Strengthening*. Geneva, Switzerland: Global Forum for Health Research. Available at: http://www.sdh-net.eu/data/uploads/publications-library/no-development-without-research.pdf [Accessed 16 Jan 2017]; Whitworth JAG Kokwaro G, Kinyanjui S, et al. Strengthening capacity for health research in Africa. *Lancet*. 2008;372(9649):1590-3.; Ogundahunsi OAT, Vahedi M, Kamau EM, et al. Strengthening Research Capacity—TDR's Evolving Experience in Low- and Middle-Income Countries. *PLoS Negl Trop Dis*. 2015;9(1):3380.

[2]United Nations (UN). 2015. *Sustainable Development Goals*. New York: UN. Available at: http://www.un.org/sustainabledevelopment/sustainable-development-goals/ [Accessed 16 Jan 2017]

[3]Whitworth JAG, Kokwaro G, Kinyanjui S, et al., *op.cit* note 2, p.1590; Hanney SR, Gonzalez-Block MA. Organising health research systems as a key to improving health: the World Health Report 2013 and how to make further progress. *Health Res Policy Syst*. 2013;11.

[4]Dye C, Boerma T, Evans D, et al. The World Health Report 2013: Research for Universal Health Coverage. Geneva: World Health Organisation, 2013.

[5]Friedman EA, Gostin L. From Local Adaptation to Activism and Global Solidarity: Framing a Research and Innovation Agenda towards True Health Equity. *Int J Equity Health*. 2017;16:18.

[6]Reeder JC, Mpanju-Shumbusho W. Building Research and Development on Poverty- Related Diseases. *WHO Bull* 2016;(94):78.; Reeder JC, Mpanju-Shumbusho W. Building Research and Development on Poverty- Related Diseases. *WHO Bull* 2016;(94):78.; Franzen SR, Chandler C, Lang T. Health research capacity development in low and middle income countries: reality or rhetoric? A systematic meta-narrative review of the qualitative literature. *BMJ Open*. 2017;7(1):e012332.

[7]Pratt B, Loff B. Linking Research to Global Health Equity: The Contribution of Product Development Partnerships to Access to Medicines and Research Capacity Building. *Am J Public Health Res*. 2013;103(11):1968-78.

[8]Tinto H, D'Alessandro U, Sorgho H, et al. Efficacy and safety of RTS,S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomised, controlled trial. *Lancet*. 2015;386(9988):31-45; Umeh R, Oguche S, Oguonu T, et al. Immunogenicity and safety of the candidate RTS,S/AS01 vaccine in young Nigerian children: a randomized, double-blind, lot-to-lot consistency trial. *Vaccine*. 2014;32(48):6556-62.

[9]INDEPTH Network. 2007. *Malaria Clinical Trial Allowance (MCTA) Goals & Objectives*. Accra, Ghana: INDEPTH Network. Available at: http://www.indepth-network.org/projects/mcta/mcta-goals-objectives [Accessed 16 Jan 2017]

[10]Ogundahunsi OAT, Vahedi M, Kamau EM, et al., *op cit*. note 3, p. 3380.

[11]Whitworth JAG, Kokwaro G, Kinyanjui S, et al., *op cit*. note 2, p. 1590.

[12]Commission on Health Research for Development (HRfD). 1990.*Health research: Essential Link to Equity in Development*. OUP: HRfD. Available at: http://www.cohred.org/downloads/open_archive/ComReports_0.pdf [Accessed 16 Jan 2017]

articulated with the intention to engage international partnerships in strengthening the governance, management, and systems of resource-limited countries to enable research, science, technology and innovation to improve health, equity, and development.[13] The Commission paper was the catalyst for more NGOs, charities, foundations and governments to fund and support health research capacity strengthening programmes. The concept of Health Research for Development has evolved slowly as a new mode of operation facilitating international co-operation between partners, mobilisation of resources, and support for strengthening national research capacity. Today, health research for development remains a focus to "improve equitable health outcomes and sustained well-being in populations around the world through a multi-disciplinary, problem-focused approach to research and practice."[14] At the heart of this concept is the idea of mutual learning for change.

Some ethics frameworks have been established in an attempt to define the responsibilities of international health research partnerships in low resource settings, such as the Council for International Organizations of Medical Sciences (CIOMS) Ethical Guidelines;[15] Fair Benefits Framework;[16] Human Flourishing Framework[17] and Health for Justice.[18] Moreover, further practical guidance tools have also been designed to foster equitable collaborative practices in global health research.[19] For example, to improve uptake of ideas on ethical partnership and health research for development, some independent organisations have established new mechanisms to educate, govern and monitor equitable global health research partnerships and to foster national capacity strengthening: KFPE Guidelines for Research in Partnership with Developing Countries, 11 Principles;[20] the TDR/World Health Organisation ESSENCE report, Six Practices to Strengthen Evaluation of Research for Development;[21] the COHRED Research Fairness Initiative;[22] Canadian Coalition for Global Health Research (CCGHR) Principles on Global Health Research;[23] and; The Access to Medicine Index[24]

This paper seeks to inform better guidance on Health Research for Development by discovering how the term is understood by implementers of international health research. In undertaking this study, we explore the views of those carrying out health research in the context of an international partnership operating in Ghana and Tanzania. The aim of this work is to ascertain how programmes of international health research can deliver on research for development in low resource settings.

2 | METHODS

An exploratory qualitative research method was employed to capture and analyse how Health Research for Development is understood from the perspective of various stakeholders working in an international collaborative, the GSK/MVI malaria vaccine candidate trial RTS,S in Ghana and Tanzania.

2.1 | Study population

All respondents were involved in the conduct of an international malaria vaccine candidate trial carried out in Ghana and Tanzania between 2009 and 2014 (GSK/MVI, RTS,S) (NCT00866619).[25] This study population was selected because it was one of the largest (multicenter studies across 11 research centers, seven African nations, enrolling 16 000 infants), most long-standing (ongoing for more than six years), and most advanced (pediatric phase III) research trials being conducted in Sub-Saharan Africa. The vaccine candidate trial and the two specific countries of Ghana and Tanzania were selected with the assistance of the Swiss Tropical and Public Health Institute. The interview respondents (clinical and research team members) were recruited from four separate research centers: Ghana: (1) Malaria Research Centre, Agogo Presbyterian Hospital, School of Medical Sciences, Kwame Nkrumah University of Science and Technology, Kumasi; (2) Kintampo Health Research Centre, Ghana Health Service, Kintampo; Tanzania: (3) Bagamoyo, Ifakara Health Institute; (4) Tanga Research Centre (NIMR), Korogwe, National Institute for Medical Research. In addition, the national and international institutions involved with the vaccine candidate trial were also recruited, e.g., GSK, PATH/MVI, government bodies, ethics review committees, and healthcare systems representatives.

The qualitative interviews were conducted to improve understanding of Health Research for Development from the perspective of an international collaborative partnership implementing health research in resource-limited regions. We used a purposive sample and applied the approach of intensity sampling.[26] We selected a sample which is known to be information-rich, due to the scale, level of international collaboration and the considerable length of time that the phase II/III vaccine trial had been on-going at the research centres of of Ghana and Tanzania.

[13]Ibid.

[14]ESSENCE on Health Research (WHO/TDR).2016. *Six Practices to Strengthen Evaluation of Research for Development*.(TDR/ESSENCE/16.2). Geneva: ESSENCE. Available at: http://www.who.int/tdr/publications/six-practices/en/ [Accessed 16 Jan 2017]

[15]The Council for International Organizations of Medical Sciences (CIOMS). 2016. International Ethical Guidelines. Geneva: CIOMS. Available at: http://www.cioms.ch/ethical-guidelines-2016/ [Accessed 16 Jan 2017]

[16]Emanuel EJ, Wendler D, Killen J, et al. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *J Infect Dis*. 2004;189(5):930-7.

[17]London AJ. Justice and the Human Development Approach to International Research. *Hastings Cent Rep*. 2005;35(1):24-37.

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[19]D.Wendler. The Potential for Infrastructure Benefits and the Responsiveness Requirement. *AJOB*. 2016;16(6):1-2.; Ballantyne AJ. How to Do Research Fairly in an Unjust World. *AJOB Empir Bioeth*. 2010;10(6):26-35; Schuklenk U. Are International Ethical Guidance Documents And Statements Lacking Legitimacy? *Dev World Bioeth*. 2015; 15 (2): i-ii.

[20]Commission for Research Partnerships with Developing Countries (KFPE). 2012. *11 Principles and 7 Questions*. Switzerland: KFPE. Available at http://www.naturalsciences.ch/organisations/kfpe/11_principles_7_questions) [Accessed 16 Jan 2017]

[21]ESSENCE on Health Research (WHO/TDR), op cit, note 13, p.1.

[22]Council on Health Research for Development (COHRED). 2016. *The Research Fairness Initiative*. Switzerland: COHRED. Available at: http://rfi.cohred.org/wp-content/uploads/2016/04/RFI_SummaryGuide_20160908.pdf [Accessed 16 Jan 2017]

[23]Canadian Coalition for Global Health Research (CCGHR). 2015. Principles for Global Health Research. Canada: CCGHR. Available at: http://www.ccghr.ca/resources/principles-global-health-research/ [Accessed 16 Jan 2017]

[24]Access to Medicine Index (AMI). 2016. *Index*. USA: AMI. Available at: http://accesstomedicineindex.org/ [Accessed 16 Jan 2017]

[25]Tinto H, D'Alessandro U, Sorgho H, et al, *op. cit*. note 8.

[26]Marshall MN. Sampling for qualitative research. *Fam Pract*. 1996;13(6):522-5.

2.2 | Sample

Individual semi-structured interviews were employed except on two occasions where group interviews were adopted for two groups of front-line staff (vaccination nurses and fieldworkers). The responses of these latter two groups were obtained in the format of group interviews (involving four individuals per group) because following preliminary consultation it was determined they felt more comfortable speaking in a group format. Methodologically this was also agreed acceptable as the respondents in these groups were peers with equivalent training and experience in their respective roles. The structure of the project was designed following an initial scoping visit by the corresponding- and third- author to Ghana and Tanzania in January 2014. In each country, we developed the project in partnership with country contacts, and also institutional contacts to guide and facilitate the recruitment of eligible interview respondents. All identified interviewees were sent invitation requests informing them of the study and inviting their participation. The interview data is collected solely by the corresponding author (November 2014 and September 2015) during country visits to Ghana and Tanzania and by phone interviews with respondents outside of those two countries.

The specific roles of respondents and their research centre affiliation have been withheld to protect the anonymity of the respondents. A unique ID has been designated to each respondent.

2.3 | Study instrument

A semi-structured interview guide was constructed following a review of current literature and consultation with project partners in Switzerland, Ghana and Tanzania. Overall, the questions consider the interaction between the international vaccine trial and the local health- and research- systems. This paper presents responses from the interview question: "how do you understand health research for development?" The interview guide was developed with a qualitative methods advisory group that consisted of the paper's authors, qualitative research methodologists and country experts from Ghana and Tanzania. The interview was then piloted with medical researchers based at the Swiss TPH who have extensive experience of conducting clinical trials in resource-limited regions (in particular Tanzania) and two research ethics committee members in Ghana. This aided in testing and revising the semi-structured interview guide for optimal functionality and coherence. Pilot interviews (N=5) were not included with the final interview data set of 52 interviews (N=52). The semi-structured interview introduced the main research topic areas while enabling respondents to determine the depth and direction of their responses. Follow-up questions were also used to obtain further explanation and clarification where necessary. Permission to proceed with this study was provided by the GSK/MVI Ancillary Studies Review Committee on 18 July 2014, along with signed agreements from all the requested health research centres. The study protocol, informed consent forms and interview guide were reviewed and approved by the University of Basel in Switzerland by the Ethikkommission Nordwest- und Zentralschweiz (EKNZ). It was also approved by each country, Ghana: Ghana Health Service Ethics Review Committee, Kintampo Health Research Centre, Committee on Human Research Publication and Ethics School of Medical Sciences, Kwame Nkrumah University of Science and Technology and; Tanzania: National Health Research Ethics Review Committee for National Institute for Medical Research (NIMR); Ifakara Health Institute IRB. Tanzania Commission for Science and Technology (COSTECH).

2.4 | Informed consent

The corresponding author conducted all 52 interviews in English between November 2014 and September 2015. All respondents were notified that the interview audio would be recorded. Written and oral informed consent was obtained ahead of the start of a respondent interview. The informed consent process informed respondents that interviews would be saved under a non-identifiable code anonymously, and confidentiality would be protected. Also, respondents could end the interview at any time, or refuse to answer any specific question(s).

2.5 | Interviews and transcriptions

Interviews lasted between 35 minutes and 2 hours, and this length of time was determined by the respondent, given their engagement with the topic and availability. The average interview duration was 50 minutes. The first author transcribed 40 interviews in full, and 12 interviews were transcribed by two departmental assistants, and then reviewed for accuracy by the corresponding author. Departmental assistants were subject to the same terms of project confidentiality.

2.6 | Data analysis

The interview transcripts formed the basis of raw data for this research. The transcripts were read multiple times by the corresponding and second author ahead of coding. The corresponding author manually coded all the transcripts to map responses to the question of how is Health Research for Development understood. Repeated ideas were identified across the transcripts and constituted into sub-themes. The sub-themes were then grouped, and this led to the establishment of themes, and the development of theme narratives.[27] To limit researcher bias, the second author consolidated the coding using the same approach. The repeated ideas, themes, and narratives were compared and discussed between authors to reach agreement on the structure of the paper and the narrative of the results and discussion sections for this article. Quotes presented in the results were selected because they are most representative of the specific themes.

In the results below we first describe the characteristics of our respondents. Then we present the responses under four broad themes. Finally in the discussion we consider how these responses define and inform Health Research for Development.

[27]Auerbach CSL. 2003. *Qualitative Data: An Introduction to Coding and Analysis*: NYU Press: p.45.

3 | RESULTS

3.1 | Respondent profiles

In total, there were 52 semi-structured interviews. Across the research centres of Ghana and Tanzania, there were 31 individual interviews and 2 group interviews (1 with a team of vaccine nurses and 1 with a fieldworker team). In respect of the wider partners in Ghana and Tanzania (government bodies, ethics review committees members and health system representatives), there were 13 individual interviews. There were six interviews with the sponsor-investigator group (GSK, CRO, PATH and MCTA); of these interviews there were 3 conducted in person, 2 by phone, and 1 via skype. See Figure 1 of total respondent numbers for each stakeholder group.

The exact term Health Research for Development was new to respondents, but all were able to interpret the phrase and provide an answer reflecting on their experiences working in international health research. The responses fell into four themes: i) Equitable Partnerships; ii) System Sustainability; iii) Addressing Local Health Targets, and iv) Regional Commitment to Benefit Sharing. Under these themes of Health Research for Development, several recommendations were identified; these are summarised in Table 1.

TABLE 1 Summary of Main Themes and Recommendations on Health Research for Development

Health Research for Development Themes	Respondent Recommendations
Equitable Partnership	• Conducive research environment • Local research independence • Increased role of local governments • Defined allocation of partner roles • Professional recognition • Engage local communities as partners
System Sustainability	• Invest in local human resources • Advance local skill base • Expansion of institutional research capacities • Health research integrated with health services and local settings. • New employment opportunity • Develop training institutions • Planning for future research
Addressing Local Health Targets	• Research to solve local health problems • Context-relevant health solutions • Inform local health policy decision-making • Health for economic development
Regional Commitment To Benefit Sharing	• Community education • Advance health seeking behaviours • Ancillary care • Post-trial access

3.1.1 | Equitable partnership

The results showed that the theme of equitable partnerships in international programmes of health research is an essential aspect in constructing Health Research for Development. The relationship, expectation, and interaction between international and local partners, requires clear definition and an active process of engagement. Professional recognition between colleagues and across partnerships was stated by several respondents as an important mechanism to sustain excellent communication and robust functioning collaborations with supportive communities. Moreover, the distinction between donor-led projects and independent research was raised several times by respondents. In connection to this, the vital role of governments in taking responsibility for health research was also addressed. Respondents identified Health

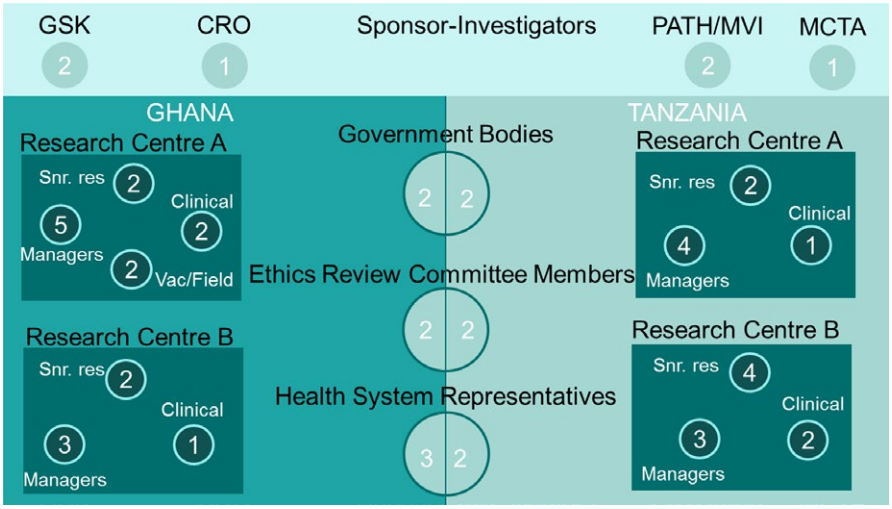

FIGURE 1 Numerical values represent the number of respondents in each stakeholder post. GSK, GlaxoSmithKline (vaccine developer); CRO, Clinical Research Officer; PATH/MVI, Malaria Vaccine Initiative (funder-development partner); MCTA, Malaria Clinical Trials Alliance (capacity developer); Government Bodies, Food and Drug Administrations and Ministries of Health; Ethics Review Committee Members, National and Institutional Ethics Review Committee Members; Health System Representatives, Hospital Managers and District Medical Officers; Snr.res, Senior Researchers; Vac/Field, Vaccination or Fieldwork teams (group interviews); Clinical, clinical (medical) personnel; Managers, operational research managers (e.g. data manager, lab manager, fieldwork manager, quality assessment manager) [Colour figure can be viewed at wileyonlinelibrary.com]

Research for Development as a mechanism to establish conducive health research environments in low resource settings.

Snr. Researcher, Epidemiologist, (GH/A/4): I would wish that the ministry of health would set out the priorities, but they don't! So it is more donor-driven. Donors come with "ok I want to do this." You put your act together and help yourself by helping them help you. So we can get our money, but it is still donor-driven. They help you to solve a problem, but they dictate what the problem is. That is the downside. So today, if they tell you they want to do something in malaria, and then even though you have Ebola, you have to go with malaria. So we go with it until we build enough capacity and find enough money.

Establishing capacities to carryout independent research were seen by respondents as central to development, and the key to improving population health.

Snr. Researcher, Epidemiologist (TZ/B/44): Since the mid-90s we have done work on bed nets. This work on bed nets was conducted over almost a decade, and bed nets now are being used everywhere, they are also being produced in this country, and the Institute is not participating in the production of these bed nets in any way; to the extent that, if the people, who are producing the bed nets, want to do any improvement on the bed nets, they have to ask somebody else.

Over-reliance on donor-led health research was found to undermine development, innovation and the responsiveness of local health and research systems.

Research Manager (GH/B/25): It [Health Research for Development] would, for me, be the way to go to eradicate diseases; that is to empower research in Africa. And that would really bring development that we are looking for… We are relying solely on foreign aid or funders who come out…, but we don't really see the drive for research to bring along the research that is needed. For me, no one understands the problems of African like the Africans.

Strong partner-relations were seen as an important means to overcome "donor-dominance" and foster effective international collaboration. Communication, professional recognition, and community engagement were identified as key aspects of equitable partnerships.

Clinical, Physician, (GH/A/10): Obviously relevance comes also from the recognition. It is not enough that you in the district feel that what you do is relevant. It is also that those who are in the metropolis, in the centres, in the ministries, in the universities acknowledge what you are doing, and sort of testify that it's relevant…So I think at the study level recognition is done very well. This study has given individuals that have worked on the study a lot of pride. We have teams of fieldworkers, interact with families, who look at patients, health and longitudinal ways, environmental factors, and I am absolutely delighted that all this is happening in the district.

A Health Research for Development-approach accounts for the community contribution to programmes of health research, and also the costs to the community. In addition, community interests and needs are recognised and accommodated in to the research objectives, and translation of results.

Research Manager, (GH/A/11): I think what it [Health Research for Development] basically means is to go beyond designing studies, designing research only to get data to publish. It should have an impact on those collecting the data, those whose data you have been collecting. Protocol may be designed to achieve a certain aim or end point, but beyond that there should also be the social intervention in the communities where the study is being done.

3.1.2 | System sustainability

Health Research for Development was often defined as when a study leads to the sustained expansion of institutional research capacities, especially local human resources. Moreover, a few respondents focused on the importance of integrating health research with health services and local settings. Health research programmes designed with a development objective were seen to establish systems which support future research and healthcare services.

Snr. Researcher, Epidemiologist, (TZ/A/52): Research can bring improvement in infrastructure, improvement in human resources, improvement in accessing maybe healthcare for the community. With my experience with RTS,S, actually RTS,S vaccine trial brought a lot of development in many ways: Jobs, lots of development, infrastructure - that lab [laboratory] was built under the same trial which now the whole community is benefitting from, because they have state of the art equipment and brought in personnel.

Health System Representative, (GH/A/06): I think it is part of the research, to try and identify what you are doing, where you are falling short, and then try to improve. I believe it is a general and total review of all the facilities. I mean all the services, all the components that we have in the system. We should not be at a standstill. It should develop, I mean with time. I believe the coming of this research and others actually is seen as a form of development.

Investing in training, education and leadership for local research and healthcare teams were identified as major objectives of Health Research for Development and considered very important for sustainable change.

Snr. Researcher, Epidemiologist, (TZ/B/44): We strongly believe when we do this type of international research we train the people who will be leaders tomorrow and who will make a difference to this country. First, they will get the exposure, they will get the skill, they will get the understanding of what it takes to make changes, and bring innovation.

Vaccine Developer, GSK, (BE/A/52): one of the big aspects of this project is that it brought quality jobs and jobs that were key to providing a huge amount of opportunity to African staff. Would it be travel, doing masters, attending conferences, but also you know they are obviously having publications and sometimes access to jobs.

Snr. Researcher, Epidemiologist (TZ/A/42): One increases the knowledge in terms of the on-job training or having formal training, changing from having a certificate to diploma, to a degree or a Masters, PhD and so forth that is one in terms of educational development. The second point is in terms of the skills development without having any formal certificate, or formal diploma or formal degree, the skills development that is the on-job training.

Collaborating with local teams and advancing research capacity can also have a spillover effect and support the development of the healthcare systems. Moreover, sustained research centres became

training institutions for future generations of early-years researchers and healthcare staff.

Snr. Researcher, Epidemiologist (TZ/B/49): You're giving some new knowledge, improving and providing training to the health care personnel and once that research has come to an end, they will still maintain that knowledge to provide care to the hospital, or the healthcare facility where the research was conducted. That is the way I see it, research for development.

Ethics Review Committee Member (TZ/A/35): You see like we used to have one doctoral researcher, and he was maybe, maybe working with another senior researcher but now he can stand on his own, and he is teaching other researchers.

Health research operating in local systems also brings new experiences and development opportunities to the wider community.

Snr. Researcher, Epidemiologist, (TZ/B/37): Some of them [community members] involved themselves as health workers in a clinical trial to help with follow up. Now most of the health workers are involved in other trials. Because from the RTS,S we train them, so they have more knowledge and skills. Some of them even went back to school and got other certificates, so you can see how this health research made a development in people.

3.1.3 | Addressing local health targets

Most frequently respondents talked about Health Research for Development in terms of the generation of a successful health intervention targeted at resolving a local health issue.

Funder-Development Partner, MVI PATH, (GH/A/27): In any given society you have health problems which are slowing down or even hindering the development of a particular society. So if you do research to solve that problem, then it is research for development. That means getting solutions to health issues, which definitely encourages development.

Clinical, Physician, (GH/A/07): If 100 children are dying in 100 minutes, and you are able to save 10%, 10 of them, you have gone a long way to save these people who one day may be presidents, head of states, and are able to develop a nation.

For some respondents, Health Research for Development related to the ability of health research data to inform policy. Development was seen as creating access to new health interventions by advancing national policy and practice with innovative, evidence-based approaches to improving health.

Snr. Researcher, Epidemiologist, (TZ/B/24): The research evidence is supposed to guide policy decision and programme uptake. So if you look at the context in which we are working now, I am far, far, far in a better position to advise the policy people on the health issues that are occurring and the decisions that they should be taking in order to improve the lives of people in Ghana.

Structuring research with mechanisms to translate findings into effective policy was identified as an important feature of Health Research for Development. This includes accepting negative results, where a tested intervention is shown to have no health impact.

Research Manager (TZ/B/26): So even if for example the vaccine that we are trying, if at the close of the day, the results, somebody would describe it as negative, these are still the results, and that is the role the research aspect plays. Research is providing information for policy decision makers to base their understanding and reasoning to decide.

Many of the respondents made a link between health research and economic development, recognizing that improved health would allow governments, communities and individuals more time and money to spend on other activities rather than on addressing ill-health.

Vaccination Nurse (group interview) (GH/B/29): Yeah so it [health research] would help in the development, because if the population is not falling sick, it will help the development of the country, even the children: if they are not sick, then their parents have time to do their own work, then contribute to the development of the country.

3.1.4 | Regional commitment to benefit sharing

Regional commitment, to bring better health to local communities, and not just generate more health data is identified as necessary for Health Research for Development. In particular, health research programmes were identified by numerous respondents as vehicles for advancing the health education levels of local communities, and an opportunity to positively change health seeking behaviours.

Government Official (TZ/A/31): I think in communities where the trials were done, there is actually less malaria now, and I think they [community members] are more educated, because they have been fed information, health information how to prevent and take care. Medical care also, it is usually improved in those trials and those areas where the communities, the trials are ongoing and usually even when the trial ends, usually you will find facilities that are being used and more access to medicines and things like that.

The presence of an international collaboration brings changes to the provision of care, both for participants and their communities

Snr. Researcher, Epidemiologist, (TZ/B/40): Health Research for Development for me is to ensure that the people around the communities in the area benefit from our presence there. So for example, the insistence, on making sure that the services we provided are not only for the study subjects. The services that are provided are for everybody, meaning that if we are required by international standards, whatever to provide a certain standard of care, this standard of care should be accessible to everyone and for the people in the whole community.

Post-trial access agreements were identified as a potential benefit of health research to communities if the agreements are honoured.

Snr. Researcher, Epidemiologist, (TZ/A/39): Like if you tested the bed nets and then confirm that they can reduce the malaria, and then it will be prudent to ensure that we have universal coverage of bed nets in the community that participated in the research; although previous experience has shown that, that has not been the case.

4 | DISCUSSION

The results of our qualitative study provide substantial insights into how stakeholders define Health Research for Development.

Interpretations of the concept differed between stakeholder groups, but not between the two countries involved in our study (Ghana and Tanzania). All stakeholders agreed that local health research is an important development goal for international health research programmes. A number of research mangers noted that development enables countries to independently generate contextually relevant solutions to their own health problems. Notably, the funders and governmental bodies interpreted Health Research for Development as research that targets local health priorities. The senior researchers and ethics committee members tended to link health research to health policy and practice and identified the need to translate new research into community health gains. The research teams generally, and especially amongst the vaccination nurses and fieldworkers, those working closest with the community understood health research for development to be the economic benefit that would be gained if an effective intervention, such as a vaccine could be introduced to the community following successful research. These results open up the discussion on how to define Health Research for Development, and show the diversity of impact that health research has when operating in weak healthcare systems. Below we turn to each theme in turn.

4.1 | Equitable partnership

Constructing an equitable partnership aligned with local health research priorities is an important baseline for guiding collaboration between local systems and health research partners. The results identified structural features of partnership that promote Health Research for Development and, can counteract distorting influences such as funding (which may distance research projects away from national health research priorities). The three structural aspects are: i) equitable representation of all relevant stakeholders in the research enterprise, ii) integration with the national healthcare system and iii) local research leadership. A locally-led research agenda was described in one interview as a means of "empowerment." Moreover, through research prioritization a culture of deliberation is created, with advocates and beneficiaries of community health leading the process. The outcome of such an inclusive process shapes the design of health interventions, research agendas, and study methodologies to account better for the local healthcare setting and relevant social-economic factors; optimising the social value of international health research partnerships. The creation of an inclusive partnership structure is also an important step to secure the commitment of local and national governments to better support research and the translation of results.[28] Therefore the relationship between international partners and governments needs to nurture collaborative working, cost-sharing, and coordination of equitable partnerships. Ultimately, sustained systems of health research will only be supported by countries if local actors are involved and appreciate the value of undertaking such work. This country-inclusive approach is a recognised principle of effective international development co-operation.[29]

Markedly, respondents stated that the inflexibility of traditional funding structures of health research programmes continues to distort organisational structures, exclude local stakeholders and skew appropriate alignment between population health needs and health research activity. A Health Research for Development-approach requires governance, monitoring and evaluation to ensure that partnerships are equitable from the inception of the research project. For example, this may require that the research enterprise supports leadership training through providing appropriate courses and mentorship. This approach is important to ensure the research is locally led and that those research leaders can take informed decisions on priority setting, strategic planning, and resource allocation.[30] This minimizes the possibility of exploitation and also strengthens local research capabilities and develops the structures of the healthcare systems. Ethically, Health Research for Development defines a partnership structure that fosters local decision-making and global collaboration in health research.

4.2 | System sustainability

Health Research for Development was defined by many participants as establishing sustainable health research capacity. For example, the conduct of research and especially the PDP platform provides an opportunity for researchers to exchange research skills, participate in knowledge-sharing, develop centres of excellence and, build-up professional networks. The research process is equipped to build sustainable capacities across partnerships in low-resource settings. The concept makes these opportunities an objective of a research partnership, and this was exemplified in the case of the GSK/ MVI malaria vaccine candidate trial through its collaboration with the Malaria Clinical Trial Alliance (MCTA), supporting clinical trials site development in Africa.[31] A similar approach has also been taken by other partnerships such as International AIDS Vaccine Initiative (IAVI),[32] over the course of developing a vaccine against Aids and, Drugs for Neglected Diseases initiative (DNDi)[33] while working to combat neglected diseases.[34] Health research generally in a low resource setting may as a consequence bring some new opportunities to a region, but the objective of Health Research for Development is to actively plan research to integrate with local healthcare settings, mobilise necessary infrastructure and, exchange skills to construct a sustainable system. Respondents reported that additional training, education and

[28]Whitworth JAG, Kokwaro G, Kinyanjui S, et al. *op cit*. note 2, 1590-3.

[29]The Organisation for Economic Co-operation and Development (OECD)/UNDP, Making Development Co-operation More Effective: 2016 Progress Report, OECD Publishing, Paris. https://doi.org/10.1787/9789264266261-en.

[30]Ogundahunsi OAT, Vahedi M, Kamau EM, et al, op. cit. note 3.

[31]Mwangoka G, Ogutu B, Msambichaka B, et al. Experience and Challenges from Clinical Trials with Malaria Vaccines in Africa. Malaria journal. 2013; 12:86.

[32]International AIDS Vaccine Initiative (IAVI). USA: IAVI. Available at https://www.iavi.org/ [Accessed 16 Jan 2017]

[33]Drugs for Neglected Disease Initiative (DNDi). Geneva: DNDi. Available at: http://www.dndi.org/[Accessed 16 Jan 2017]; Heymann DL, Lillywhite L. Partnerships, Not Parachutists, for Zika Research. *NEJM*. 2016.; Angwenyi V, Asante KP, Traore A, Febir LG, Tawiah C, Kwarteng A, et al. Health Providers' Perceptions of Clinical Trials: Lessons from Ghana, Kenya and Burkina Faso. *Plos One*. 2015;10(5).

[34]Heymann DL , Lillywhite L. Partnerships, Not Parachutists, for Zika Research. *NEJM*. 2016.

mentorship best supported local system building. To establish this, it is important to define an explicit development component with an agreed plan of action in a research project.[35]

Moreover, collaborations that take steps to move away from unbalanced partnerships to ones of shared ownership demonstrate a commitment to the Health Research for Development objective. As a respondent noted, "one study does not make a research centre." Affording ownership and building capacities promotes a research project from an individual study, towards the development of a research platform.[36,37] The ability to sustain capacity was raised throughout the interviews. How it is achieved varies between programmes, but typically requires establishing structures that are financially independent with local autonomous decision-making powers.[38] To build sustainable research capacity into research partnerships, stakeholders need to address the barriers and opportunities to sustain system developments; for example, maintenance of equipment and incentives to retain highly skilled researchers locally.[39]

Endorsing a development objective in health research is not merely an operational decision of capacity strengthening.[40] Research partnerships do not only bring finances, but they also create a forum for communication, sharing expertise, building trusted professional relationships, and coordinating multi-sectoral partners. Constructing such a conducive research environment provides the conditions in which locally-led systems can be built to deliver on evidence based practice, treatment and disease prevention.[41] Building a community of local researchers that are engaged in a global network shows respect and solidarity for communities with urgent health needs, and overtime will strengthen health security globally.

4.3 | Addressing local health targets

Delivering on improvements to local health was described in the interviews as an important aspect of Health Research for Development; both through improving health capacity for the communities and by improving the translation of findings into public health action. It was recognised by all the stakeholders of the research partnership that health research had the potential to target local health through different means: establishing health education, providing additional ancillary care in health services, improving health research skills and infrastructure and, through delivering new health interventions. This broad understanding of how health research supports local health is outlined in recent literature which discusses the true effects of health research for local study populations. Arguably, there is both a trial effect and an infrastructure effect.[42] Industry and ethics guidelines tend to focus on direct trial effects and have given less consideration to infrastructure effects, and the responsibility to contribute to research capacity - a pillar of health system development.[43] This discussion brings into question the public health value of health research for resource-limited regions. Health Research for Development promotes the goal of public health through addressing the broader ethical considerations of equity and improving local health capabilities. Critical for addressing local health targets is the adequate framing of development objectives through knowing the country specific context. This requires comprehensive mapping of the social, health, legislative and political setting.

4.4 | Regional commitment to benefit sharing

An effective Health Research for Development-approach demonstrates regional commitment by enhancing translation of health research into good health policy and practice, and this was strongly emphasised by senior researchers and ethics committee members as the key function of Health Research for Development. However, this component of many research programmes has been identified as the major weakness, and greater support is needed for research to deliver on policy recommendations, improved standards of care and creating access to new interventions.[44] The strength of conducting health research in local contexts allows a health intervention to be evaluated with awareness of socio-economic determinants, local care seeking behaviours, and barriers to access along with an appreciation for regional resource constraints.[45] This broad understanding of an intervention's effectiveness in a particular setting enhances the value of the research for beneficiaries through facilitating the dissemination and translation of results.[46] Moreover, Health Research for Development advocates decentralised health system decision-making to facilitate translation, engaging communities, healthcare facilities, and policymakers along the pathway.[47] The aim being to establish regional commitment and overcome the communication gap often reported to exist between researchers, health systems, and policy makers.[48] Research dissemination through a decentralised system of health facilitates communication and enhances local commitment, political uptake and the responsiveness of new health interventions to local

[35]Bates I, Boyd A, Smith H, et al. A Practical and Systematic Approach to Organisational Capacity Strengthening for Research in the Health Sector in Africa. Health Research Policy and Systems. 2014;12:11.

[36]Whitworth JAG, Kokwaro G, Kinyanjui S, et al. *op cit*. note 2, 1590-3.

[37]Cole DC, Nyirenda LJ, Fazal N, et al. Implementing a national health research for development platform in a low-income country – a review of Malawi's Health Research Capacity Strengthening Initiative. *Health Res Policy Syst* 2016;14(1):24.

[38]Bates I, Boyd A, Smith H, et al. *op cit*. note 39.

[39]Sewankambo N, Tumwine JK, Tomson G, et al. Enabling Dynamic Partnerships through Joint Degrees between Low- and High-Income Countries for Capacity Development in Global Health Research: Experience from the Karolinska Institutet/Makerere University Partnership. *PLoS med*. 2015;12(2):e1001784.

[40]Bates I, Boyd A, Smith H, et al. *op cit*. note 39; Chanda-Kapata P, Campbell S, Zarowsky C. Developing a national health research system: participatory approaches to legislative, institutional and networking dimensions in Zambia. *Health Res Policy Syst*. 2012;10.

[41]Lang TA, White NJ, Hien TT, et al. Clinical research in resource-limited settings: enhancing research capacity and working together to make trials less complicated. *PLoS Negl Trop Dis*. 2010;4(6):e619.

[42]Denburg A, Rodriguez-Galindo C, Joffe S. Clinical Trials Infrastructure as a Quality Improvement Intervention in Low- and Middle-Income Countries. *AJOB*. 2016;16(6):3-11; Wendler D. *op cit*. note 15, p. 1-2; Asante KP, Jones C, Sirima SB et al,. Clinical Trials Cannot Substitute for Health System Strengthening Initiatives or Specifically Designed Health Policy and Systems Research. *AJOB*. 2016;16(6):24-6.

[43]Ibid; Pratt B, Ali J, Hyder AA. If Research Is a Pillar of Health System Development, Why Only Focus on Clinical Trials? *AJOB*. 2016;16(6):14-7.

[44]Ogundahunsi OAT, Vahedi M, Kamau EM, et al. *op cit*. note 3.

[45]Weigmann K. The ethics of global clinical trials: In developing countries, participation in clinical trials is sometimes the only way to access medical treatment. What should be done to avoid exploitation of disadvantaged populations? EMBO reports. 2015;16(5):566-70.

[46]Emanuel EJ, Wendler D, Killen J, et al. *op cit*. note 16.

[47]Uzochukwu B, Onwujekwe O, Mbachu C, et al. The challenge of bridging the gap between researchers and policy makers: experiences of a Health Policy Research Group in engaging policy makers to support evidence informed policy making in Nigeria. *Global Health*. 2016;12(1):67.

[48]Ibid: 67.

settings.[49] As respondents noted, the design of research programmes must account for the translational factors very early on in research planning to best achieve the ultimate goal of improved health.

5 | LIMITATIONS

One limitation is that the results may not be generalisable because the research programme was a phase II/III clinical trial for a paediatric malaria vaccine candidate and the budget included skills and site capacity building. As noted in the literature, clinical trials are often better funded than other programmes of health research and tend to undertake important development initiatives in the regions where they are conducted.[50] Product Development Partnerships and the testing of vaccines in resource-limited regions are becoming more regular occurrences, and this response group is representative of such research. The fact that we involved two different countries, Ghana and Tanzania, one in West and one in East Africa also adds resilience to the findings. Secondly, respondents were speaking in English, which for the majority of respondents was their second language, and this may have altered how responses were articulated, or analysed.

6 | CONCLUSION

The concept of Health Research for Development has been the focus of recent campaigns and guidance documents. This study provides empirical evidence on how to define the concept from the perspectives of stakeholders working in international research partnerships in Ghana and Tanzania. The results identified four major themes, namely, Equitable Partnership, System Sustainability, Addressing Local Health targets and Regional Commitment to Benefit Sharing. Six learning points for achieving Health Research for Development were distilled: 1) Ensure there is local research leadership working in collaboration with the PDP, and healthcare system, to align project agenda and activities with local research and health priorities; 2) Know the country specific context - map the social, health, legislative and political setting; 3) Define an explicit development component and plan of action in a research project; 4) Address the barriers and opportunities to sustain system developments; 5) Support decentralized health system decision-making to facilitate the translation pathway; 6) Govern, monitor and evaluate the development components of health research partnership. Finally, the opinions and experiences of stakeholders of international health research show that an unequivocal commitment to equity and unity between partners is required to construct health research for development.

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CONFLICT OF INTEREST

No conflicts declared

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[50]Denburg A, Rodriguez-Galindo C, Joffe S. *op cit*. note 45, 3-11.