

Case study: Evaluation of KWTRP Engagement

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KEMRI | Wellcome Trust

Increasing calls for PE/CE evaluation

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Towards a science of community engagement

The implementation of HIV prevention trials in developing countries is a crucial component of combating the most devastating pandemic in modern history. The closures of several trials across the globe—including tenofovir trials in Cambodia, Cameroon, and Nigeria—suggest that it might be prudent to devote as much effort to addressing the complex community challenges of successful trial implementation as we dedicate to the formidable biomedical challenges of developing new forms of HIV chemoprophylaxis.

In this regard, Kimberly Page-Shafer and colleagues—the investigators on the ill-fated tenofovir trial among Cambodian sex workers—should be lauded for their willingness to share their experiences, and particularly in a non-combative and conciliatory tone

(Oct 22, p 1499).¹ Their openness to considering that there might have been alternatives to the way in which the trial was implemented is a good start.

Page-Shafer and colleagues identify mistrust among intended participants as a crucial issue and a likely obstacle to trial implementation. They document early difficulties in engaging sex workers in a community advisory group. The description of trial consultation also suggests a disjunction between formative research, ostensibly focused on refining informed consent processes, recruitment and retention procedures, and translation of study materials, and the equally important processes of ongoing community engagement. Local stakeholders' reported feelings of lack of power and the perceived absence of a forum for dialogue with the investigators also suggests gaps in community engagement.

Rather than lament the failure of further ex-post-facto, trial-and-error attempts to redress complex social, cultural, and behavioural pitfalls of clinical trial implementation among vulnerable communities, we might seize the lessons learned from recent clinical trial shutdowns and treat future trials as an opportunity to apply our best science not only to product development, but to the community dimensions of clinical trial planning and implementation.

Engaging vulnerable community stakeholders in medical research is less of a controlled and predictable science than we might wish. Nevertheless, it seems curious that we invest millions of dollars in product development, clinical training, design and building of facilities, etc, but often leave vital processes of community engagement largely to trial and error. Rigorous qualitative research methods, including focus groups and key informant interviews,² and ethnographic investigations³ could provide an empirical basis for theory-based interventions (eg, diffusion of innovations⁴) and social marketing strategies⁵ to support successful fieldwork and preparation on the part

of trial investigators and to develop best practices in engagement with local communities.

Do such measures guarantee success? No more than a product's reaching a phase III trial guarantees success. But it would be unheard-of—moreover unethical and illegal—to launch a candidate for HIV chemoprophylaxis in a phase III trial without rigorous science, including phase I and II trials behind it. We might similarly aspire to evidence and rigour in designing and initiating strategies for community engagement, which is crucial to successful trial implementation. Not only might we fare better in implementing and sustaining HIV chemoprophylaxis trials, but we might learn valuable lessons for the much greater challenges of future microbicide and HIV vaccine dissemination among vulnerable communities worldwide. I declare that I have no conflict of interest.

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Department of Error

Sazawal S, Black RE, Ramsan M, et al. Effect of routine prophylactic supplementation with iron and folic acid on admission to hospital and mortality in preschool children in a high malaria transmission setting. *Lancet* 2006; 367: 133–43. In this Article (Jan 14), the penultimate sentence of the fifth paragraph of the Discussion (p 141) should read: "The Gera and Sachdev review did not assess separately studies from malaria-endemic areas or studies in different age groups."

"...it seems curious that we invest millions of dollars in product development, clinical training, design and building of facilities, etc., but often leave vital processes of community engagement largely to trial and error."

Newman, Peter ; The Lancet, 2008

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Reprints

*...Evaluation needs to take account of
elements of CE - complex & contested*

**Communities?
Representatives?**

**Type, stage & depth of
engagement?**

Goals? Conflict?

CE implemented pragmatically...

KEMRI-Wellcome Trust Research Programme (KWTRP)

linked surveillance



INTERNATIONAL SCIENTIFIC
AND ETHICAL STANDARDS

KEMRI WELLCOME TRUST

RESEARCH THEMES

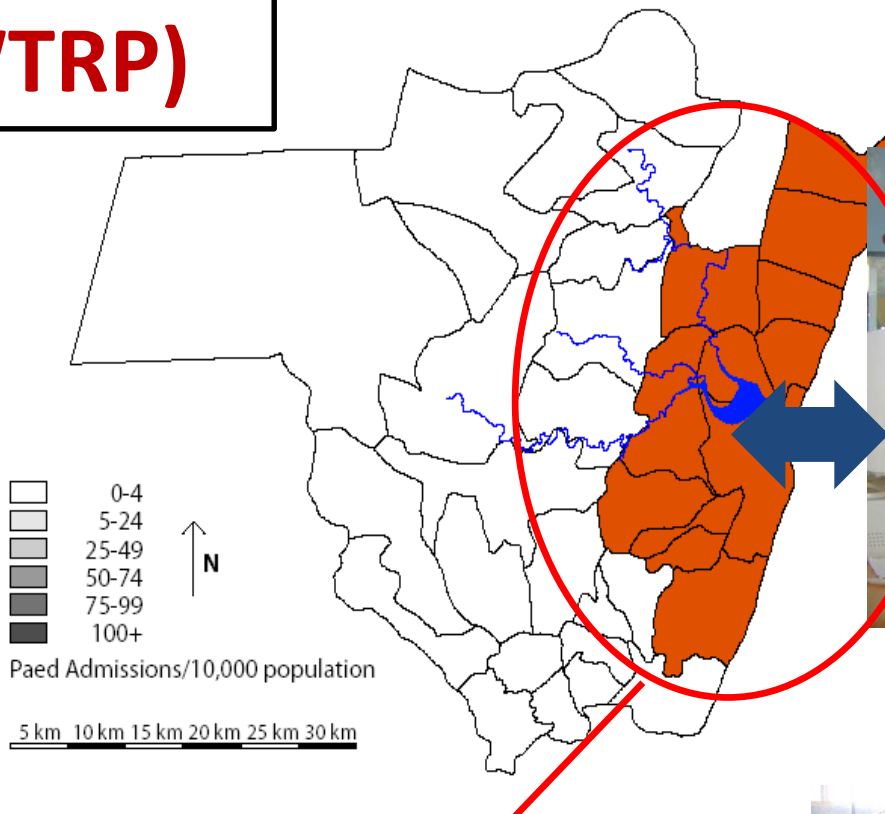
HEALTH SYSTEMS RESEARCH
— Health systems research is undertaken by researchers based in Kilifi and Nairobi.

OUR STATISTICS

77	Researchers
564	Current Studies
1095	Publications

PATHOGEN, VECTOR, AND HOST, BIOLOGY Department

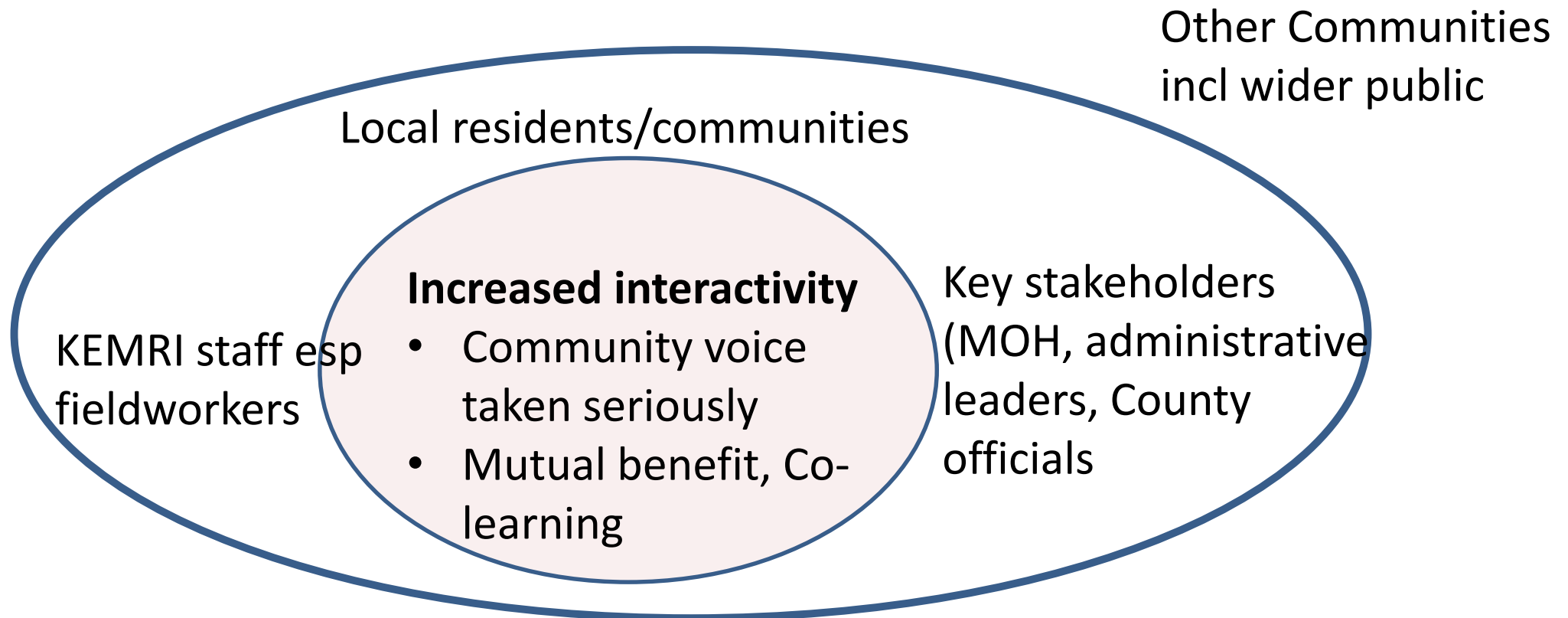
The Pathogen, Vector, and Host, Biology (PVHB) Department brings together eight groups in Kili...



Community Engagement (CE) at KWTRP

Goals (*evolving*)

1. Build mutual understanding, appropriate levels of trust and respect;
2. Enhance the ethical conduct of research and of the Programme's activities; and
3. Strengthen the translation of research findings into policy





Partnership?

Feedback and responding

Consultations/seeking opinions/views (e. deliberative)

Seeking support

Awareness raising/information sharing



Range of community engagement activities – community, staff, stakeholders



Trust Video (5 mins)

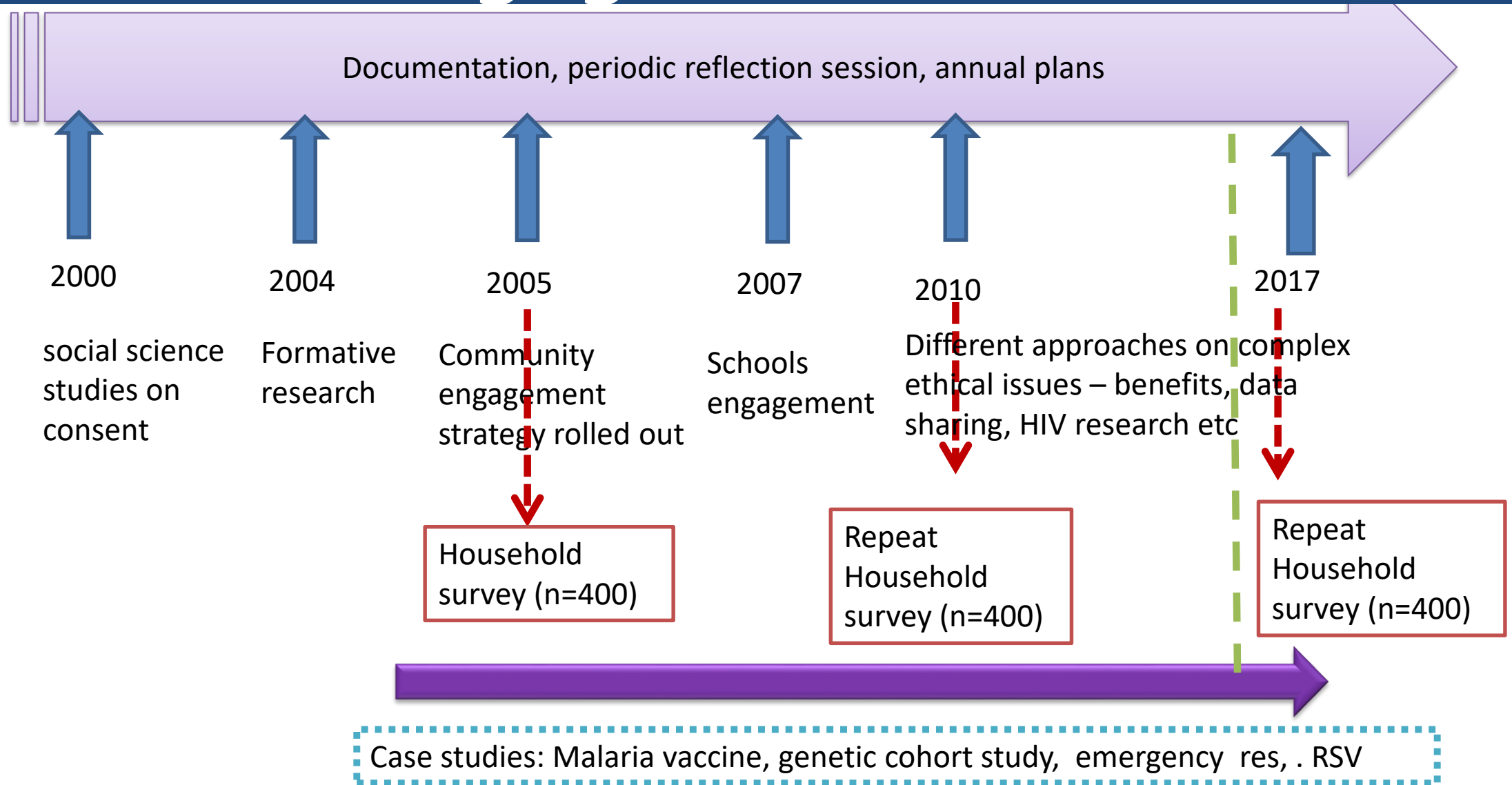
Evaluation – Programme-wide

- Whether **achieving the objectives and contributing towards the goals**
- Reflect on **changes** (what, why and in what ways, and how to take account) = goals, stakeholders, approaches, depths of engagement
 - **nature of relationship** with the ‘communities’, (i.e. mutual understanding, trust, respect)
- Feed into subsequent planning of engagement strategies

Evaluation methodology

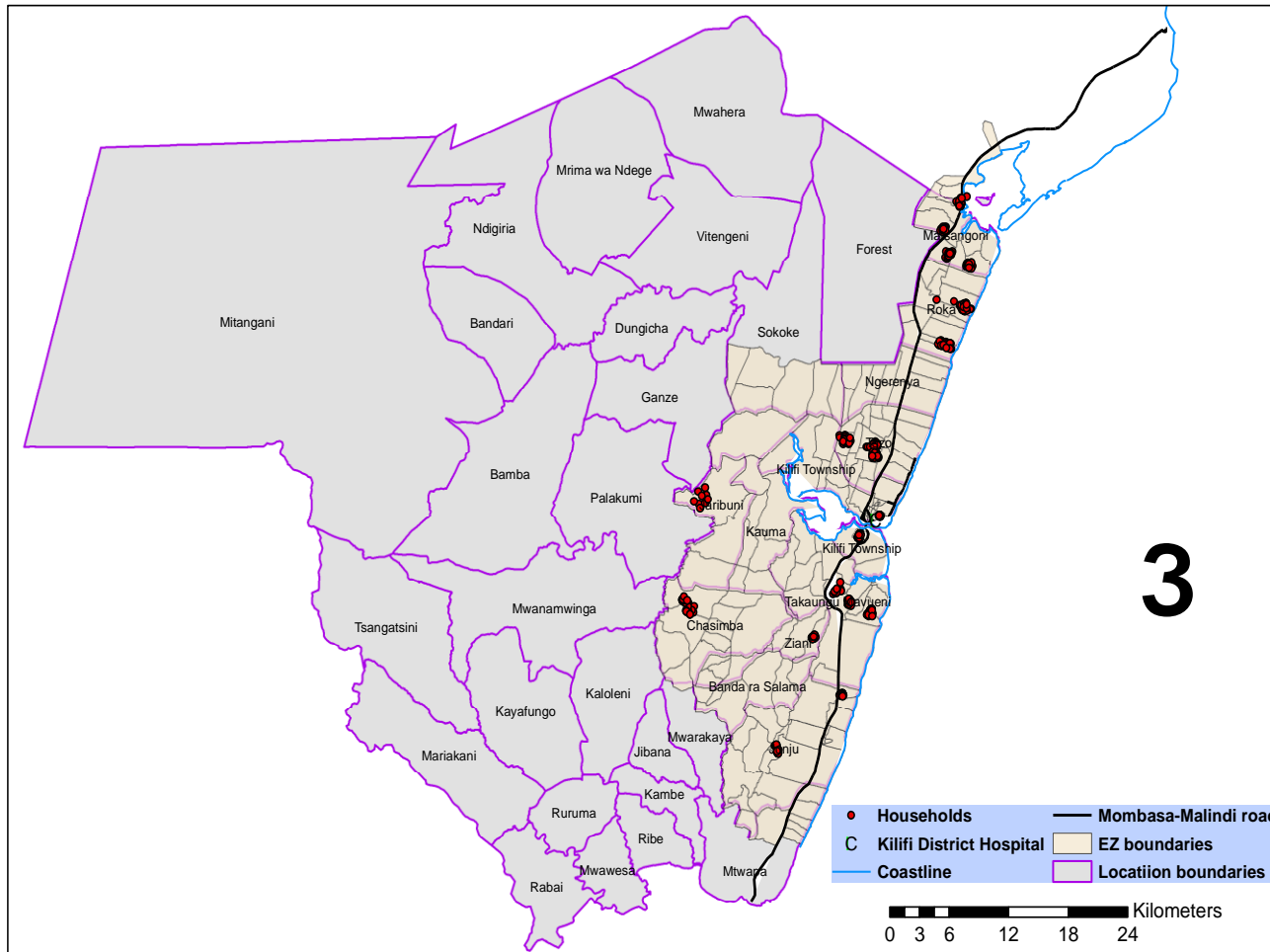
- A **pre and post intervention household survey** conducted with the same households in 2005 and 2010/11
 - Semi-structured, coding scheme for responses
- A series of **case studies** aimed at exploring CE in depth for specific and across very different studies;
 - a malaria vaccine trial, a genetics cohort study, an Respiratory Syncytial Virus (RSV) trial, and an emergency intervention trial among sick children
 - Each used multi-method (observation of CE activities; FGDs, IDIs, household surveys, facility exit interviews)
- **Group reflection** on CE practice based on participatory observations of activities and review of all minutes.
- **Observations** on engagement activities and **interviews** with scientific staff and CLG members - by social scientists who are relatively independent of the CLG team

Evaluation of the Evolving community engagement...



Some Results

Household survey – comparison of 2005 and 2010 (400 households)



Relatively stable population

Code	2005 (%)	2010 (%)
Treating	288 (89.16%)	296 (81.77%)
Aid	140 (43.34%)	100 (27.62%)
Learning* (research as researchers define it)	41 (12.69%)*	52 (14.36%)
Teaching	33 (10.22%)	26 (7.18%)
Experience* (learning through experience, similar to 'research')	1(0.31%)	4 (1.10%)
Developing/making/testing drugs*	None	13 (3.59%)

Quantitative survey HH (n=362)

Community support towards KWTRP work

	2005	2010
Strongly supportive	138 (42.72%)	215 (59.39%)
Supportive	125 (38.70%)	69 (19.06%)
Indifferent	49 (15.17%)	74 (20.44%)
Unsupportive	4 (1.24%)	4 (1.10)
Strongly Unsupportive	-	-
Missing	7 (2.17%)	-
Total	323	362

Generally supportive of KWTRP's work

Defining the concepts, clarity on how these present in our setting/context (community, engagement – depths, approaches)



Social Science & Medicine 67 (2008) 721–733

SOCIAL
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Beginning community engagement at a busy biomedical research programme: Experiences from the KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi, Kenya

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Abstract

There is wide acknowledgement of the need for community engagement in biomedical research, particularly in international settings. Recent debates have described theoretical approaches to identifying situations where this is most critical and potential mechanisms to achieve it. However, there is relatively little published experience of community engagement in practice. A major component of the Kenya Medical Research Institute (KEMRI) Wellcome Trust Research Programme is centred on Kilifi District General Hospital and surrounding community of 240,000 local residents. Documented community perceptions of the research centre are generally positive, but many indicate a low understanding of research and therapeutic misconceptions of its activities. As in other settings, these misunderstandings have contributed to concerns and rumours, and potentially undermine ethical aspects of

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Working with Concepts: The Role of Community in International Collaborative Biomedical Research

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The importance of communities in strengthening the ethics of international collaborative research is increasingly highlighted, but there has been much debate about the meaning of the term 'community' and its specific normative contribution. We argue that 'community' is a contingent concept that plays an important normative

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ENGAGING COMMUNITIES TO STRENGTHEN RESEARCH ETHICS IN LOW-INCOME SETTINGS: SELECTION AND PERCEPTIONS OF MEMBERS OF A NETWORK OF REPRESENTATIVES IN COASTAL KENYA

DORCAS M. KAMUYA, VICKI MARSH, FRANCIS K. KOMBE, P. WENZEL GEISSLER AND SASSY C. MOLYNEUX

Keywords

research ethics,
community network,
community engagement,
developing countries,
representation

ABSTRACT

There is wide agreement that community engagement is important for many research types and settings, often including interaction with 'representatives' of communities. There is relatively little published experience of community engagement in international research settings, with available information focusing on Community Advisory Boards or Groups (CAB/CAGs), or variants of these, where CAB/G members often advise research-

Specific engage.
activities

Molyneux et al. Health Research Policy and Systems (2016) 14:40
DOI 10.1186/s12961-016-0106-3

Health Research Policy
and Systems

COMMENTARY

Open Access



Public/community engagement in health research with men who have sex with men in sub-Saharan Africa: challenges and opportunities

Sassy Molyneux^{1,2,3*}, Salla Sariola^{2,4}, Dan Allman⁵, Maartje Dijkstra⁶, Evans Gichuru¹, Susan Graham⁷, Dorcas Kamuya^{1,2}, Gloria Gakii^{8,9}, Brian Kayemba¹⁰, Bernadette Kombo¹, Allan Maleche¹¹, Jessie Mbwambo¹², Vicki Marsh^{1,2,3}, Murugi Micheni¹, Noni Mumba¹, Michael Parker², Jasmine Shio¹³, Clarence Yah¹⁴, Elise van der Elst^{1,6} and Eduard Sanders^{1,6}

Molyneux et al. Health Research Policy and Systems (2016) 14:40
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Health Research Policy
and Systems

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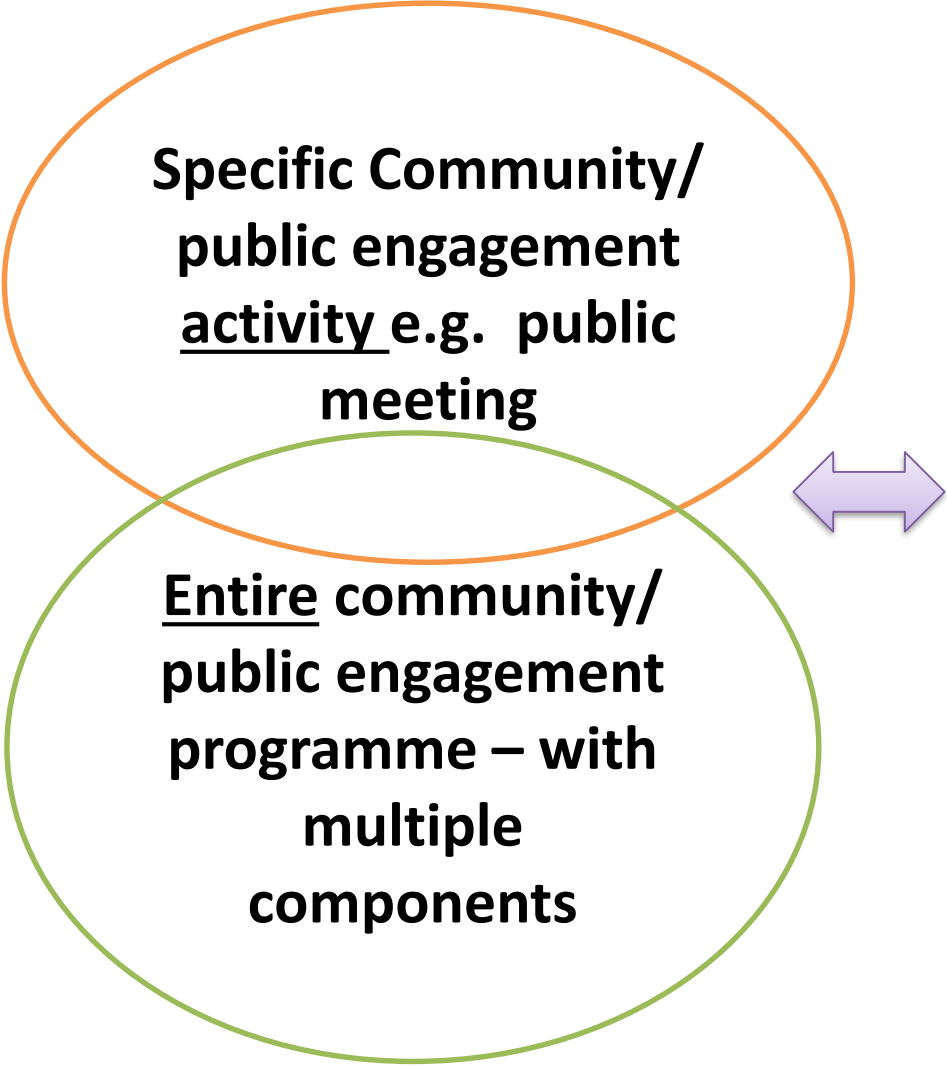
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Experiences,
and lessons

Some lessons learnt ...

1. **Use of mixed methods in evaluation of CE**
 - Complementarily use of quantitative and qualitative methods
 - provided both breadth (how widespread an issue is) and depth (perspectives from different respondents)
2. Aim for **plausibility and not causality**
3. Inputs from on-going engagement critical friends & reflection (a strength);
 - Increasing recognition that our CE has to **respond to the public health needs** and priorities of community members
 - **A shift over time:** from a focus on strengthening mutual understanding towards **strengthening relationships** through greater interaction CE goals/activities shifting over time

Evaluation - Clarity about



The diagram consists of two overlapping circles. The top circle is orange and contains the text 'Specific Community/public engagement activity e.g. public meeting'. The bottom circle is green and contains the text 'Entire community/public engagement programme – with multiple components'. A purple double-headed arrow points from the right side of the orange circle to the right side of the green circle, indicating a relationship or flow between the specific activity and the overall programme.

**Specific Community/
public engagement
activity e.g. public
meeting**

**Entire community/
public engagement
programme – with
multiple
components**

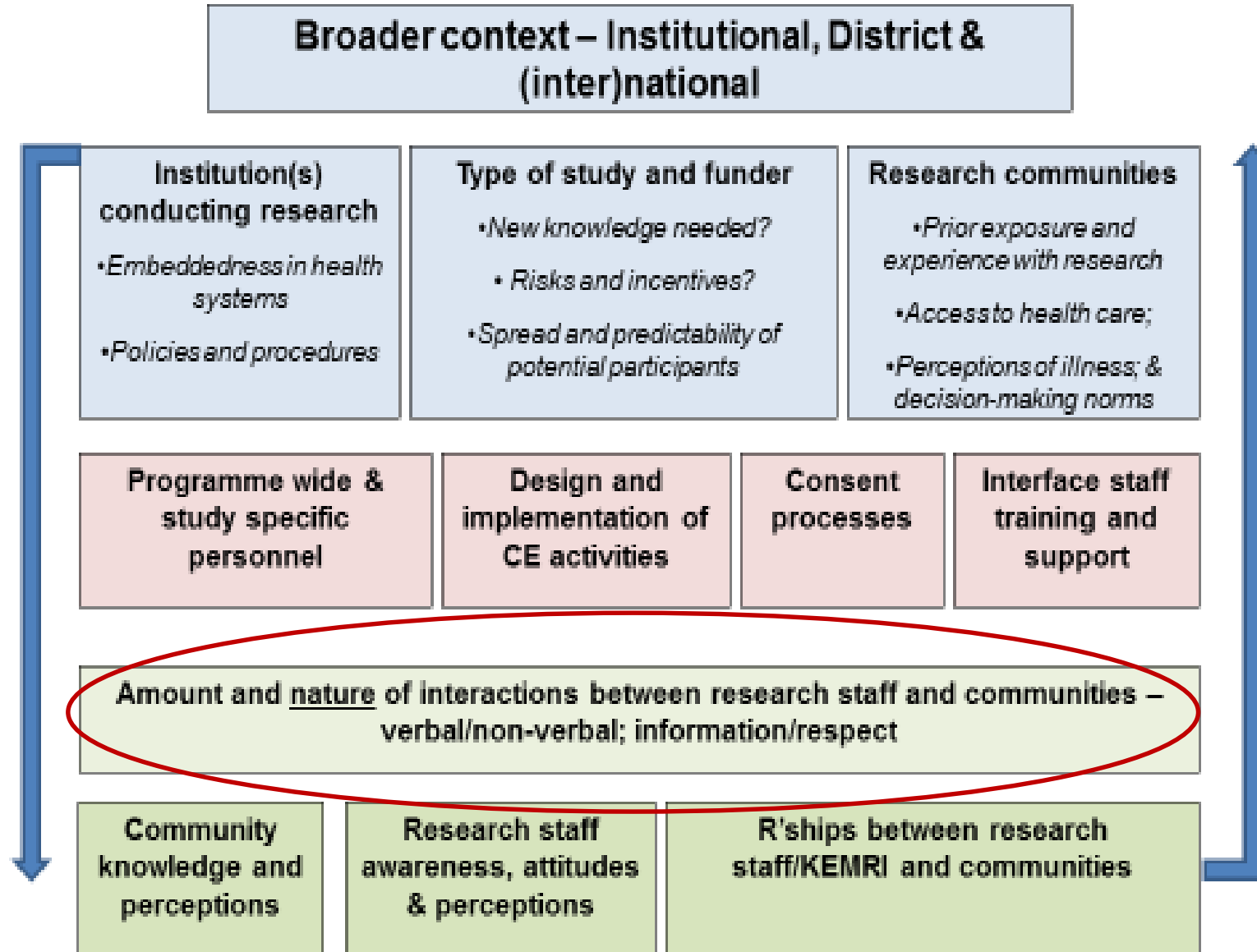
Consider

- **Goal/objectives** (why do you want to evaluate)
- How will you make the assessment? What **data/information** do you need?
- How will you make sense of the data (**analysis plan**)
- What **theories** (reflect on theories underpinning the CE/PE - if available)
- **Methodology** – mixed, qualitative, quantitative and the arguments for and against
- Whose **perspectives** (respondents), how will you identify and recruit them
- **Informed consent** – how to gain it?
- Your **own position and influences**

Trust video – engagement and relationship building



Conceptual framework CE



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SASSY C. MOLYNEUX

A series of **case studies** aimed at exploring
CE in depth for specific studies, and across
very different studies



**A Pre- and post
intervention household
survey (semi-structured)**

Evaluation methodology



Group reflection on
CE practice



Interviews and observations on engagement activities and with scientific staff and
CLG members - by social scientists who are relatively independent of the CLG team