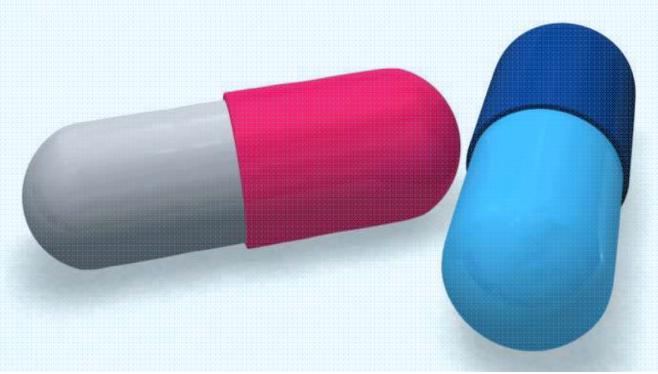
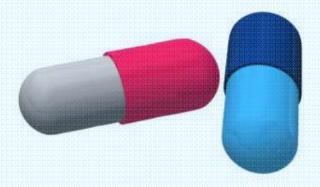
George F. O. Okoth MSc, Lucas Otieno MD MPH, Victorine Owira BA, Bernhards Ogutu MD, Med (Paeds) PhD and Walter Otieno MD, Med (Paeds) PhD



Background

- Ethical Principles on Human Subject Protection in Clinical Research revolves around Autonomy, Beneficence and Justice.
- Beneficence requires that the benefits to research participants are maximized as you minimize the risk¹
- There's need to enhance health, healthcare and general well being of communities participating in research².
- Many local communities in developing countries have limited access to basic healthcare making them vulnerable and open to undue influence.



Background cont...

- Without collaborative partnership, strong interest and investment by government, research results may not influence policy making decisions and allocation of scarce healthcare resources.
- The KEMRI/Walter Reed Project a collaborative research program has conducted clinical trials for over 20 years in Kenya.
- During this period its objectives have included working with partners to maximize research benefits in the community in which it works by effectively utilizing the available resources to address local health needs.

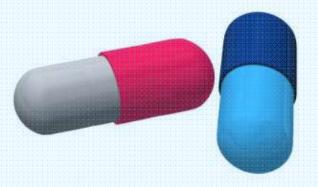
Methods

- KEMRI/Walter Reed Project has collaborated with the Ministry of Health (MoH) and partners like PATH-Malaria Vaccine Initiative (MVI), Malaria Clinical Trial Alliance (MCTA), GlaxoSmithKline (GSK), Henry Jackson Medical Research Foundation (HJMRF), and other study sponsors to make healthcare accessible to local community in Kombewa and Kisumu.
- Harnessed partnership resources to improve health infrastructure in Kombewa and Kisumu.
- Provided capacity building opportunities to local healthcare workers through post graduate training, internships, attachments, malaria microscopy training and mentorship of young investigators.

Results

Healthcare is now more accessible to the local communities in Kombewa and Kisumu.

- Kombewa District modern X-ray department with a digital X-ray machine and ultrasound equipment
- Obama Children's Hospital at Jaramogi Oginga
 Odinga Teaching and Referral Hospital
- Baby Friendly Kombewa Pediatric Ward
- Training opportunities for Health Care Workers from Kenya/Other Countries
- Comprehensive out-patient unit

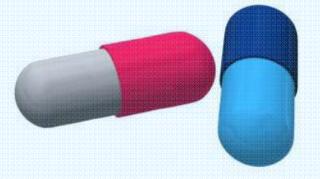


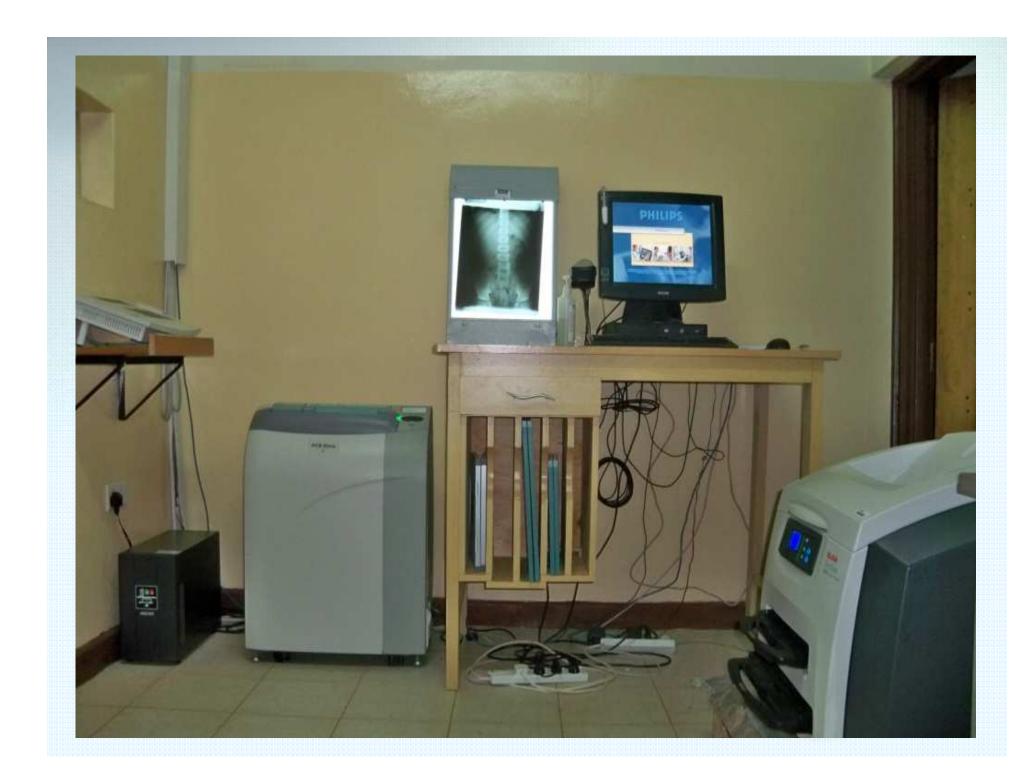
Modern Ultra Sound Machine

Digital X-ray Machine



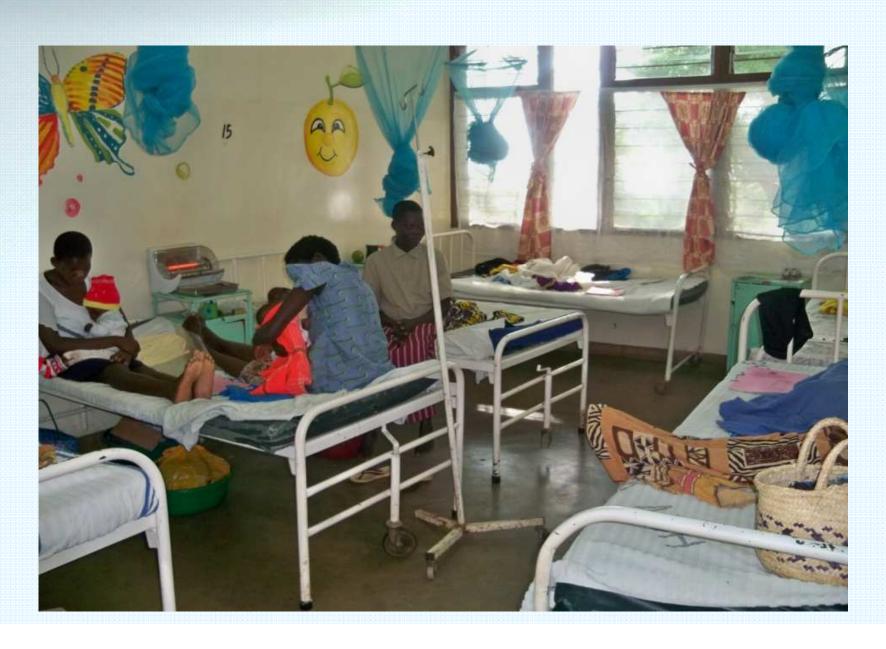








Baby Friendly Kombewa Pediatric Ward



Comprehensive out-patient unit

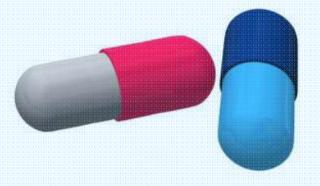


Discussion

- The success of clinical research depends highly on public trust and confidence built through understanding and collaborative participation in addressing community needs⁵.
- Making mainstream healthcare more accessible/ available to participating communities like in Kombewa eliminates vulnerability of research communities.

Discussion cont...

- The cost of meeting local communities' healthcare needs, building/improving infrastructure is very high requiring a collective effort.
- Strong Research Partnerships has helped maximize direct and indirect research benefits to communities participating in research⁶ resulting in reduced mortality and morbidity.



Discussion cont...

- Partnership empowers communities to address their healthcare needs to achieve self sufficiency.
- Empowered local investigators have better opportunities and equipments to assess local healthcare needs and set the research agenda to conduct studies addressing them.
- Empowered Local investigators can effectively negotiate with study sponsors and partners to allocate resources for further developm

Conclusion

- To promote beneficence, funding of clinical trials in developing countries should aim at achieving greater impact in communities participating in them.
- Achieving clinical research social aim of generating new generalizable knowledge should not leave participating communities still vulnerable to exploitation but happy and self sufficient.

Reference

- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical principles and Guidelines for the protection of Human Subjects in Research [Online] available at http://www.hhs.gov/ohrp/humansubjects/guidence/belmont.htm. (accessed 20 August 2009)
- 2. Diallo DA, Doumdo OK, Plowe CV, et al. Community permission for research in developing countries. *Clinical Infectious Diseases* 2005;41;255-9
- 3. Emmanuel EJ, Wendler D, Killen J, Grady C. What makes Clinical Research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Diseases* 2004;189;930-7
- 4. Eva H, Building scientific capacity in developing countries. Embo reports, 2004.
- 5. Owira V. 2009, Effective use of clinical research site resources in supporting the community. 2009
- 6. Baldes A. S. et al. Sharing benefits in international health research. *Embo reports,* 2007.