



*RTS,S Safety Post Approval Programme
Partnership Committee (SPSAP PC) meeting*

US Army Medical Research Unit – Kenya

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10 Nov 2015



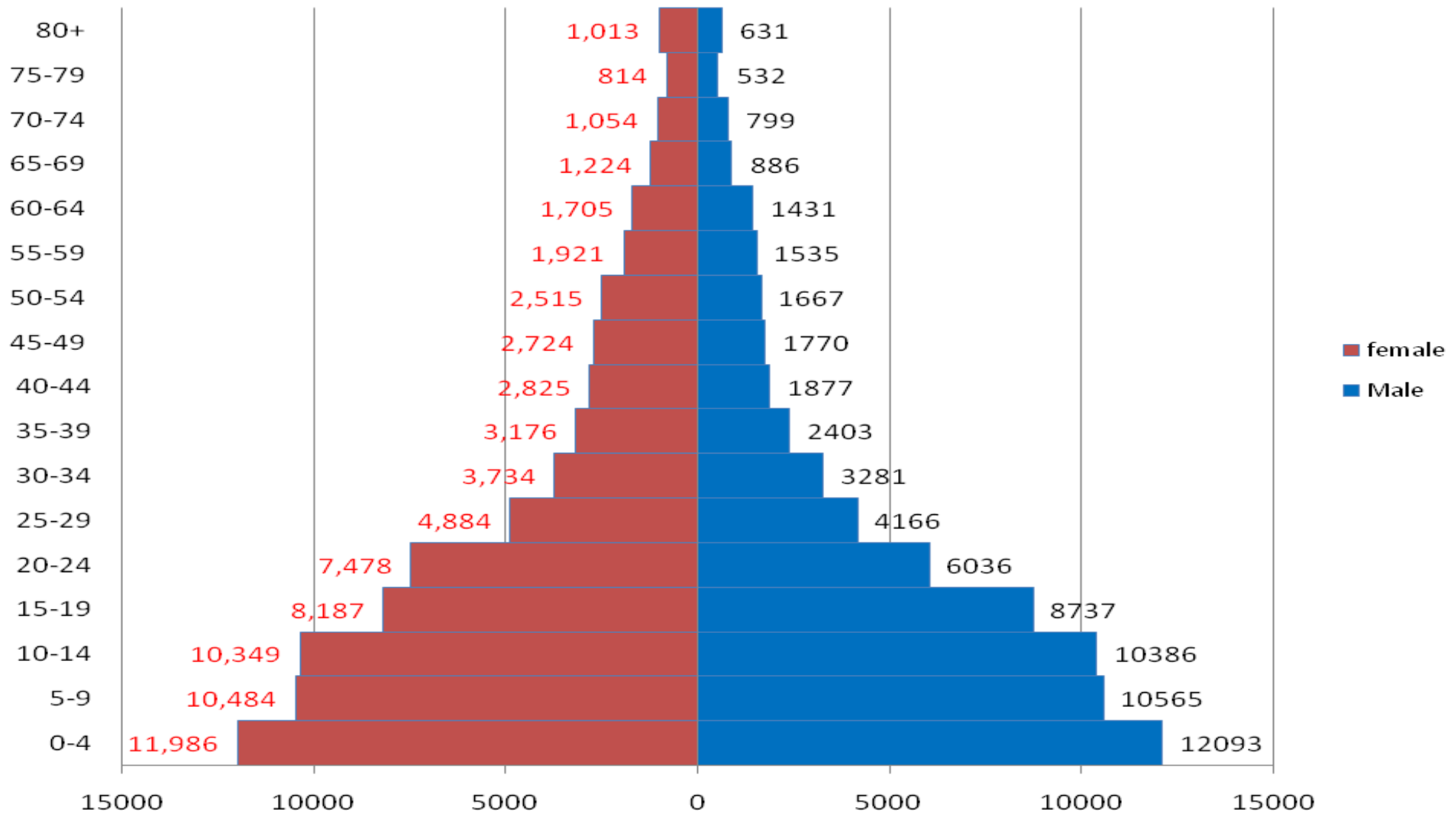
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Malaria Incidence/Prevalence

Age group	Parasite Prevalence
6months to 4 yrs	43.75%
5yrs to 19 yrs	53.40%
20yrs+	17.35%

KENYA - KOMBWEWA

K. W District Population Pyramid



Population Description (2013, mid year averages)

Index	Result
Total resident Population	145 011
Male: female ratio	88:100
Households	34, 720
Population of children aged <1 year	3,124
Population of children aged 1-4 years	18, 427
Population of children aged 5-9 years	23,392
Population of children aged 10-14 years	20, 896
Population 15+ years	79,201
Crude Birth rate (Births per 1 000 residents)	12.9
Crude Death Rate (Deaths per 1 000 residents)	8.5
Life expectancy at Birth-Female (Years)	54.1
Life expectancy at Birth-Male (Years)	46.7

Population

- Population of about **144 907** habitants
- Birth cohort of about **7400** newborns.
- The population of children < 3 years old is estimated at **17 437**.

DSS

- The area is entirely **covered by DSS**.
- The DSS is **updated 2 times** a year.
- Newborns are **registered into DSS at birth or first contact**.
- Its surface is spread out over 360 km².
- The linkage between DSS data and Health care facilities is **NOT** implemented.
- National ID is linked to health care documentation

Health care facilities

- **30 primary (22 EPI)** health care facilities. 14 with at least 2 nurse . Variable number of EPI mobile teams.
- **Existing paper /ambulance referral system** to higher health care facility
- **All HCW are trained to perform clinical assessment** and prescribe basic drugs.
- Distance to travel to hospital would be about 6 km.
- On average there are 190 **children < 5 y seen** in health care facilities **a day**

Recruitment strategy

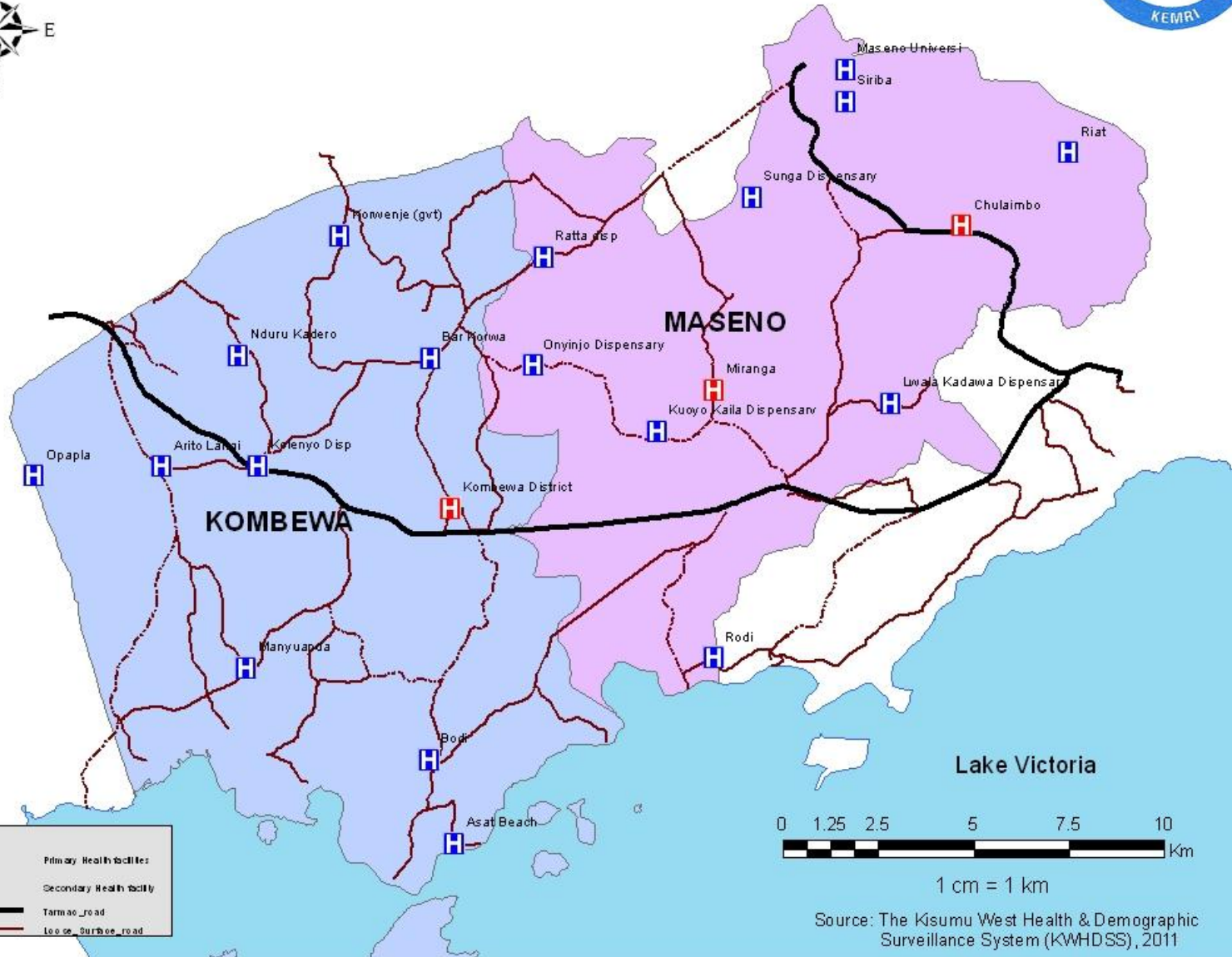
- Field workers will be assigned to various field stations to recruit from the field stations
- We will collaborate with MoH staff and community health workers to help with recruitment
- Research staff will attend chiefs' barazas to sensitize potential volunteers on the study
- We will use Community Advisory Board (CAB) to sensitize the community

Retention Plan

- Adequate consenting – continuous process and provision of any relevant additional information to participants
- Obtaining complete locator information and updating when necessary during the course of the study
- Provision of clinical care when a participant falls sick during the course of the study – the unit is operational 24/7
- Provision of refreshments/meals during scheduled clinic visits
- Provision of transport to and from the clinic (by utilizing available unit vehicles or by giving transport reimbursement)
- Visit reminders and home visit follow ups by field workers
- Mitigation of any study related issues raised by participant or community.



Health facilities in the District





TARGET ENROLLMENT FOR KOMBEWA



- Active Surveillance=7500
- 50% in 6-12 weeks group= 3,750
- 50% in 5-17 months group= 3,750
- Enhanced Hospitalization Surveillance=419



MONTH	Projections	MONTH	Projections
DEC-2015	400	AUG-2016	500
JAN-2016	470	SEP-2016	500
FEB-2016	470	OCT-2016	500
MAR-2016	470	NOV-2016	470
APR-2016	470	DEC-2016	470
MAY-2016	470	JAN-2017	470
JUN-2016	470	FEB-2017	470
JULY-2016	500	MAR-2017	470



recruitment projections-EH SURVEILLANCE



MONTH	Projections	MONTH	Projections
DEC-2015	17	AUG-2016	17
JAN-2016	17	SEP-2016	17
FEB-2016	17	OCT-2016	17
MAR-2016	17	NOV-2016	20
APR-2016	17	DEC-2016	17
MAY-2016	20	JAN-2017	17
JUN-2016	17	FEB-2017	17
JULY-2016	17	MAR-2017	17



recruitment projections-EH SURVEILLANCE

MONTH	Projection	MONTH	Projection
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JUL-2017	17	NOV-2017	20



ACTIVE SURVEILLANCE



- Participants in the Active surveillance group will be recruited from immunization clinics as they come for the first time to receive the birth polio or BCG and from the maternity wards after delivery prior to discharge. This group will later be enrolled into the study during their 1st Pentavalente vaccine at 6weeks.



ACTIVE SURVEILLANCE



- Participants will be recruited on first contact during hospitalization before administration of 1st pentavalente vaccine or those in age bracket of 5 to <18 months during hospitalization or at home visit, these will be included in catch up group.
- Participants will be recruited and consented prior to receiving their scheduled dose of vaccine for the day.



ENHANCED HOSPITALIZATION SURVEILLANCE



- Enhanced Hospitalization surveillance participants will be recruited from the participants who get hospitalized for treatment in any of the participating health facilities with admission facilities within the Kombewa Health Demographic and Surveillance System



Target Groups



- **Active Surveillance Group**
- **During the First 12 months**
- 2 out of 3 enrolled from 6-12weeks group
- 1out of 3 enrolled from 5-17 group
- **Month 12-16**
- All recruitment from 6-12 weeks group until expected number reached.
- **Recruitment first 4months of study**
- Children aged 5 to <18months enrolled in 5-17months in catch up group
- **Enhanced Hospitalization Surveillance Group**
- Child aged <3years hospitalized anytime during the Study but not enrolled in the active Surveillance.



ENROLLMENT AND IQC CHECKS

Enrollment will be carried out in HCF/Field

ICF administration by Field workers

ICF QC Check by Field supervisor/clinician/nurse

1st level IQC Check done in the field/HCF

2nd level IQC Check done in Kombewa CRC Clinic.