

Country Name	Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever
Republic of Kenya	

## I. Project Outline

Background	Outbreaks of arthropod-borne viral (in short, “arbovirus”) infections such as Yellow Fever (YF) and Rift Valley Fever (RVF) have been periodically reported in Kenya and the neighboring countries. YF outbreaks occurred in the northwestern region of Kenya and the southern region of Sudan in 2005 (555 clinical cases, 142 death cases, fatality rate of 25.6%). RVF outbreaks occurred in Kenya, Somalia, and Tanzania in the period from 2006 to 2007 (1,062 clinical cases, 315 death cases, fatality rate of 29.7% among the three counties). To control the disease infection, it was considered that early detection of infectious cases to implement emergency vaccinations and vector control after cases (so-called “early containment” measures) were more effective than periodic vaccination. However, simple diagnostic test kits for YF and RVF were not commercially available in Kenya and other East African countries; thus, most countries with high risks of outbreaks of those diseases, required to acquire simple diagnostic test kits.												
Objectives of the Project	Through development of rapid diagnostic kits, enhancement of reference capacity for rapid confirmation of YF and RVF, development of Mobile SMS-based Disease Outbreak Alert system, the project aimed at strengthening the outbreak containment system of YF and RVF in Kenya through the development of rapid diagnostics and establishment of a sustainable outbreak vigilance and response mechanism.												
	<ol style="list-style-type: none"> <li>Expected Overall Goal: N.A.</li> <li>Project Purpose: The outbreak containment system of YF and RVF is strengthened in Kenya through the development of rapid diagnostics and establishment of a sustainable outbreak vigilance and response mechanism.</li> </ol>												
Activities of the Project	<ol style="list-style-type: none"> <li>Project site: Nairobi and regions at risk of arbovirus infection (study sites).</li> <li>Main activities: Production of rapid diagnostic kits for point-of-care (POC) testing of YF and RVF, preparation of ELISA tests for YF and RVF, strengthening of reference capacity for rapid confirmation of YF and RVF at KEMRI HQs and Center for Infectious and Parasitic Diseases Control Research (CIPDCR), development of the Mobile SMS-based Disease Outbreak Alert System (mSOS), pilot operation of mSOS, etc.</li> <li>Inputs (to carry out above activities) <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Japanese Side</td> <td style="width: 50%;">Kenyan Side</td> </tr> <tr> <td>1) Experts from Japan: 6 persons</td> <td>1) Staff allocated: 20 persons</td> </tr> <tr> <td>2) Training in Japan: 4 persons</td> <td>2) Land and facilities: office space for research and test activities at KEMRI, etc.</td> </tr> <tr> <td>3) Equipment: Bio-safety cabinet, clinical chemistry analyzer, LAMP machine, real-time PCR, DNA sequencer, vehicles, etc.</td> <td>3) Local cost: travel expenses, costs for facility update, acquiring and maintaining ISO, website maintenance, etc.</td> </tr> <tr> <td>4) Local cost: cost for research activities, etc.</td> <td></td> </tr> </table> </li> </ol>			Japanese Side	Kenyan Side	1) Experts from Japan: 6 persons	1) Staff allocated: 20 persons	2) Training in Japan: 4 persons	2) Land and facilities: office space for research and test activities at KEMRI, etc.	3) Equipment: Bio-safety cabinet, clinical chemistry analyzer, LAMP machine, real-time PCR, DNA sequencer, vehicles, etc.	3) Local cost: travel expenses, costs for facility update, acquiring and maintaining ISO, website maintenance, etc.	4) Local cost: cost for research activities, etc.	
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Project Period	January 2012 to January 2017	Project Cost	(ex-ante) 365 million yen, (actual) 361 million yen										
Implementing Agency	Kenya Medical Research Institute (KEMRI)												
Cooperation Agency in Japan	Nagasaki University Institute of Tropical Medicine (NUITM)												

## II. Result of the Evaluation

<Special Perspectives Considered in the Ex-post evaluation>

- For this SATREPS project, no expected Overall Goal was set forth. At the terminal evaluation, the following efforts for utilization of the research outcomes by this SATREPS project were confirmed. At the ex-post evaluation, these efforts were interpreted as “Expected Overall Goals” but verified as part of expected positive impacts.

- Upgrading of mSOS pilot version to mSOS (nationwide scale-up) and integration into the national health information system.
- Commercialization of the test kits.

### 1 Relevance

<Consistency with the Development Policy of Kenya at the time of ex-ante evaluation >

In the “Second National Health Sector Strategic Plan (NHSSP)” (2005-2010) and the “Strategic Plan of the Ministry of Public Health and Sanitation” (2008-2012), capacity development in disease surveillance and research for infectious diseases covering not only HIV/AIDS, Malaria and Tuberculosis but YF and RVF were indicated as priority areas

<Consistency with the Development Needs of Kenya at the time of ex-ante evaluation >

The outbreaks of YF and RVF were periodically reported in Kenya and its neighboring countries, and there were needs for improvement of the diagnostic technique and development of the alert system model well designed for the social and economic infrastructure of not only Kenya but all the East African countries. Thus, the project was relevant with development needs of Kenya.

<Consistency with Japan’s ODA Policy at the time of ex-ante evaluation>

In the Country Assistance Program for Kenya (2000), one of the priority areas was health and medical care. In the “Yokohama Action Plan” adopted at the 4<sup>th</sup> Tokyo International Conference on African Development in 2008, infectious disease control was listed on the priorities of the health sector. At G8 Toyako Summit of the same year, global effort for infectious disease control was agreed on in the

<sup>1</sup> SATREPS: Science and Technology Research Partnership for Sustainable Development.

concept of the “Health System Strengthening.” Thus, the project was consistent with Japan’s ODA policy at the time of ex-ante evaluation.  
<Evaluation Result>

In light of the above, the relevance of the project is high.

## 2 Effectiveness/Impact

<Status of Achievement of the Project Purpose at the time of Project Completion>

The Project Purpose was partially achieved. Rapid diagnostic test kit for detection of Immunoglobulin M<sup>2</sup> (IgM) against YF and Enzyme-linked Immunosorbent Assay (ELISA) test kits for RVF and YF (both IgM-capture) were developed. However, the external evaluation was not conducted due to the lack of funds, and therefore the test kits for YF and RVF were not produced and marketed (Indicator 1). The Operational Manual of mSOS was officially authorized, and it was decided to be integrated into the District Health Information System 2 (DHIS2) (Indicator 2). The time taken from the first clinical suspicious cases to confirmation of diagnosis attained the target value (Indicator 3). It was less than one week in the cases identified at the airport in 2016, although they might be different from cases at the community level.

<Continuation Status of Project Effects at the time of Ex-post Evaluation>

The project effects have partially continued. By deploying the scientific knowledge, skills and techniques gained through the project, the rapid diagnostic test kits for RVF available from other partners such as US Army Medical Research Institute for Infectious Diseases and World Health Organization have been utilized by KEMRI, although the external evaluation of the kits developed through the project has not yet been conducted as of May 2020. On the other hand, key research outputs produced by the project have been utilized. For example, KEMRI has utilized functions of the Biosafety Level-3 (BSL-3) Laboratory for (i) outbreak response and research on arboviruses and Viral Hemorrhagic Fever and (ii) VHF amplification for in-depth virus characterization. Furthermore, KEMRI has started new research projects based on the research outputs, such as the RVF genomics study (molecular epidemiology), surveillance for Chikungunya Virus, and HIV drug resistance using genetic sequencing. Major research facilities and equipment installed by the SATREPS project have been continuously utilized, including the Infectious Diseases Research Laboratory at Alupe, thermocyclers, sequencers, incubators, lyophilizers, genetic analyzers, etc. The Operational Manual of mSOS has been integrated into the Kenyan Health Information System (KHIS) which was renamed from DHIS2.

<Status of Achievement for Expected Overall Goal at the time of Ex-post Evaluation>

Since the Expected Overall Goal was not set forth for this SATREPS project, the ex-post evaluation verified “utilization of the research outcomes by the project.” The utilization of the research outcomes by the SATREPS project has been progressed through utilization by the implementing agencies. Since the project completion, mSOS has been integrated into KHIS as a public health event reporting model, but it has not been scaled up nationwide as part of the national surveillance system. The reasons cited by MOH include limited internet connectivity infrastructure in the counties, limited financial sources for internet connection and data transmission through bulk SMS, unavailability of mobile phones for the county staff for reporting data, unavailability of a gateway for SMS, and others. As reported by KEMRI, the rapid diagnostic test kits for YF and RVF have not been commercialized yet, because they have not received external evaluation and third-party accreditation as mentioned above. KEMRI has not secured the necessary funds for these processes yet.

<Other Impacts at the time of Ex-post Evaluation>

Several positive impacts have been confirmed within and outside KEMRI. At KEMRI, first, diagnostics of other arboviruses (Dengue fever and Chikungunya) and infectious diseases have been strengthened. These have been brought by improved diagnostic and surveillance techniques with the installed real-time thermocycler at the Center for Virus Research (CVR) and the ELISA reader at the Coast Provincial General Hospital in Mombasa. Second, the outbreak alert system mSOS was customized to mSOS-Ebola with the addition of notification of laboratory diagnostic results. The system has been used by the National Rapid Response Team of MOH to enhance preparedness in the country. Third, a machine installed by the project (Real-time PCR machine) has been utilized for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) sample tests since March 2020. Four of the researchers who strengthened techniques through the project have actively been working for sample tests. Fourth, in line with KEMRI’s affirmative action policy for creating equal opportunities across gender, there was targeted recruitment of two female scientists at Nairobi and Busia sites as research associates and were mentored as immunologists and laboratory analysts through the Project. Since the project completion, both completed their master’s degree.

Outside KEMRI, first, MOH has improved its scientific literacy. According to KEMRI, through training on mSOS during the project, MOH has improved disease surveillance knowledge and techniques. Second, KEMRI in collaboration with the National Police Service has utilized analyzers and thermocyclers for training 60 forensic analysts from Kenya’s Directorate of Criminal Investigation on DNA detection.

<Evaluation Result>

Therefore, the effectiveness/impact of the project is fair.

### Achievement of the Project Purpose and Overall Goal

Aim	Indicators	Results
(Project Purpose) Outbreak containment system of YF and RVF is strengthened in Kenya through the development of rapid diagnostics and establishment of a sustainable outbreak vigilance and response mechanism.	1. Rapid diagnostic test kits for YF and RVF are stably available in the target area.	<u>Status of achievement: Partially achieved (Not achieved).</u> (Project Completion) - KEMRI acquired all the necessary ISO certificates for the production and sale of the test kits, but the external test was not completed. (Ex-post evaluation) - The external evaluation on the test kits has not been conducted and the test kits have not been available yet, but MOH has utilized kits available from other partners for routine surveillance while KEMRI has offered reference laboratory support.
	2. The Operational Manual is integrated into the national surveillance and response system for priority diseases by the MOH by the end of project period.	<u>Status of achievement: Partially achieved (Achieved).</u> (Project Completion) - The Project supported development of mSOS pilot version and verified its effectiveness scientifically, which led to an official authorization of the operation manual of mSOS by MOH. In addition, mSOS pilot was included in the Principal Secretary’s performance contract with the Cabinet Secretary (CS) 2014-15.

<sup>2</sup> Immunoglobulins are antibodies that play a major role in immunity, and the Immunoglobulin M is the first antibody that is produced when a bacterial or viral infection occurs.

		(Ex-post evaluation) - MOH decided to scale mSOS up nationwide as part of the national surveillance system, upgraded mSOS pilot version to mSOS national version and integrated it into the national health information system, DHIS2 (renamed as KHIS).
	3. The time taken from the first clinical suspicious cases to confirmation of diagnosis is 1 week or less.	<u>Status of achievement: Achieved (Continued).</u> <u>(Project Completion)</u> - When the three clinically suspicious cases of YF, who were coming back from outside of Kenya, were identified at Jomo Kenyatta International Airport in 2016, the time taken from the first suspicious case to confirmation of diagnosis was less than one week. (Ex-post evaluation) - In 2019, samples from the suspected outbreak of RVF in Nyandarua County took two days to reach KEMRI. Upon receipt of the samples, KEMRI was able to test and release the results in under three days.
(Expected Overall Goal) Utilization of the research outcomes	1. Upgrading of mSOS pilot version to mSOS (nationwide scale up) and integration into the national health information system.	<u>Status of achievement: Achieved.</u> (Ex-post Evaluation) - mSOS was integrated into KHIS as an event reporting module although the system is yet to be made fully operational in the 47 counties.
	2. Commercialization of the test kits.	<u>Status of achievement: Not achieved.</u> (Ex-post Evaluation) - Test kits for YF and RVF have not been commercialized yet, because they have not gone through external verification.

Source: Terminal Evaluation Report, JST Completion Report, information provided by MOH and KEMRI.

### 3 Efficiency

Both the project cost and period were within the plan (ratio against the plan: 99% and 100%, respectively). Outputs were produced as planned. Therefore, the project efficiency is high.

### 4 Sustainability

#### <Policy Aspect>

Promotion of infectious disease control including YF and RVF has been prioritized in the “Kenya Health Policy” (2014-2030), “eHealth Policy” (2018-2030), “Health information Policy” (2014-2030), “Health Act” (2017), and so on.

#### <Institutional Aspect>

The institutional arrangement of KEMRI for utilizing the research outputs has not changed, with the Headquarters (HQs) and seven regional clusters to cover all 47 counties. Most of the key researchers trained by the project have continuously worked at both HQs and the Alupe Center. However, some have been transferred to other centers to provide technical expertise, while some senior researchers would be retiring in a year (as of May 2020). At the time of ex-post evaluation, KEMRI was undertaking the recruitment of research scientists to strengthen its technical expertise. KEMRI has collaborated with JICA for the third country training program that started in 2019, aiming for strengthening laboratory preparedness and building resilience against public health emergencies in East Africa. KEMRI has sustained its research network with the National Public Health Institutes, National Health Research Institutes, and Regional Health Authorities, besides MOH. Regarding the research facility and equipment, KEMRI HQs has made them open to its satellite centers and universities or graduate schools for research and training purposes. CIPDCR has been fully operated and maintained by KEMRI. However, there has been a challenge due to limited resources for repair and replacement of some broken devices such as the power back up system.

#### <Technical Aspect>

KEMRI researchers trained by the project have been retained at KEMRI as follows. A researcher has worked at CVR using BSL-3 laboratory to analyze samples for his Ph.D. work on RVF. Other scientists have continuously stationed at the production department and KEMRI CIPDCR to research on arboviruses and publishing papers. In addition, researchers from other KEMRI centers such as Kisumu (Global Health Research) and Kilifi (Geographic Medicine Research-Coast) have used the facilities and equipment at the production department for their studies. KEMRI researchers have sustained skills and knowledge to properly operate and maintain the research facility and equipment installed by the project, as they have fully operated CIPDCR and maintained the equipment. They have planned to gain more experience by conducting a variety of research activities and publishing research papers. As well, KEMRI has supported to improve the scientific literacy of the government authorities such as MOH and DCI, as mentioned in <Other Impacts at the time of Ex-post Evaluation>.

#### <Financial Aspect>

KEMRI has gained no revenue accruing from the commercialization of the test kits for YF and RVF. However, external research funds (4,649 million KES in 2016) have been secured from the National Research Fund, the Wellcome Trust, the Government of Kenya, and other international partners and funding organizations. Besides, KEMRI has internally generated income (361 million KES in 2016). The funding from the Government of Kenya to KEMRI (2,030 million KES in 2016) has been mainly for recurrent expenditure, and research activities have heavily relied on funding from external grants dependent upon successful proposals. Also, the cost for operation and maintenance has been secured from KEMRI’s annual budget, although the details of allocations and expenditures could not be confirmed in the ex-post evaluation. Regarding county governments, although they have been expected to budget for disease surveillance activities, it has been challenging to secure funding to pay costs for bulk SMS for mSOS. For securing health financing, MOH has been developing the “Public-Private Partnership (PPP) Strategy” and an innovative health financing mechanism towards UHC.

#### <Evaluation Result>

There have been some issues in the financial aspect. Therefore, the sustainability of the effects is fair.

### 5 Summary of the Evaluation

The Project Purpose was partially achieved. Rapid diagnostic test kits for YF and RVF were developed. However, since the external evaluation was not conducted due to the lack of funds, they were not ready for mass production and sales. The mSOS was developed and integrated into the national health information system. The project effects have continued, as research outputs produced by the project have been utilized. Regarding sustainability, securing sufficient funding for research activities has been an issue, but KEMRI has sustained a

necessary organizational setting and technical expertise to continue research related to infectious disease control.

Considering all of the above points, this project is evaluated to be satisfactory.

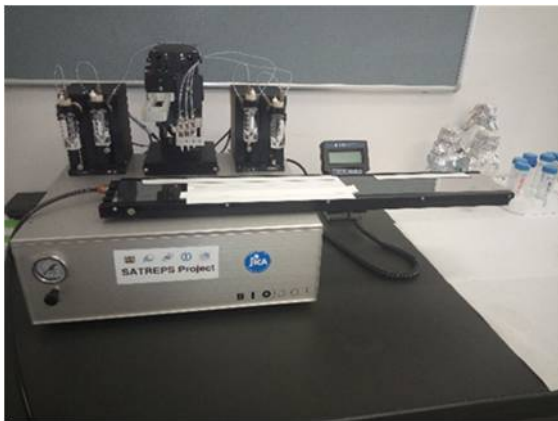
### III. Recommendations & Lessons Learned

Recommendations for Implementing agency:

- It is recommended to principal researchers of KEMRI to reconfirm the specificity and sensitivity of the test kits for YF and RVF at the laboratory, conduct field trials for the external validation, and make an application to the National Public Health Laboratory Services for mass production, sales, and distribution, in line with its “Strategic Plan” (2018-2023). KEMRI should prioritize these activities in its Annual Work Plan and discuss with partners including JICA Kenya about the possibility of support.
- It is recommended to MOH to fully operationalize KHIS including mSOS in all counties. To do this, MOH should seek partnerships with other enabling sectors such as ICT and Energy to support county infrastructure development. It will serve as a surveillance and alert system for not only RVF and YF but also suspected SARS-CoV-2.

Lessons learned for JICA:

- As a result of utilization of the research outcomes, the project had a goal of commercializing and distributing rapid diagnostic test kits for YF and RVF to points of care. However, the project could not complete the external validation of the test kits by the time of project completion, because the project design did not include an output of developing and testing a model for commercialization. In SAREPS projects where research outcomes are expected to be commercialized after the time of project completion, it is necessary to include activities for modeling and testing of the commercialization strategies that would eventually be up-scaled by the implementing agencies. And, potential stakeholders for sales, such as authorization organization, should be engaged in the project activities.



Rapid test kit (stripping machine) installed at the Production Department of KEMRI HQs



Scientist working at the Production Department of KEMRI HQs