

## 付 属 資 料

1. 協議議事録
2. 評価グリッド（調査結果）



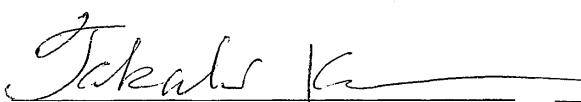
**MINUTES OF MEETING  
BETWEEN THE JAPANESE FINAL EVALUATION TEAM  
AND  
THE AUTHORITIES CONCERNED OF THE GOVERNMENT  
OF THE REPUBLIC OF KENYA  
ON JAPANESE TECHNICAL COOPERATION  
FOR  
THE RESEARCH AND CONTROL OF INFECTIOUS DISEASES PROJECT**

The Final Evaluation Team (hereinafter referred to as “the Team”), organized by the Japan International Cooperation Agency (hereinafter referred to as “JICA”) and headed by Prof. Takashi Kurimura, Professor Emeritus of Osaka University, visited the Republic of Kenya (hereinafter referred to as “Kenya”) from 16 October to 13 November 2005. The purpose of the Team was to review and evaluate the achievements made so far by the Research and Control of Infectious Diseases Project (hereinafter referred to as “the Project”).

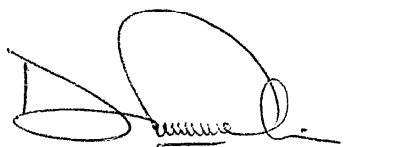
During its stay in Kenya, both the Team and authorities concerned of Kenya (hereinafter referred to as “both sides”) had a series of discussions and exchanged views on the Project. Both sides jointly reviewed the activities and evaluated the achievement based on the Project Design Matrix (hereinafter referred to as “PDM”).

As a result of the discussions, both sides agreed upon the results of the evaluation compiled in the Evaluation Report attached hereto with mutual understanding.

Nairobi, 11 November 2005



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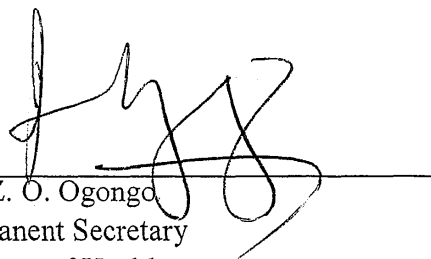


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**EVALUATION REPORT**  
**ON THE JAPANESE TECHNICAL COOPERATION**  
**FOR THE RESEARCH AND CONTROL OF INFECTIOUS**  
**DISEASES PROJECT**

**JAPAN INTERNATIONAL COOPERATION AGENCY**  
**JAPAN**

**KENYA MEDICAL RESEARCH INSTITUTE**

**AND**

**MINISTRY OF HEALTH**  
**OF THE REPUBLIC OF KENYA**

**10 NOVEMBER 2005**

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## ABBREVIATIONS

<b>A</b>	AHSC	African Health Science Congress
	AIDS	Acquired Immunodeficiency Syndrome
	AMPATH	Academic Model for the Prevention and Treatment of HIV
	AMREF	African Medical Research Foundation
	ART	Anti-Retroviral Therapy
	ARV	Anti-Retroviral
<b>B</b>	BTC	Blood Transfusion Centre
<b>C</b>	CBRD	Centre for Biotechnology Research and Development
	CCR	Centre for Clinical Research
	CDC	Centers for Disease Control and Prevention
	CGMRC	Centre for Geographic Medicine Research
	CHW	Community Health Worker
	CIPDCR	Centre for Infectious and Parasitic Diseases Control Research, Busia
	CMR	Centre for Microbiology Research
	CMV	Cytomegalovirus
	CP, C/P	Counterparts
	CPHR	Centre for Public Health Research
	CRDR	Centre for Respiratory Diseases Research
	CTMDR	Centre for Traditional Medicine and Drug Research
	CVBCR	Centre for Vector Biology and Control Research, Kisumu
	CVR	Centre for Virus Research
	<b>D</b>	DELIVER
DH		District Hospitals
DST		Drug Susceptibility Test
<b>E</b>	ELISA	Enzyme-Linked Immuno-sorbent Assay
	EQA	External Quality Assessment
	EQC	External Quality Control
	ERC	(KEMRI) Ethical Review Committee
	ERS	Kenya Economic Recovery Strategy
<b>G</b>	GLP	Good Laboratory Practice
	GMP	Good Manufacturing Practice
<b>H</b>	HBV	Hepatitis B virus
	HC	Health Centre
	HCV	Hepatitis C virus
	HEPCELL	KEMRI-produced Hepatitis B kit (generally refers to all the HEPCELL kits)
	HEPCELL II	KEMRI-produced Hepatitis B kit (Second-generation HEPCELL, an improved version of lyophilised Kit that does not require refrigerated transportation nor storage)
	HIV	Human Immuno-deficiency Virus
	HIV PA-1	KEMRI-produced HIV Type1 kit
	HPV	Human Papilloma Virus
	HSV	Herpes simplex virus
<b>I</b>	IAEA	International Atomic Energy Agency
	ICAAP	International Conference on AIDS in Asia and Pacific
	ICASA	International Conference on AIDS and STDS in Africa

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	IFA	Immuno-fluorescent Assay
	INTROMID	Institute Of Tropical Medicine and Infectious Diseases
	IPR	Institute for Primate Research
<b>J</b>	JCC	Joint Coordinating Committee
	JICA	Japan International Cooperation Agency
	JSI	John Snow, Inc.
<b>K</b>	KEMCOM	KEMRI HIV 1&2 diagnostic kit
	KEMRI	Kenya Medical Research Institute
	KEMSA	Kenya Medical Supply Agency
	KNH	Kenyatta National Hospital
	Kshs.	Kenya Shillings
<b>M</b>	MM	Man Month
	MOH	Ministry of Health
	MRSA	Methicillin Resistant <i>Staphylococcus aureus</i>
<b>N</b>	NASCOP	National AIDS and STD Control Programme
	NBTC	National Blood Transfusion Centre
	NIH	National Institute of Health
	NPHLS	National Public Health Laboratory Service
<b>O</b>	ODA	Official Development Assistance
	OI	Opportunistic Infections
	OT	Opportunistic Tumor
<b>P</b>	PA	Particle Agglutination
	PCP	<i>Pneumocystis carinii</i> pneumonia
	PCR	Polymerase Chain Reaction
	PDM	Project Design Matrix
	PEPFAR	President's Emergency Plan for AIDS Relief
	PGH	Provincial General Hospitals
	PHE	Public Health Education
	PLWHA	People living with HIV/AIDS
	PMTCT	Prevention of Mother-to-Child Transmission
<b>Q</b>	QA	Quality Assurance
	QC	Quality Control
<b>R</b>	R/D	Record of Discussions
	RIBA	Recombinant Immunoblot Assay
	RBTCs	Regional Blood Transfusion Centres
	RH	Reproductive Health
	RHRU	Reproductive Health Research Unit
<b>S</b>	SADC	Southern African Development Community
	SSC	Scientific Steering Committee
	STD	Sexually Transmitted Diseases
<b>T</b>	TCTP	Third Country Training Programme
	TSI	Tentative Schedule of Implementation
	USAID	United States Agency for International Development
<b>V</b>	VCT	Voluntary Counselling and Testing
	VH	Viral Hepatitis

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## 1. Introduction

### 1.1. Evaluation Study Team

JICA(Japan International Cooperation Agency) dispatched the Final Evaluation Team (hereinafter referred to as “the Team”) to Kenya from 17th October to 11th November 2005 for the Research and Control of Infectious Diseases Project (May 2001~April 2006) (hereinafter referred to as “the Project”). The Team is headed by Prof. Takashi KURIMURA, Professor Emeritus, Osaka University. The Team reviewed the achievements made in the past five-year cooperation period of the Project and prepared this Evaluation Report in collaboration with Project implementers, to summarise the achievements of the Project, to give recommendations for the remaining period of implementation, and to report the lessons learnt for future cooperation in this field.

The members of the Japanese Evaluation Team are shown as follows:

#### Japanese Evaluation Team

	Name	Designation	Affiliation	Duration of Stay
1	Prof. Takashi KURIMURA	Team Leader / HIV / AIDS	Chairperson, Advisory Committee, Professor Emeritus, MD & Doctor in Medical Science, Osaka University	6~13 Nov.2005
2	Prof. Michitani YANO	Viral Hepatitis (VH)	Advisory Committee, President Emeritus, Nagasaki Medical Centre	6~13 Nov. 2005
3	Prof. Shigeru KAMIYA	Opportunistic Infections (OIs)	Advisory Committee, Professor, Kyorin University	6~12 Nov. 2005
4	Ms. Saeda MAKIMOTO	Evaluation Planning	Staff, Infectious Diseases Team, Human Development Department, JICA	6~13 Nov.2005
5	Ms. Yoko OGAWA	Evaluation Analysis	Researcher, Social Development Department, Global Link Management, inc.	16 Oct.~ 12 Nov. 2005

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## 1.2. Background of the Project

JICA has a long-standing cooperation with the Kenya Medical Research Institute (KEMRI) dated back to 1979. Table 1-1 shows summary inputs with each phase of four technical cooperation projects and Table 1-2 summarises other Japanese support through Japanese Official Development Assistance to KEMRI.

**Table 1-1: Summary Inputs of JICA's Technical Cooperation with KEMRI on Infectious Diseases Preceding the Current Cooperation Period**

[Unit: Kenya Shillings]

Project Name (Duration)	Communicable Diseases Control and Research	Project of the Kenya Medical Research Institute	Research and Control of Infectious Disease (I)	Research and Control of Infectious Disease (II)	Cumulative
	(1979-84)	(1985-90)	(1990-96)	(1996-2001)	
<b>JAPAN'S CONTRIBUTION</b>					
Long-term Experts	14 Persons	28 Persons	17 Persons	15 Persons	74 Persons
(Duration Total)	223MM	275MM	365MM	359MM	1,222MM
Short-term Experts	8 Persons	29 Persons	49 Persons	39 Persons	125 Persons
(Duration Total)	32MM	46MM	100MM	51MM	229MM
Persons Trained in Japan	10 Persons	21 Persons	21 Persons	20 Persons	72 Persons
Equipment Provided	161,291,383	125,521,117	221,239,683	164,543,226	662,595,409
Implementation Costs	n/a	n/a	73,361,565	84,547,903	157,909,467
<b>KENYA'S CONTRIBUTION</b>					
Counterparts	n/a	31 Persons	48 Persons	59 Persons	138 Persons
Building/Facilities	Land, buildings, facilities and utilities	Land, buildings, facilities and utilities	Land, buildings, facilities and utilities	Land, buildings, facilities and utilities	Land, buildings, facilities and utilities
Implementation Costs	n/a	n/a	18,300,000	9,421,719	27,721,719

Source: JICA Evaluation Reports for the above Projects

**Table 1-2: Summary Inputs of Other Japanese Cooperation on Infectious Diseases with KEMRI**  
 [Unit: Kenya Shillings]

Project Name (duration)	KEMRI Construction Project (1982~83)	KEMRI Improvement Project (1997)	Blood Screening Seminar (1998~2001, 03~07)	Improvement of Facilities for Infectious and Parasitic Disease (2004)	Cumulative
<b>JAPAN'S CONTRIBUTION (OTHER)</b>					
Grant Aid	1,785,261,482	152,186,225	-	632,487,813	2,569,935,520
TCTP	-	-	172,347,648	-	172,347,648
<b>KENYA'S CONTRIBUTION</b>					
Cost-sharing	20,000,000	4,948,856	8,454,790	58,467,812	91,871,459

Source: KEMRI Administrative Records (October 2005); ODA home page, Ministry of Foreign Affairs (<http://www.mofa.go.jp/mofaj/gaiko/oda/index.html>)

In continuum to the last phase (1996~2001), a new 5-year technical cooperation project - "Infectious and Parasitic Diseases Research and Control Project" has commenced in May 2001. The original Project Design Matrix (PDM) was modified for better managerial efficiency and officially signed on 21 March 2003<sup>1</sup>. The Overall Goal, Project Purpose, and Outputs in the PDM are as follows:

<b>Overall Goal</b>	Research and Control programs of infectious diseases are strengthened in Kenya through capacity building of research activities and human resources development at KEMRI and related institutions, such as National Public Health Laboratory Services (NPHLS).
<b>Project Purpose</b>	Research and production capacity, human resources and human/information network at KEMRI, in collaboration with other institutions in Kenya such as NPHLS, are developed in order to strengthen effective control of the targeted diseases (HIV/AIDS, viral hepatitis, and Opportunistic Infections).
<b>Output 1</b>	An HIV/AIDS and viral hepatitis diagnosis system, also including other blood-borne infections, for blood safety (testing and confirmation) is established with widespread utilization of quality assured blood-screening kits.
<b>Output 2</b>	The methods for diagnosis, prevention and treatment of opportunistic infections in both adults and children with HIV/AIDS are established.

<sup>1</sup> Original PDM as well as revised PDM are attached in ANNEX I.

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## 2. Evaluation Methodology

### 2.1. Method of Evaluation

In line with the “JICA Project Evaluation Guideline,” the Final Evaluation of the Technical Cooperation Project: “Research and Control of Infectious and Parasitic Diseases Project(1 May 2001~30 April 2006)” was conducted. This evaluation process was consisting of three steps, namely, i) adopting the PDM which was revised at the time of visit by the Project Management Consultation Mission (10~26 March 2003), as a framework of the Project; ii) confirming and analysing the present status of the Project on its achievement levels, adequacy of implementation process as well as causal relationships between the Project-related activities and the present status; and, iii) examining the value of the Project against the criteria, namely, “relevance”, “effectiveness”, “efficiency”, “impact”, and, “sustainability”.

Through the above analysis, the Evaluation team specified factors that promoted or inhibited the achievement levels, so that the lessons learnt from the Project could be applied to other similar projects in the future.

Table 2-1 : Contents of a Master Plan (PDM)

<b>Overall Goal</b>	Broader effects that affect a larger population, sought to be achieved through the achievement of the Project Purpose.
<b>Project Purpose</b>	Direct and positive effects expected to prevail as a consequence of the Project interventions. Intended to benefit the target group and a segment of the society.
<b>Outputs</b>	Physical goods and services that can be produced through conducting the planned activities
<b>Activities</b>	Actions necessary to produce the planned Outputs
<b>Objectively Verifiable Indicators</b>	Criteria to measure the attainment level of the Project Outputs, Project Purpose and Overall Goal
<b>Means of Verification</b>	Sources of information to verify indicators
<b>Important Assumptions</b>	Situations, events, conditions necessary for project success, but beyond the control of the project management
<b>Preconditions</b>	Necessary conditions that must be overcome before a project is initiated
<b>Inputs</b>	Personnel, equipment, and costs required for Project Activities

### 2.2. Five Evaluation Criteria

Definition<sup>2</sup> of the five evaluation criteria that were used as viewpoints in analysis for the Final Evaluation is given in Table 2-2.

<sup>2</sup> “JICA Project Evaluation Guideline (revised: January 2004),” Office for Evaluation and Post-Project Monitoring, JICA.

**Table 2-2: Definition of the Five Evaluation Criteria for the Terminal Evaluation**

Five Evaluation Criteria	Definitions as per the JICA Evaluation Guideline
1. <b>Relevance</b>	The question whether the “Overall Goal” and “Project Purpose,” as stipulated in the PDM, are still in line, at the time of the evaluation, with the needs of the target group, the policy directions of Kenya, as well as the adequacy of selected solutions to the issues concerned, of the strategy that the Project has taken, and of the nature of the Project as an official development assistance.
2. <b>Effectiveness</b>	The question as to what extent the Project has benefited or would benefit the target group or a segment of the society. More specifically, the question as to clarify the causal relationship between the Project Purpose and Outputs.
3. <b>Efficiency</b>	The question on the relationship between the cost and the effects obtained by the Project, whether the Inputs has been effectively utilized.
4. <b>Impact</b>	The question on what changes, whether positive/negative or anticipated/unanticipated, have been produced as a result of the implementation of the Project.
5. <b>Sustainability</b>	The question on self-reliance of the Project in terms of organizational, financial and technical aspects: whether the benefits of the Project will continue after the discontinuation of external assistance.

### 2.3. Evaluation Design

In formulating an evaluation design, two aspects of the Projects entail particular consideration.

The first aspect is that this Project is a part of the long-lasting cooperation between KEMRI and the Japanese Official Development Assistance (ODA), which began since 1979. The second aspect is that the project design, which has been produced in PDM format at the beginning of the Project, was modified by a unilateral decision among the stakeholders into the second PDM in March 2003 in the occasion of the project Management Consultation Mission. The major change was the splitting of the Project into two, between the components of strengthening infectious diseases research/control and of establishing a regional centre for parasitic diseases control. Although review and revision of the Project has been conducted reflecting the progress of the Project, closer review in target indicators for performance measurement could not take place at this occasion.

Hence, an evaluation design for this Project is required 1) to take due consideration to what had already been invested and achieved at the outset of the Project, 2) to adjust the levels of given indicators in the current PDM, and 3) to be supplemented with adequate alternative indicators in addition to what are already given in the PDM for determining its performance.

Table 2-3 shows the evaluation questions and required information based on the five-evaluation criteria.

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Table 2-3: Evaluation Questions and Information Required

Evaluation Criteria / Questions	Sub-Questions / Required Information
<p>0. To what extent the Project have made its achievements. How did implementation process go? (Implementation Process)</p>	<p>Achievements in Inputs                      Implementation of Activities                      Trends in performance measurement indicators at Outputs level                      Trend in performance measurement indicators at Project Purpose level                      Trend in performance measurement indicators at Overall Goal level                      Implementation process                      Adequacy of monitoring/management structure of the Project                      Mode/means of technical transfer                      Relationship between stakeholders                      Extent of ownership by Kenyan government and KEMRI</p>
<p>1. Are the Project Purpose and Project Design of the Project still applicable as an approach to effectively responds to the development challenges in the area, looking forward the next several years to come? (Relevance)</p>	<p>Consistency of Overall Goal and Project Purpose with development goals/policies of the Government of Kenya                      Consistency of the Project Purpose with needs of target group.                      Adequacy of Project's strategy (selection of Project Purpose, target areas, target field(s), target group(s))                      Consistency of the Overall Goal and Project Purpose with Japanese development cooperation policy</p>
<p>2. To what extent has the Project contributed to human resource development in the area of reproductive health? What are the challenges still remained to be tackled? What were the factors that inhibited or promoted the achievement of the results? (Effectiveness)</p>	<p>Extent of the Project Purpose being achieved                      Contribution of the Outputs to achievement of the Project Purpose                      Influences by other conditions and/or factors on the achievement level of the Project Purpose</p>
<p>3. What were the factors that has enforced or lowered productivity and/or efficiency of the Project implementation? (Efficiency)</p>	<p>Extent of achievement of Outputs                      Adequacy of Inputs from Kenya (quality, quantify and timing)                      Adequacy of Inputs from Japan (quality, quantify and timing)                      Causal link between Inputs and Outputs/Project Purpose</p>
<p>4. Were there unexpected negative / positive effects brought about due to the Project intervention? (Impact)</p>	<p>Contribution to scientific society, health-sector policies, health service provisions, patients, etc.                      Causal link between the Overall Goal and Project Purpose                      Unexpected positive/negative effects due to the Project interventions                      Influences by other conditions and/or factors on the achievement level of the Overall Goal</p>
<p>5. Was the Project successful in establishing sustainability in terms of institutional, technical and financial aspects? (Sustainability)</p>	<p>Likelihood of continued political supports, changes in organisational capacity to manage the Project                      Likelihood by KEMRI to secure necessary budget to continue/maintain its improved functions                      How the benefits of the technical assistance continue to reach the ultimate beneficiary                      Promoting and inhibiting factors to maintain the effects obtained through the Project</p>

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## 2.4. Data Collection Methods

Both quantitative and qualitative data was gathered and utilised for analysis. Data collection methods used by the Evaluation Team were as follows:

1. *Literature/Documentation Review (MOH documents, Project reports, national and regional statistical data, various donor reports, etc.);*
2. *Questionnaires (Counterparts, Japanese Long-term and Short-term Experts);*
3. *Key Informant/Group Interviews (MOH officials, KEMRI Counterparts, Japanese Long-term Experts, other donor agencies); and,*
4. *Direct Observation*

## 2.5. Data Analysis & Report Making

Analysis and interpretation of the collected data was done using the five evaluation criteria. Overall conclusion, recommendations as well as lessons learnt were drawn through the analysis based on the five evaluation criteria, in order to make use of such results for more effective programming of similar projects in the future. Analysis and interpretation of the collected data will be done using the five evaluation criteria. Overall conclusion, recommendations as well as lessons learnt will also be drawn through the analysis, in order to make use of such results for more effective programming of similar projects in the future.

The Final Evaluation Team first compiled a draft evaluation report based on above-mentioned process. The content of the draft was then discussed among the core Counterparts and in the Evaluation Meeting with Joint Coordinating Committee (JCC) members, held on the 8<sup>th</sup> and 10<sup>th</sup> of November 2005, respectively. Feedback obtained through the discussion was reflected in the final document as the Joint Evaluation Report. Summary part of the Evaluation Report is to be signed by both Kenyan and Japanese Evaluation Teams.

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### 3. Achievements and Implementation Process

#### 3.1. Inputs

It should be noted that the current phase (2001~2006) was preceded by a continuous technical and financial support from Japanese cooperation for the purpose of strengthening KEMRI's research functions as shown in Table 1-1 and Figure 3-1. Hence, any achievements captured during this phase can also be attributed to inputs made during the past 20 years.

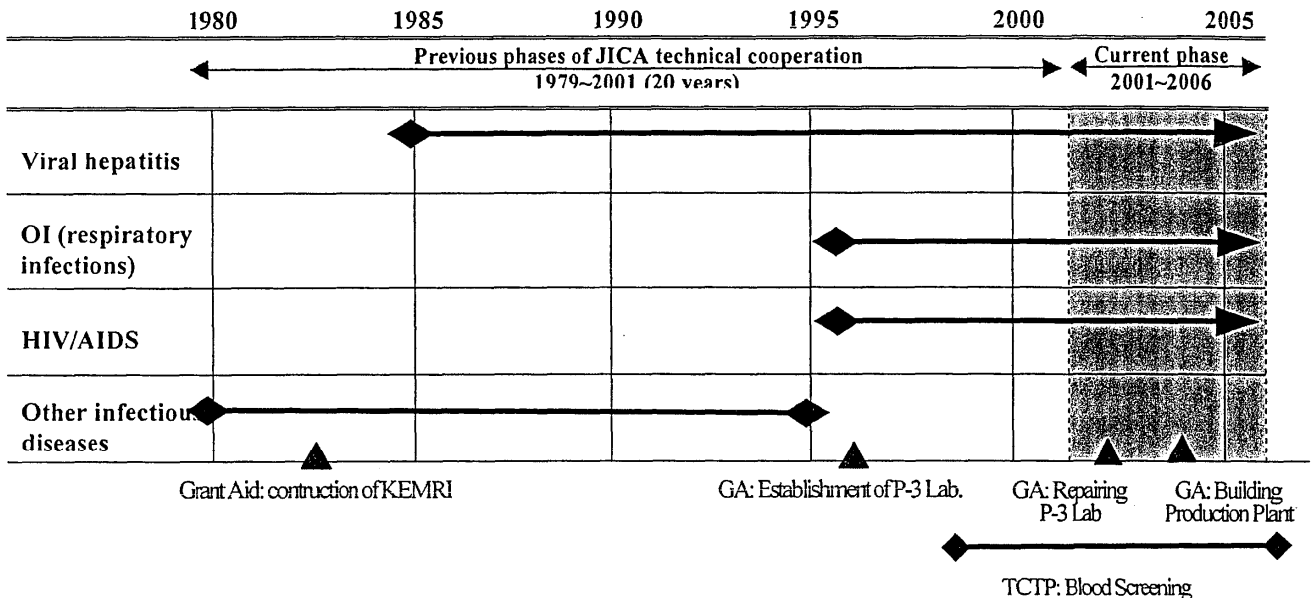


Figure 3-1: Prior JICA-supported Technical Cooperation to Infectious Diseases

#### 3.1.1 Japanese Contribution

##### a) Long and Short-Term Experts

The list of experts is shown in ANNEX II.

A total of **11 Long-term Experts** in 5 areas of expertise, totalling 269MM, will have been assigned by the end of the Project under the current phase. The areas of expertise are as per the agreement in the Record of Discussions (R/D), and include Chief Advisory, Project Coordination as well as various sub-disciplines in HIV/AIDS, Viral Hepatitis (VH) and Opportunistic Infections (OIs).

A total of **15 Short-term Experts** in 33 visits and in three (3) areas of expertise, totalling 22 MM, will have been dispatched at the time of the Final Evaluation, and 3 more are planned by the end of the Project. Average duration of stay per visit was 0.7 MM (21 days), ranging from two (2) days to 1.4 MM. The fields of expertise were as per R/D, and include various sub-disciplines under the area of HIV/AIDS, VH and OIs, namely, blood safety, traditional medicine, molecular epidemiology, vertical transmission of HIV, opportunistic tumours (OT), test-kit production, operations of particular medical equipment, blood screening and research advisory.

##### b) Provision of medical and training equipment

The list of equipment provided to KEMRI is shown in ANNEX III.

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Laboratory and training equipment worth 70,720,149 KShs. (¥ 106,302,600 equivalent) in total has been provided by the completion of the Project. Long and Short-term Experts also brought equipment and reagents / consumables to the Project, worth 42,036,782 Kshs. (¥ 65,577,502 equivalent). This amount include equipment for the parasitic diseases component until April 2003, and does not include 662,595,409Kshs (¥ 1,018,800,000 equivalent) contribution of laboratory/training equipment to KEMRI between 1979~2001, quite a portion of it is still in use.

*c) Training for Counterparts and Management Consultation Missions*

The list of training activities for the Counterparts as well as of the Management Consultation Missions is shown in ANNEX IV ~ VI.

The total of sixteen (16) persons, with total and average duration of 98 MM and 6.1 MM, respectively, will have been trained under the Counterpart (C/P) training scheme.

The areas of training include the following:

Virology and molecular epidemiology, cultivation and molecular epidemiological monitoring of HIV, blood transfusion system and blood screening system, molecular diagnosis of hepatitis viruses (HBV/HCV) (3 persons), research for opportunistic infection, animal care, medical microbiology (2 persons), molecular diagnosis for HIV screening in blood, public health (epidemiology), phytochemistry (traditional medicine), HIV culture, quality control and quality assurance and molecular biology of human papilloma virus (HPV).

In addition, the Counterparts have benefited from an exposure to numerous international and national conferences and programmes in which a cumulative sum of 68 had participated. Among them were:

1. *Exchange Program with National Institute of Health, Thailand*
2. *The International Conference on AIDS & STDs in Africa (ICASA) in Burkina Faso, Kenya, Nigeria*
3. *AIDS Conference in Thailand*
4. *African Health Sciences Congress (AHSC) in Uganda, in Ethiopia, in Kenya*
5. *The 7th International Congress on AIDS in Asia and the Pacific in Japan*
6. *The 17th Japan AIDS Conference*
7. *The 27th Annual Meeting of Cancer Registries in Uganda*
8. *South African Development Community HIV/AIDS Workshop in Zambia*

The Project also received eight (8) Management Consultation Missions in which overall directions of the Project were given. The number of visits is relatively larger compared with other Projects, due to absence of Chief Advisor on the ground.

Three (3) Counterparts benefited from long-term PhD training programmes in the field of HIV/AIDS and opportunistic infections as well as the Third Country Training. Programme that were supported by non-Project sources (both JICA and non-JICA funds). Total training period will be 90 MM, averaging 23 MM per person.

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*e) Operational Cost for the Project*

Annual Operational Cost (actual expenditure and estimated allocation) from the JICA Project fund is shown in the table below (Also in ANNEX VII).

A total of 92,826,000Kshs (¥ 144,216,114) has been expended for local operational costs at the time of Final Evaluation from the JICA Project Fund. The amount has mainly been expended to reagents and other consumables for research activities, attendance to international, regional and national conferences, running and maintenance costs for equipment, in-country training and miscellaneous costs for effective and smooth implementation of the Project. For instance, employment of temporary staff (a clinical officer, nurses, and community health workers) under research activities, and fee for obtaining samples from public hospitals.

**3.1.2 Kenyan Contribution**

*a) Appointment of core Counterpart personnel*

The name list both core and non-core Counterpart personnel in KEMRI is provided in ANNEX VIII.

A total of fifteen (15) core Counterparts in eight (8) specialised centres, as well as three (3) for management of the Project have been allocated by KEMRI, as stipulated in R/D. In addition to the core Counterparts, seventy-four (74) KEMRI staff have worked with the Project.

*b) Facilities and Office space for Japanese Experts*

As per the R/D, 1) space for implementation of the Project, 2) offices and other necessary facilities for the Japanese Experts, 3) facilities and services such as the supply of electricity, gas and water, sewerage systems, telephones and furniture necessary for the activity of the Project, and, 4) other facilities mutually agreed upon as necessary, have been provided in sufficiency. Among them, major activities have occurred in the KEMRI buildings, which were built through the Japanese Grant Aid scheme (Ksh 1,962,396,563<sup>3</sup>).

*c) Allocation of Budget to Project Activities*

A table showing annual Operational Cost (actual expenditure and estimated allocation) from KEMRI budget is shown in ANNEX IX.

A total of 182,629,600 Kshs (¥277,753,609) have been allocated and expended for the Project at the time of the Final Evaluation. The expense includes personnel costs, utilities, motor vehicle running costs, seminars, per diem and travelling cost for Kenyan Counterparts, a portion of maintenance cost for equipment and service agreement of the P3 Laboratory. This is inclusive of all the personnel costs of all the Counterparts in addition to the operational contribution to the Project.

The share of Kenyan funds is 88% of all the contributions to the Project from both parties (See ANNEX X).

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<sup>3</sup> The amount includes Grant Aid (both Japanese and Kenya contributions) for construction of KEMRI buildings (1982~83) and establishment of the P-3 laboratory (1997). This does not include Ksh 632,487,813 (J) and Ksh 58,467,812 (K) for the establishment of a plant for the KEMRI blood screening kit and training facilities (2004).

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### 3.2. Results of Activities

Activities consisting of the following twenty-three (23) areas are shown in PDM. Most of the activities have been initiated, implemented and approaching to their completion. Some items have experienced delays and changes in directions.

Details of the status of ongoing and completed activities at the time of final evaluation are presented as follows:

Activities as per PDM	Actual Achievement
<i>Activities under Output 1: HIV/AIDS and viral hepatitis diagnosis system also including other blood-borne infections, for blood safety is established with widespread utilisation of quality assured blood screening kits.</i>	
(1) Quality control of production and quality assurance of KEMRI HEPCELL II (hepatitis B) and KEMRI HIV-I PA kits	<ol style="list-style-type: none"> <li>1. One manual each for HEPCELL II and PA-1 has been revised.</li> <li>2. Preparation of panel sera is in progress as indicated under activity below.</li> <li>3. Three persons in the HIV laboratory were trained in quality control (QC) and quality assurance (QA).</li> <li>4. A total of 228 technologists and technicians from public hospitals and KEMRI (106 for HEPCELL II and 122 for PA-1), as well as 141 from the other countries in the region (through Third Country Training Programme<sup>4</sup> (TCTP)) were trained on blood safety and in use of HEPCELL II and PA-1 kits.</li> <li>5. Five abstracts on blood safety were presented at the African Health Science Congresses (AHSC).</li> <li>6. Two organisations (American Medical Research Foundation (AMREF), National AIDS and STD Control Programme (NASCOPI)) were identified as QC collaborators, and the terms of working are to be discussed.</li> </ol>
(2) Production of HBsAb test kits (PHA) -KEMRI HEPSAB.	<ol style="list-style-type: none"> <li>1. Eight personnel in KEMRI were trained locally for the production of HBsAb test kits.</li> <li>2. An HBsAb detection kit (HEPSAB) has been developed.</li> <li>3. One hundred and twenty-five HEPSAB kits were produced.</li> <li>4. Five hundred blood donor samples were tested and 15.2% positive.</li> <li>5. Accordingly, HBV infection rate in Kenya can be estimated as approximately 20% whereby 3.4% of HBs antigen and 15.2% of HBsAb positive.</li> <li>6. Sixteen provincial medical technologists were trained for the usage of HEPSAB.</li> <li>7. Two abstracts in AHSC (2003, 2004) regarding the HEPSAB has been submitted, while 2 proposals have been developed.</li> </ol>
(3) Production of HBsAg test kits as trials	<ol style="list-style-type: none"> <li>1. Two (2) people received partial training on generation of monoclonal antibodies against antigens.</li> </ol>

<sup>4</sup> Operational costs for the TCTP in Blood Safety derives from non-Project resources. Facility, equipment and Counterparts are provided from this Project.

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Activities as per PDM	Actual Achievement
	<p>2. However, trial kits have not been produced because of unavailability of purified HBeAb and Experts to guide the process. Discontinuation was also due to universal shift in testing methods for infectivity and activity from HBeAg to HBV DNA during this phase</p>
(4) Establishment of technology to prepare HIV type 1&2 synthetic peptides	<p>1. One proposal approved by KEMRI SSC and ERC (SSC No. 779). 2. One person is training in Tokushima University in Japan for 5 months on the preparation of HIV-1/2 synthetic peptides.</p>
(5) Development of agglutination kits, incorporating HIV-type1 and type2 antigens	<p>1. One person was trained locally for the development of agglutination kits. 2. An agglutination kit for HIV-1/2 (KEMCOM) was developed, and 180 kits (36,000 tests, 2 batches) have been produced as a trial. 3. Two hundred and seventy-five samples (263 from STI clinics, 12 from western Africa) have been tested, and 4 and 5 kits were provided to NASCOP and to KEMRI/AMREF, respectively, for an evaluation. Moreover, application of KEMCOM for practical use has been submitted to the Ministry of Health for evaluation, awaiting the results on approval. 4. One abstract was presented regarding KEMCOM at AHSC in 2004.</p>
(6) Giving advice for the distribution of the kits to hospitals through MOH and other organisations such as AMREF	<p>1. An office (marketing unit) with a marketing officer, 2 assistants and necessary office equipment has been established. 2. Nine visits (two per year) made with each visit covering all BTCs and 35 public hospitals for follow-ups after training. Ten mission hospitals were also visited. 3. Production of pack inserts, posters, branded pens and note pads have been done and the advertisement for a distribution agency has been placed for more aggressive marketing.</p>
(7) Development and implementation of training curriculum for blood safety in Kenya through Mid-Level Manpower Training Programme and In-Country Training Programme.	<p>1. Three curricula (one HIV/PA, one VH) were developed. 2. Ten districts-focused workshops were held. 3. Three hundred and fifty-two personnel (both in country and in other African countries through TCTP) were trained on blood safety.</p>
(8) Development of a serum bank for HIV and hepatitis B virus positive blood	<p>1. Two BTCs were involved (National Blood Transfusion Centre of Nairobi and RBTC, Nakuru) for the development of a serum bank. 2. Forty, 52 and 12 units of HIV-1, HBV and HCV positive blood, respectively, were stocked at KEMRI at the time of evaluation. 3. However, HIV-2 positive blood could not be obtained. 4. One, two and none units of HIV-1, HBV and HCV positive sera, respectively, have been aliquoted and cryopreserved.</p>
(9) Monitoring of window period for improved quality of blood for transfusion	<p>1. One proposal approved by KEMRI Scientific Steering Committee (SSC) and Ethical Review Committee (ERC) (SSC No. 870). 2. One Counterpart was trained for 11 months at Kanazawa University in Japan. 3. National Blood Transfusion Centre is collaborating on this theme,</p>

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Activities as per PDM	Actual Achievement
	<p>and 3,000 samples negative for HIV antibody were collected, while 814 blood samples have been tested by Polymerase Chain Reaction (PCR). As a result, PCR positive blood sample were found none for HIV-1/-2, and 9 for HBV and 1 for HCV.</p> <p>4. One abstract have been accepted by AHSC in 2005. A manuscript is currently in preparation for publication.</p>
(10) Application of IFA for confirming HIV sero-status	<p>1. Four KEMRI personnel were trained in-house on preparation of antigen slides, and are now able to confirm for HIV using Immuno-fluorescent Assay (IFA).</p> <p>2. Eighty-two participants were trained through TCTP.</p> <p>3. Regular stock of 200 slides was prepared, and 1 paper has been published on the application of IFA for confirming HIV sero-status.</p>
(11) Strengthening of technical capacities to isolate HIV and check for HIV antigen	<p>1. One person is currently undergoing 5-month training on isolation of HIV and checking for HIV antigen at Osaka and Kanazawa in Japan.</p> <p>2. Three cell-lines are kept for the use of HIV isolation, and 83 isolation trials were performed.</p>
(12) Monitoring the epidemic of HIV strains	<p>1. Four Counterparts went through training programmes ranging 11 months ~ 3 years at Kanazawa University on monitoring the epidemic of HIV strains. Another 4 KEMRI personnel received in-house training on the same issue.</p> <p>2. Eleven sites {Nairobi (1), Northern Kenya (5), Rift valley (3), and western Kenya (2)} were established for the collection of samples.</p> <p>3. One thousand and five hundred thirty blood samples {Nairobi (530), Northern Kenya (600), Rift valley (200) and Western Kenya (200)} were collected.</p> <p>4. Of the collected samples, 896 have been analysed, and percentage distribution of subtypes were obtained (A 50%; C 20%; D 16% and, recombinants 14%).</p> <p>5. Four papers were published in journals and 11 abstracts were presented to ICASA, AHSC, International AIDS Conference (IAC), International Congress on AIDS in Asia and the Pacific (ICAAP), and 3 abstracts have been accepted.</p>
(13) Monitoring of the prevalence/incidence of HCV infection	<p>1. A total of 17,417 samples from blood donors were tested for HCV and 0.9% was tested positive with Murex.</p> <p>2. A thousand and hundred fifty-five clients {766 general patients from Kenyatta National Hospital (KNH) (1.3% positive), 56 liver patients (3.5% positive), 333 drug users (22.2% positive)} were tested for HCV with Murex.</p> <p>3. One hundred and eighty-nine samples were confirmed with Recombinant Immunoblot Assay III (RIBA III), with the result of 3 positive and 53 indeterminate.</p> <p>4. Accordingly, HCV infection rate in Kenya can be estimated less than 0.9%.</p> <p>5. Two KEMRI personnel were trained for 6~7 months at Nagasaki Medical centre in monitoring of HCV infection.</p>

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Activities as per PDM	Actual Achievement
	<ol style="list-style-type: none"> <li>6. One batch of anti HCV kit was produced as a trial.</li> <li>7. Four abstracts on this theme has been submitted.</li> </ol>
<p>(14) Establishing gene diagnosis laboratory of various known types of HIV and hepatitis virus.</p>	<ol style="list-style-type: none"> <li>1. Eleven KEMRI personnel were trained in-house on diagnosis of various known types of HIV.</li> <li>2. Four Counterparts were trained on hepatitis B virus (HBV) &amp; hepatitis C virus (HCV) molecular diagnosis.</li> <li>3. Two laboratories in Nairobi and in Kisumu are being strengthened for the gene diagnosis.</li> <li>4. Two assays (DNA and RNA PCR) have been evaluated, with 10 PCR primer sets: HIV (5); HBV; and HCV (5), have been identified.</li> <li>5. Two abstracts were accepted by AHSC on HIV-related theme.</li> <li>6. A total of 74 samples (Samples from Intravenous Drug Users) were screened, and 38 were found positive for HCV-RNA, while 100 samples (Blood donors) were screened for HBV, and 28 were found positive for HBV-DNA.</li> <li>7. Three abstracts were published on viral hepatitis.</li> </ol>
<p>(15) Monitoring of other blood-borne infections</p>	<ol style="list-style-type: none"> <li>1. One person has been trained in detection of cytomegalovirus (CMV).</li> <li>2. One (CMV) pathogen was screened among one-hundred blood donors sample. However, no CMV in donated blood was found.</li> </ol>
<p>(16) Training of community health educators and conducting community health and conducting community health education (e.g. HIV/AIDS seminars on behaviour change and PMTCT of HIV and HBV) in western Kenya</p>	<ol style="list-style-type: none"> <li>1. One proposal has been approved by KEMRI SSC and ERC (SSC No. 739).</li> <li>2. Thirty-two KEMRI and related personnel received training on community-based HIV/AIDS interventions {24 Community Health Workers (CHWs) and 8 Counterparts}.</li> <li>3. One person was trained for 6 months in data management at Shiga University in Japan.</li> <li>4. Five training curricula developed: 2 for CHW; 1 for both CHWs and Counterparts; and 1 for Counterparts; and, 1 for both opinion leaders and other community members.</li> <li>5. Fifty-six seminars were conducted, with cumulative 3,120 participants as of 7 October 2005 (528 in pilot study, 502 opinion leaders, and 2,094 other community members).</li> <li>6. Seven abstracts have been accepted on this issue.</li> </ol>

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Activities as per PDM	Actual Achievement
<i>Activities under Output 2: The methods for diagnosis, prevention and treatment of opportunistic infections in both adults and children with HIV/AIDS are established with the application and development of traditional medicines.</i>	
(1) Development of appropriate proposals on OIs in both adults and children with HIV/ AIDS in Nairobi and Western Kenya	1. Four proposals were developed on OIs and approved by SSC and currently being implemented as shown below.
(2) Establishment of a cohort(s) of HIV infected individuals in Nairobi	<ol style="list-style-type: none"> <li>1. Cohorts of 76 HIV positive children from Cottolengo homes and of 166 HIV negative children from Thomas Bernardos were established. Analyses of collected samples will be consolidated until the planed completion of the Project.</li> <li>2. A cohort of 300 HIV positive adults from Mbagathi DH was established. However, this cohort was discontinued due to poor follow-up.</li> <li>3. A total of 269 adults were recruited in a cross-sectional study in Western Kenya. The research team has almost completed the target 300, after which the final analyses on prevalence as well as drug resistance will be conducted.</li> </ol>
(3) Regular clinical follow up of AIDS patients to determine the epidemiological profile of OIs	<ol style="list-style-type: none"> <li>1. Seventy-six HIV positive children were recruited to monitor for OIs as in Activity (2)-1.</li> <li>2. Two hundred fifty HIV positive adults were also recruited to monitor for OIs as in Activity (2)-3.</li> <li>3. Eight hundred and eighteen samples were examined (498 Nairobi and 320 Busia) for OIs, among which 271 pathogens were isolated (175 Nairobi and 96 Busia). As a result, 68 patients were suspected with OIs.</li> <li>4. One proposal on opportunistic tumours (OT) was accepted by KEMRI SSC and ERC (SSC No. 900).</li> <li>5. Four areas: health education; recruitment; examination &amp; sample collection; and record keeping, were identified for further training to conduct the research on OT. Eleven (11) personnel were trained (3 doctors, 4 technologists and 4 nurses).</li> <li>6. Twelve thousand and four hundred sixty-five were reached (11,875 females, 590 males) on topics related to cervical cancer through health education seminars.</li> <li>7. Six hundred fifty clients were screened for the cancer of cervix by Pap smear method, and for HPV by PCR. (25% abnormal Pap smear, HPV prevalence 28%)</li> <li>8. Sixty-six percent (452 clients) have come for the results.</li> <li>9. Among the clients screened by Pap smear for cervical cancer, 62 clients were examined by colposcopy and histology, and 11 were confirmed with high degree lesions of the uterine cervix.</li> <li>10. Nineteen abstracts on the issues relating to OIs were presented in national and international forum.</li> </ol>

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Activities as per PDM	Actual Achievement
(4) Designing of preventive and nutritional interventions and assessment of their impact on the incidence of OIs	<ol style="list-style-type: none"> <li>1. All children in both Cottolengo and St. Bernardos homes received well-balanced meals including supplementation (vitamin A).</li> <li>2. Children were monitored on the incidence of OIs using their growth and HIV as a variable. Results are being analysed.</li> <li>3. Two (well-balanced meals and ARVs) interventions were applied to the above children: All children who are HIV positive were on Cotrimoxazole and 2 developed PCP on follow up. Twenty-nine (29) children were clinically treated for TB. 54 Ziehl-Neelsen examinations were done and none was positive. TB cultures were yet to be done.</li> </ol>
(5) Strengthening of laboratory capacities to diagnose OIs	<ol style="list-style-type: none"> <li>1. Eight and five Counterparts received training on special laboratory techniques in Nairobi and in Japan, respectively.</li> <li>2. One Counterpart studied a PhD degree from Kyorin University.</li> <li>3. Three training workshops have been held for the diagnosis of OIs, in which additional 45 technologists from public hospitals were trained at Centre for Respiratory Diseases Research (CRDR).</li> <li>4. Six techniques have been acquired by KEMRI-CRDR Personnel through the above-mentioned training activities. <ul style="list-style-type: none"> <li>■ Techniques on detection of MRSA using PCR</li> <li>■ Culture and identification of <i>Mycobacterium</i>.</li> <li>■ Detection of <i>C. difficile</i> toxins genes using PCR.</li> <li>■ Techniques on culture and identification of mycoplasmas (<i>M. pneumoniae</i>, <i>Ureaplasma</i>)</li> <li>■ Immunoassay for diagnosis of <i>Chlamydia</i> infections</li> <li>■ Detection of Virulence related genes in <i>E. coli</i> by PCR</li> </ul> </li> <li>5. A PCR, safety cabinet, distiller and freezer were provided as new tools for the diagnosis of OIs.</li> <li>6. One laboratory (Centre for Infectious and Parasitic Diseases Control Research (CIPDCR), Busia) has been upgraded for the diagnosis of OIs whilst three (3) other laboratories were strengthened on cytology, histology, and HPV diagnosis.</li> <li>7. Sixteen personnel were trained in-house: five technologists in cytology; five in histology processing (in-house training); two technologists and one doctor on HPV hybridisations; one technologist for five months in Japan; and, two gynaecologists updated on colpo-scopy.</li> </ol>
(6) Establishment of diagnosis and treatment of OIs for children in orphanages with or without HIV/AIDS	<ol style="list-style-type: none"> <li>1. Children from Cottolengo and Thomas Bernardos homes were diagnosed with <i>Pneumocystis carinii pneumonia</i> (PCP), tuberculosis (TB), <i>Pneumococcus</i>, <i>Salmonella</i> infections.</li> <li>2. Major pathogens were isolated from OI study (<i>S.aureus</i>, <i>Salmonella spp</i>, <i>K.pneumoniae</i>, <i>E.coli</i>, <i>Shigella spp.</i>, <i>S.pneumoniae</i> and <i>Candida spp</i>, <i>Proteus spp</i>, <i>P.aeruginosa</i>, <i>C.neoformans</i>, and moulds).</li> </ol>
(7) Development and application of traditional medicine to OIs	<ol style="list-style-type: none"> <li>1. Twenty-six field trips have been undertaken (East, Central and Coast Provinces of Kenya) to collect medicinal plants from their natural habitats), from which fifty medicinal plants were collected and identified.</li> <li>2. Eighty extracts/fractions were screened for in-vitro activity against herpes simplex virus (HSV) and CMV, among which 14</li> </ol>

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Activities as per PDM	Actual Achievement
	<p>medicinal plants were identified as having desired <i>in vitro</i> anti-<i>HSV</i> activity.</p> <ol style="list-style-type: none"> <li>3. Phytochemical profile has been determined in 5 medicinal plants.</li> <li>4. Eight purified compounds obtained from 2 out of the 5 medicinal plants.</li> <li>5. Five extracts/fractions evaluated in-vivo for efficacy and toxicity in murine models.</li> <li>6. Three products were formulated: <i>Carissa edulis</i> 5% &amp; 10% creams, <i>Prunus africana</i> 10% cream and <i>Melia azedarach</i> 5% cream.</li> <li>7. One core Counterpart was trained in Japan for 3 months in 2005. He carried out studies in areas of phytochemistry and herbal medicines at the Tokushima Bunri University in Japan.</li> <li>8. Additionally, the visiting JICA expert trained 3 Counterparts locally on anti-CMV assays in KEMRI.</li> <li>9. Three papers have been published in peer-reviewed journals, as well as one MSc thesis ("A herbal remedy for HSV infection") and 8 abstracts at international conferences (see attachments) were presented on traditional medicine.</li> </ol>

Some items that have experienced delays and changes in directions and the reasons are as below:

1. Production of HBeAg test kits as trials was discontinued due to unavailability of purified HBeAb and Experts to guide the process. Discontinuation was also due to universal shift in testing methods for infectivity and activity from HBeAg to HBV DNA during this phase {Output 1-(2)};
2. Establishment of technology to prepare HIV types 1 and 2 synthetic peptides was delayed due to lack of expression systems {Output 1-(4)};
3. The adult arm of the study on regular follow-up of HIV/AIDS patients at Mbagathi hospital was dropped as a result of poor follow-up status of patients {Output 2-(2), (3)};
4. Designing of preventive and nutritional interventions and assessment of their impact on the incidence of opportunistic infections was discontinued due to the lack of orientation on the focus of research {Output 2-(4)}; and,
5. Clinical studies against HSV and CMV on those newly developed products from medicinal plants have yet to be started, due to difficulty in obtaining primate models. Plans and discussion with the Institute for Primate Research is being implemented {Output 2-(7)}.

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### 3.3. Results of Outputs

*OUTPUT 1: HIV/AIDS and viral hepatitis diagnosis system also including other blood-borne infections, for blood safety is established with widespread utilisation of quality assured blood screening kits.*

#### 3.3.1 Observed Outputs relating to Blood Safety

Output for the blood safety component is achieved, with MOH's decision to purchase HEPCELL II for use in all the BTCs. The technique to diagnose HIV type 1&2 has also been acquired, and an HIV diagnosis kit is being developed in-house. Details on achievements are described below.

At the outset of the Project, technical capacity has already been in place to produce hepatitis B screening kit (HEPCELL II) as well as HIV-type 1 screening kit (PA-1) at KEMRI-Centre for Biotechnology Research and Development (CBRD)/Centre for Virus Research (CVR). Under this phase, the Project mainly focused on further strengthening production and development aspect of the blood safety team in order to ensure quality of HEPCELL II and PA-1 kits, as well as development of other blood screening kits for viral hepatitis and for both HIV types 1&2. As a result of on-site technical guidance and orientation by long-term and short-term Experts, sufficient capacity has been established to produce quality-assured HEPCELL II and PA-1 kits, and some essential techniques has been acquired to develop and produce other blood screening kits, namely, for HEPsAB (HBsAb) and KEMCOM (HIV types 1&2).

Such achievement has been recognised by both Kenya and Japan, which is evident from the Grant Aid awarded by the Japanese government to construct a production plant for blood screening kits at KEMRI in 2004. KEMRI Production and Marketing Unit is currently in the process of hiring a production manager with experience in the private sector, appointing a distribution agency, as well as negotiating approval for sales in Tanzania and Uganda. Marketing to private hospitals will start after the plant has met quality compliance.

Furthermore, through organising training on blood screening kits by KEMRI-CBRD/CVR in collaboration with the National Blood Transfusion Centres, good working relationships has been established between KEMRI and provincial, district hospitals as well as national and regional BTCs. Sufficient capacity has also been built within KEMRI-CBRD/CVR to train health personnel on blood safety. This network of collaboration resulted not only in a follow-up system of production kit where it has been used, but also in a future prospect to benefit KEMRI in turn, to secure samples for research/surveillance use as well as for the quality assurance of HEPCELL II and PA-1 kits.

Adequate expertise, training opportunities provided not just a few, but wider range of Counterparts in varied forms (local and in Japan), availability of well-equipped laboratory, critical mass of devoted and trained personnel at KEMRI-CBRD/CVR through the past Japanese cooperation all contributed to attainment of the said achievements. Japanese Experts also played instrumental role in facilitating and securing the overall research needs i.e. operational funds, scientific work and linkage between KEMRI and JICA officials.

Some tasks are remained for completion, either during or beyond the Project period: 1) KEMCOM has yet to resolve the problem of non-specific reaction, to obtain approval from the Ministry for its

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practical application and distribution, and, subsequently, finding a feasible market; and, 2) Monitoring of produced batches is still weak at KEMRI.

Some factors were pointed out through group exercises and questionnaire as slowing down the progress: 1) bureaucratic procedures that bind KEMRI administration, which limited prompt and aggressive marketing, and, 2) poor motivation among the production team due to slow promotion and poor remuneration despite profits the team has brought to the institute.

### **3.3.2 Observed Outputs relating to basic research on HIV, viral hepatitis and other blood-borne infections**

Outputs for research activities on HIV, viral hepatitis and other blood borne infections will have been achieved, as most of the techniques and skills for research activities are acquired, and most research activities have produced results and/or been awaiting their completion.

The Project under current phase continued providing various forms of training opportunities to several Counterparts of different positions in KEMRI-CVR on basic research techniques on HIV and viral hepatitis, including individualised training in Japan, on-site technical guidance training and orientation guided by long-term and short-term Experts, and presentations of research results to national and international forum. The Project also mobilised JICA and non-JICA resources for seven (7) Counterparts to obtain PhD and MSc degrees from the HIV group. Financial and material support for research activities is also provided by the Project. As a result, the CVR laboratories are capable to establish molecular framework for HIV, conduct surveillance of HIV/HCV/HBV for different strains circulating in the country, conduct gene diagnosis of hepatitis, and support quality production of particle agglutination (PA) kits. The Kisumu Centre for Vector Biology and Control Research (CVBCR) laboratory also developed gene diagnosis. Local HIV-1 isolates sequences were also accepted and deposited in the Genbank. The team also contributed to blood safety programme through communicating results of confirmatory testing of BTC bloods at KEMRI to relevant authorities. Research function of the centres was also strengthened, which is evident from the number of abstracts presented (19) at local/international conferences.

Several factors were identified in the group exercise that promoted the achievement in research: 1) Critical mass of skilled personnel were available, again, from efforts in prior phases; 2) Technical support and commitment of JICA Experts and Counterparts, enhanced by the "coupling method" of CPs and Experts, facilitated focused and quality research; 3) collaboration with laboratories in Japan provided analyses beyond the capacity of KEMRI laboratories; 4) collaborative working relationship with BTCs, public Hospitals secured collection of samples; 5) Improved KEMRI budget allocation system as well as the assignment of the Project Coordinator facilitated faster disbursement of operational funds and improved communication and decision making practices; 6) Worldwide focus and attention on the HIV/AIDS research motivated Counterparts to engage in research activities; and, 7) Collaboration with other Japanese ODA schemes enabled Counterparts to obtain Higher diploma, PhDs and MSc.

Some tasks remained to be completed under this component: 1) Gene diagnosis laboratory of hepatitis is yet to be established; 2) Advising on ways to manage blood donated during window period is still to be completed; and, 3) the technique of producing peptides of HIV-1/2 to support development and

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production of a HIV types 1&2 detection system, as well as HIV culture and phenotyping is yet to be acquired.

Some of the factors that were identified as inhibiting factors for achievements are administrative / managerial whilst others are influence of external factors: 1) insufficient duration of stay by some Short-term Experts, who could not complete what they initiated, and thus limited technological expertise was obtained by the Counterparts, 2) delay in purchasing materials for research due to lengthy bureaucratic procedures in Kenya, 3) communication problems that decreased efficiency in technical transfer, and, 4) general expensive costs for HIV basic research.

### 3.3.3 Observed Outputs relating to Public Health Education

On the whole, the Outputs have satisfied the expectations, as human and technical capacities in conducting community-based interventions, including data management, among stakeholders were established, and as strong indication was observed in changing behaviours of residents in intervened areas.

Since its commencement of activities in the mid 2003, the Project has been successfully implementing public health education activities in Kisumu (Nyanza Province) and Busia (Western Province), though limited to several villages in six sub-locations as intervention sites (covering 45,695 residents living in 123 km<sup>2</sup>), and 2 sub-locations as control sites. Budget spent on activities till date was 6,352,219 Kshs., about 140 Kshs. per resident, 1,058,703 Kshs. per sub-location.

Sufficient technical capacity has been established among the teams in Kisumu and Busia in the area of community-based interventions that aims at bringing about attitudinal and behavioural changes. Eight Counterparts at KEMRI-CVBCR (Kisumu) and at KEMRI-CIPDCR (Busia) as well as twenty-four 24 Community Health Workers (CHWs) employed for this purpose, have been equipped to introduce and operate socio-behavioural interventions with regards to HIV/AIDS in rural communities, both through pre-organised training programme as well as through experiencing community-based activities. Additionally, one KEMRI-CIPDCR person has been trained in data management for analysing and stocktaking effectiveness of such interventions.

Post intervention studies revealed that participants' knowledge on the basic facts about HIV/AIDS has increased from 82.6% at the baseline (May ~ October 2003) to 95% after the first seminar. Awareness on risky traditional practices has been increased: At the time of the baseline, 11.5% and 27.3% raised polygamy and wife inheritance, respectively, as a risky practice to contract HIV, while after the first seminar, the rate increased to 24% and 88%, respectively. Participants also came to recognise other practices, such as early marriage, festivities which end up in sexual intercourse, and circumcision /scarification with unhygienic instruments as risky. Moreover, percentage of participants who sought Voluntary Counselling and Testing (VCT) services has increased from 13% to 20% after the first seminar. There are also strong indications in behaviour change, in that the use of condoms have increased from 15%(n=34) to 25% (n=59) in Kisumu, and from 25% (n=59) to 41% (n=115) in Busia after the second seminars. Additionally, increase in number of VCT visits was observed in intervened areas after the third seminars, from 8% (n=17) to 13% (n=46) in Kisumu and from 10% (n=23) to 28% (n=77) in Busia<sup>5</sup>.

<sup>5</sup> In total, Kisumu, Busia, Bondo and Siaya Districts has 7 Divisions, 36 Locations and numerous Sub-Locations with the size of

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One of the major factors that can explain the observed gradual shifts to behavioural changes despite short intervention period is that in some of the communities, free ARV therapy was made available at several VCT centres since 2002 supported by several non-government organizations (NGOs). This not only have given some hope for PLWHAs, but also eased many other community members to accept and face the epidemic. Many good practices were also raised by the implementation team that enhanced the effectiveness of the intervention: 1) the baseline survey that provided general view and rich contents to intervention strategy; 2) eagerness among community leaders and members to do something about the “national emergency”; 3) ample and patient persuasion and orientation of chiefs and opinion leaders on pertinent issues prior to approaching the larger segments of community; 4) varieties of interactive learning methods/techniques applied that promoted participants’ mutual- and self-understanding (free discussions, mixed age/sex groups, testimonies by People Living With HIV/AIDS, dramas and dances, etc.); 5) curricula developed for different role players in the intervention; 6) dedication of the team especially the Principal Investigators and CHWs; 7) acquisition of VCT skills by CHWs that could readily satisfy the increased demands for services; 8) KEMRI and JICA’s provision of operational funds, especially vehicles and fuel being readily available; 9) that CHWs were drawn from the communities that eased rapport making and communication; and, 10) MOH personnel’s cooperation in seminars, etc.

Both external and internal factors have limited the level of achievement: 1) limited access to the VCT centres in some communities discouraged the seminar participants to go to the centres; 2) weak Public Address System hampered reaching wider community members; 3) community members were used to receiving incentives from NGOs to attend seminars while the Project did not have such provision; and 4) short period and reduced budget allocated for the activities (August 2003~: 15 months).

*Output 2: The methods for diagnosis, prevention and treatment of opportunistic infections in both adults and children with HIV/AIDS are established with the application and development of traditional medicines.*

### **3.3.4 Observed Outputs pertaining to capacity development on diagnosis of OIs**

OI studies led to the establishment of technical and infrastructural capabilities for diagnosis and research on OIs, especially bacterial and fungal infections. This is essential for understanding the spectrum, control and management of OI pathogens and the formulation of plant extracts with potential use in management of opportunistic viral pathogens. Descriptions are presented below.

Under this component, major outputs were summarised into two parts, namely, 1) strengthening research capacity on OIs that could contribute to prevention and treatment of OIs, as well as strengthening diagnostic capacity to support the said OI research within KEMRI, and 2) development of formulations using traditional medicinal plants for treatment of OIs.

*1) Research capacity building on OIs at KEMRI:* Through various on-site guidance and packaged training, founded upon existing capacity in CMR and CRDR through quite a long-standing cooperation by JICA, capacity in diagnoses of different types of OIs have increased, in KEMRI-CRDR/CMR/RHRU laboratories as well as Busia-based CIPDCR laboratory. Ability to develop sound research proposals were also strengthened, with four (4) research proposals being developed

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and accepted by SSC, while results of research have been summarised into abstracts for presentations and shared at national/international forum. Details in capacity built in each laboratory is as follows:

- KEMRI-CRDR/CMR is now able to diagnose different bacterial and fungal pathogens that support research on OIs, such as an ability to detect *Chlamydia* using PCR and MRSA (one case). Mortality among HIV infected cohorts reduced from 3 in 56 to 1 in 65 as research activities included clinical diagnosis and prescription of medication. Additionally, One senior research officer has obtained a PhD in microbiology. For the team to investigate into the comparison of drug resistance among HIV infected and non-infected groups, more data bank is required and thus it could not be completed. Confirming the significance of *Pneumocystis carinii* pneumonia (PCP) and TB in HIV infection is also an unfinished task.
- KEMRI-CIPDCR has established sufficient functions to support OI research: Collaboration with VCT services as well as built-in HIV confirmatory testing enabled OI research team to establish stable cohorts for OI research. Several laboratory staffs have also acquired diagnostic techniques on OIs and has been accumulating data on OI profiles.
- KEMRI- Reproductive Health Research Unit (RHRU) has increased their ability to screen and confirm cervical cancer, through screening HIV positive cohorts. However, establishment and maintenance of HPV typing is yet to be completed. Establishment of research collaboration with University of Kanazawa on cancer of cervix are identified as remaining challenge.

Nevertheless, there is a long way towards reaching the initial target to determine general incidence and types of OIs among HIV infected population, both in adults and in children.

2) *Development of formulations for treatment of OIs:* At KEMRI-Centre for Traditional Medicine and Research (CTMDR), fourteen (14) medicinal plants were found to have *in vitro* anti-herpes simplex virus (HSV) activity, five (5) extracts were found with *in vitro/vivo* anti-viral activity, and three (3) formulations active against HSV were developed. Through such undertakings that were supported with operational funds, required equipment/materials and guided by Experts, technology on screening of natural products for anti-viral activity has been strengthened at CTMDR. However, clinical evaluation of 3 formulations against HSV and CMV in non-human primate could not be conducted due to difficulty in obtaining primate model, which is being solved through discussion with Institute of Primate Research.

Factors that contributed the above achievement include: 1) availability of a thick layer of skilled staff through various training schemes and again, through capacity built in previous phases, 2) availability of equipment and consumables for research activities, 3) good working relationship between Counterparts and experts, and among Counterparts, 4) though extent varies individually, commitment and excellent work by Experts, 5) provision of treatment to clients in Mbagathi, which was instrumental and retaining cohorts, 6) collaboration with AMPATH and NASCOP, and, 7) multi-donor support to KEMRI.

Factors that seemed to have limited the level of Outputs were raised both through individual questionnaires and through group exercise. Some relates to adequacy of Inputs required, while others are circumstantial: 1) shortage in time spent by short-term Experts for the Counterparts to be conversant with the acquired skills, 2) shortage in skilled technical staff in some section such as in

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mycology laboratory or in data analysis, 3) weak maintenance of equipment, and, 4) difficulty in establishing adequately controlled cohorts that fits specific research purposes.

The following factors were also raised through a questionnaire and group exercises as affecting the smooth running of the Project: 1) poor motivation due to sense of unfairness felt by some Counterparts towards JICA's regulations (e.g. lack of scheme to support local MSc/PhD training, unavailability of multi-year allocation status for research funds) and 2) poor local procurement system that caused delay and compromised quality of materials. There were times, when due consultation with the Counterparts were neglected by some Experts in determining/changing the direction of research activities, which also affected morale among a research team.

### 3.4. Results of Project Purpose

*Project Purpose: Research and production capacity, human resources and human/information network at KEMRI, in collaboration with other institutions in Kenya such as NPHLS, is developed in order to strengthen effective control of the targeted diseases (HIV/AIDS, viral hepatitis and opportunistic infections).*

Overall, the Project has made major contributions in enhancing KEMRI in four aspects, which hold potential to strengthen effective control of the targeted diseases.

One aspect is ability to conduct laboratory-based research activities in HIV, viral hepatitis and OIs at KEMRI, especially at seven centres involved with the Project.

The second is technical capacity to produce quality blood screening kits and ensure appropriate use. These achievements were made not only through support under this phase, but also through a long-standing human, material and financial investments to strengthen KEMRI as a high-level medical research institute. It has also started a new initiative to directly benefit the community - the PHE team in western Kenya is on their way in finding an effective socio-behavioural intervention model on HIV/AIDS that are appropriate in rural setting in western Kenya.

The third aspect is human resource capacity development, which also involves a major and visible step forward made during this phase that KEMRI started to disseminate their skills and knowledge to benefit other Kenyan and regional counterparts.

The fourth aspect is a human / information network of KEMRI. Details of achievement in research capacity, production capacity, human resources development and human / information networks are described below.

#### 3.4.1 Research Capacity

High level of research technology, comparable to global standard, has been established through structured and on-site training and guidance on research itself, and on compiling and summarising results. Number of proposals submitted to SSC has been on increase in the past years, with their contents greatly improved in quality<sup>6</sup>. This is attributed to Project's supporting a series of research activities involving a number of Counterparts, as well as mobilisation of resources for Counterparts to

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<sup>6</sup> Interview from a member of SSC.

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pursuit degree-based training in Japan. Another major contribution from the Project (and past cooperation) was its investment into advanced diagnostic laboratory equipment. KEMRI's own efforts to establish supporting structures to accommodate researchers needs, e.g. encouraging pursuit of research-based degrees, revision of the guidelines, and making SSC a monthly meeting instead of every two months, also explain such advancement. Some of concrete results were described in the followings.

Presentations to national, regional and international conferences / meetings occupies most of the results with 86 abstracts prepared and presented (See Table 3-1 and ANNEX XI). This includes research results that were carried on from the last phase. Entries to journals are rather limited, with 14 articles in the area of HIV and OI. Several theses were also published for PhD and MSc. Potentials to source research funds have increased to a certain degree, by an increase of PhD and MSc holders in different sections, although this requires additional and rigorous efforts.

Furthermore, KEMRI is now one of the few laboratories that could conduct surveillance on major infectious diseases, and serves not only as a regional reference laboratory for measles, yellow fever, rift valley fever and polio but also as a part of the national surveillance team for the epidemic. Ministry of Health sees KEMRI as an institution to conduct surveillance of different strain of HIVs, but also to monitor extent of drug resistance among ART clients.

**Table 3-1: Number of Publication and Abstracts**

	HIV (OT,PHE)	Viral hepatitis	OI (TM)	TOTAL
Journal Publications	7	0	7	14
Abstracts	45	14	27	86

*Source: Documentation prepared by KEMRI/JICA Project, October 2005*

The Project also dealt with a research topic in social and behavioural aspects, with promising results. Preliminary statistical analyses found increase in use of condoms as well as visits to VCTs. Interviews from CHWs, a community leader and a participant also revealed the sense of acceptance and their felt need to take actions on HIV/AIDS as their own issue to tackle. The team initially wished to have achieved to empower and build enough capacity of the communities in selected sites to carry on the PHE activities on their own, which is yet to be achieved. This is due to some delays, including the reluctance amongst some communities to accept HIV/AIDS-related activities at the very first stage. As such, although enough capacity have been established in KEMRI-CVBCR and KEMRI-CIPDR to strategise, program and conduct socio-behavioural interventions at community levels, the team has yet to reach the critical mass of residents in the intervened communities in order for the members to feel confident enough to keep up the activities and changes on their own.

### 3.4.2 Production Capacity

The underlining principle of the Project in strengthening production capacity of affordable blood screening kits is to establish a sustainable supply system. For this reason, HEPCELL II, which was developed in the last phase, is designed for domestic production by local technical professionals, and with locally available materials. Thus, establishing capacity at KEMRI in production of HEPCELL II

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means developing resilience against fluctuation in supply of foreign blood-screening products, which are currently provided from externally sourced funds.

Quality assured and low-cost HBsAg screening kits, HEPCELL II, has been fully produced using locally available materials. Having established sufficient technical capacity to produce the kits, KEMRI has also strengthened quality control of blood screening kits through establishment of panel sera for HIV, HBV and HCV, and negotiating a link with AMREF and NPHLS for external quality assessment. Continuous efforts are also made to secure the market for the kits as well as to ensure proper usage of the kits through training. A total of 228 technologists and technicians from public hospitals and KEMRI (106 for HEPCELL II and 122 for PA-1), as well as 141 from the other countries in the region (through Third Country Training Programme) were trained in use of HEPCELL II and PA-1 kits. As a result, HEPCELL II has been utilised in all the BTCs in the country as well as in some public hospitals. Additional achievements are described as follows.

- A total of 1,710 HEPCELL II kits and 485 PA-1 kits were produced (June 2001~June 2005) respectively, among which 2,120 HEPCELL II kits and about 365 PA-1 kits were distributed to the Ministry of Health<sup>7</sup> for their subsequent dissemination to BTCs, public hospitals and mission hospitals.
- From 2001 to date, total of 171,925 blood units were screened by HEPCELL II in BTCs, and 72,500 samples were assayed by PA-1 in Provincial General and District Hospitals.
- KEMCOM, KEMRI-developed blood screening kit for HIV types 1&2, has been produced and currently been evaluated by the Ministry of Health.

On the other hand, demand for PA-1 kit that screens HIV type 1 has been reduced since 2002 as per WHO recommendation to utilise the screening kits that screens for both HIV types 1&2. Additionally, the above achievements may not be retained for long, as Kenya Medical Supply Agency (KEMSA) through external funds is procuring and distributing an alternative imported test kit for hepatitis B, which may jeopardise stable demands for HEPCELL II kits in the future

Factors that contributed the above performances include: 1) reliable quality of HEPCELL II kit in confirming results (specificity of 99%), 2) publicity and marketing efforts such as newspapers that increased the knowledge of the kit, and, 3) good relationship between MOH-NPHLS and KEMRI that secured use of kit in BTCs.

Some factors hold keys to the sustainability of Project's achievements, including 1) user preference that prefers less cumbersome methods to RTHA methods, coupled with rapid as well as ELISA kits procured and provided through external funds, 2) whether external resources could accommodate purchase of KEMRI-produced kits, and, 3) regular purchase order from MOH. Capacity building in management of production process, as well as securing necessary materials required for production in the upcoming new production unit will also be essential in the future.

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<sup>7</sup> The amount includes those, which were produced in the prior phase of the Project. A thousand and six hundred (1,600) kits were supplied to MoH through the National Public Health Laboratory Service (NPHLS) and 50 kits were supplied directly to mission hospitals.

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### 3.4.3 Human resources Development

As mentioned in 3.4.1, KEMRI has significantly strengthened its human resources capacity in the past several years. It has a “critical mass” of health research scientists, with 80 scientists with PhD degrees, 140 scientists with Masters and Bachelors degree and 250 highly trained and skilled technical staff. The Project had tremendous contribution in this regard, through numerous and various training opportunities provided during 25 years of cooperation. During this phase, three people have undergone and two obtained the PhD from Universities in Japan, through Japanese funds mobilised by the Project. Sponsorship for attending regional and international conferences also provided valuable exposure to KEMRI researchers.

Moreover, during the past 5 years, KEMRI has started to disseminate its knowledge / skills through training activities for regional and national laboratory professionals and other stakeholders (see ANNEX XII). For instance, OI team has contributed to improve techniques and knowledge on laboratory diagnosis of OIs in public hospitals. Roughly 70% of laboratory staff in targeted public hospitals (All the Provincial General Hospitals (PGHs) and 16 District Hospitals (DHs)<sup>8</sup>) has been reached through training workshops on laboratory techniques and diagnoses in microbiology. Through follow-up site visits by the KEMRI OI team of trainers, further strengthening of PGHs and DHs, especially on GLP programme, is identified as a future challenge. Support from the Ministry of Health in sponsoring the DHs and PGHs staff for training enabled diffusion of capacity beyond KEMRI to health service providers. Counterparts has also promoted their knowledge and skills through lectures / presentations at various occasions as shown below (Table 3-2).

Table 3-2: Number of Lectures performed by KEMRI Counterparts

	HIV (OT,PHE)	Viral hepatitis	OI (TM)	TOTAL
Lectures	22	56	8	86

Source: Documentation prepared by KEMRI/JICA Project, October 2005

### 3.4.4 Human/information network at KEMRI

Through engagement in research and training activities, KEMRI has enhanced not only an inter-laboratory network within KEMRI but also strengthened ties with other Kenya-based laboratories and clinical service providers such as AMREF, NPHLS, BTCs, PGHs and DHs. KEMRI-CTMDR staff are networking with stakeholders with medicinal plants research groups such as National Universities, International Research Institute and National Herbarium. Such ties are further strengthened through KEMRI's provision of training to those institutions, and in turn benefits KEMRI in obtaining samples for its research activities.

Networking with national bodies for infectious control programme has also started, with a research officer at KEMRI-CCR being a member of the task force in reproductive health and cervical cancer, and a research officer at KEMRI-CVR being a member of the task force in ARVs and in the National Guideline of HIV. MOH recognises KEMRI as a reliable laboratory for monitoring HIV drug resistance as well. These hold great potentials for KEMRI to promote use of medical research as well as in influencing policies in the future.

<sup>8</sup> There are eight PGHs and 78 DHs in the country. Some District Hospital does not provide laboratory diagnoses on OIs.

Furthermore, international and regional network has also been enhanced, with five regional and eleven international collaborators. The Project substantially contributed to such development: 1) Sponsoring attendance of selected KEMRI researchers in AHSC for dissemination and exchange of health research information with other African and international Counterparts; 2) Strengthening technical collaboration with the Suez Canal University (Egypt); and 3) Technical cooperation and exchange of scientists with Kanazawa University and Kyorin University in Japan for intensive training of selected researchers.

### 3.5. Contribution to Overall Goal

***Overall Goal: Research and Control programs of infectious diseases are strengthened in Kenya.***

Research undertakings of the Project have a good potential in being utilised and influencing policies, guidelines and ways to improve health service deliveries in Kenya. Among the list of Project-supported publications and presentations, key informants from National AIDS Control Council (NACC) and KEMRI/CDC considered all of them are either useful (87%, 91%) or very useful (18%, 9%) for use in policy/guideline formulations, while a CDC/KEMRI person considered one abstract and six publications were referred to. There are a few indications that KEMRI's advisory role has been increased. National Guideline for VCT (2001) cites "*VCT: improved access for the poor through integrating same day services into public primary health care clinics,*"<sup>9</sup> compiled by a Counterpart of the Project. KEMRI researchers are member of the Reproductive Health-Cervical Cancer Task Force as well as NASCOP-ARV Task Force. One of the research undertakings on monitoring cervical cancer among HIV positive clients by Counterparts provided justification for the HIV positive clients to be covered under the Programme in the "National Cervical Cancer Prevention Programme (July, 2005)." Additionally, identification of important agents in use in opportunistic diseases provided useful information for potential clinical interventions. Furthermore, enhanced capacity for diagnosis of opportunistic fungal/bacterial pathogens holds a key to understand the spectrum and drug susceptibility of opportunistic pathogens. Hence, the knowledge can contribute to control of OIs. Similarly, identification of potential plant extracts could be utilised in the treatment of OIs.

KEMRI, through production and assurance in its proper use of low-cost and quality blood screening kits, has made a valuable contribution to assuring blood safety in Kenya. HEPCELL kit has been in use in all the BTCs<sup>10</sup> since 1991, and approximately 300,000 unites have been screened for hepatitis B till date. Taken the positive rate of 3.4%, it had prevented 10,900 cases of potential transmission through blood transfusion during the past 14 years, and 5,845 during this phase. With the establishment of the production unit, KEMRI will have capacity to meet the annual national demand of approximately 200,000 blood units. The production unit can also accommodate regional demands.

With the PA-1 kit, 72,500 cases of positive blood were assayed by trained District and Provincial Hospital staff for diagnostic purposes. Whether the BTCs will select application of ELISA kits as the first screening alternative --- supplies of which depend on availability of external resources --- or continue the utilisation of HEPCELL II will rest upon decision by the relevant government authorities. With such significant contribution of KEMRI in assuring blood safety, however, transmission of HIV through blood

<sup>9</sup> A presentation made at the 13<sup>th</sup> International Conference on AIDS, Durban in 2000.

<sup>10</sup> Prior to the BTCs separation from the Provincial Hospitals, HEPCELL has been in use in the Provincial Hospitals.

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transfusion accounts for approximately 5% of all the new transmissions<sup>11</sup>, compared to other mode of transmission such as sexual intercourse and vertical (mother to child) transmission. Hence, the impact it could make to the epidemics would naturally be limited.

Cases of such impact actually observed were less frequent than desired. Several aspects could explain reasons for this limited impact. One aspect is weak coordination mechanism for research in HIV/AIDS and other infectious diseases in the country, as well as weak linkage between MOH and KEMRI, despite efforts made by KEMRI staff in this regard. Another aspect is that although advisory role to the Ministry is part of KEMRI's mandate, improvement and review of policies themselves are given less focus, as, naturally, the core interest of KEMRI researchers are scientific research that be presented and valued in international science arena. On the same note, MOH officials in policy / guideline formulations tend to focus on current situation and issues of the health systems on the ground rather than consuming scientific journals and abstracts from conferences.

This situation is expected to change, however, as in the "Kenya National HIV/AIDS Strategic Plan (2005/6 – 2009/10)," KEMRI is assigned a role of 1) establishing research coordination mechanism on HIV/AIDS, 2) identifying research priorities and financing arrangement for research activities to formulate a national HIV/AIDS research strategy, and, 3) establish and update an inventory of HIV/AIDS research, and, 4) establishing a mechanism for the dissemination of research findings. The first NASCOP Research task force has met in October 2005.

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<sup>11</sup> The percentage is taken from a brochure published by MOH/NASCOP

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### 3.6. Implementation Process

#### 3.6.1 Formulation of Master Plan and Project Design Matrix

At the formulation stage, various forms of consultation had taken place, involving stakeholders in the previous phases of the Project, during the Preliminary Study (9~22 April 2000) as well as the Short-term Study (20~26 August 2000). Formulation process accommodated two factors: Continuation of research activities from the last phase and integration of Hashimoto initiatives into the continued infectious diseases Project. Thus, formulation team integrated two components, namely, establishment of an international training centre for Parasitic Control, and capacity development of infectious control and research, under one project management structure, although each component had separate PDMs.

#### 3.6.2 Change of Master Plan and Project Design Matrix

After two years from the commencement, the Project was split into two, between the components of strengthening infectious diseases research/control and of establishing a regional centre for parasitic diseases control, at an occasion of a visit by the Project Management Consultation Mission on March 2003. A major change was less in the content of the PDM but rather on the Project management and administration structure, as the original R/D had a separate PDM for the infectious diseases component. Changes in contents of the Master Plan were also made at this occasion, as shown in Figure 3-2.

As the Project develops, and objectives of the component for parasitic diseases control became more defined, it has become evident that managing two components with different orientations under one structure is not adequate. It was an anonymous decision of all the stakeholders to split the Project into two separate entities. Therefore the change is considered appropriate.

At the time of the split, the logicity of the Plan (PDM) has been reviewed, and some modification was made, so that it could best accommodate on-going research activities and organise groups of activities with similar orientations. However, objectively verifiable indicators could not be reviewed thoroughly at the time of the said Management Consulting Mission, perhaps due to preoccupation with the splitting process. As a result, logical sequence as well as performance indicators was not adequately established at Outputs, Project Purpose and Overall Goal levels, leading to weak outcome-orientated activities.

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**\*\*\* Underlined parts were omitted at the revision\*\*\***

**MASTER PLAN as per R/D (12 April 2001):**

**Overall Goal:** Research and control programmes of infectious and parasitic diseases are strengthened in Kenya and its neighbouring countries through capacity building of research activities and human resources development at KEMRI and related institutions.

**Project Purpose:** Human resources and human/information network of institutions in Kenya and its neighbouring countries are developed in order to strengthen effective control of the targeted diseases (HIV/AIDS, viral hepatitis, opportunistic infections, parasitic diseases)

**Output 1:** An HIV/AIDS and viral hepatitis diagnosis system for blood safety (testing and confirmation) is established with widespread utilization of quality assured blood screening kits

**Output 2:** The methods for diagnosis, prevention and treatment of opportunistic infections in both adults and children with HIV/AIDS are established with the application and development of traditional medicines.

**Output 3:** Strengthening of KEMRI as a centre for international parasitic disease control for targeted diseases (Malaria, Geohelminths, Schistosomiasis and Filariasis)



**\*\*\*Italicised and bolded parts were added at the revision\*\*\***

**UNDER the REVISED PDM (21 March 2003):**

**Overall Goal:** Research and Control programs of infectious diseases are strengthened in Kenya through capacity building of research activities and human resources development at KEMRI and related institutions, *such as NPHLS.*

**Project Purpose:** *Research and production capacity*, human resources and human/information network at KEMRI, *in collaboration with other institutions in Kenya such as NPHLS*, is developed in order to strengthen effective control of the targeted diseases (HIV/AIDS, viral hepatitis and opportunistic infections).

**Output 1:** An HIV/AIDS and viral hepatitis diagnosis system, *also including other blood-borne infections*, for blood safety (testing and confirmation) is established with widespread utilization of quality assured blood-screening kits.

**Output 2:** The methods for diagnosis, prevention and treatment of opportunistic infections in both adults and children with HIV/AIDS are established.

Figure 3-2: Change of the R/D Master Plan to the current PDM

### 3.6.3 Adequacy of Implementation Process

At an earlier stage, one Chief Advisor was allocated for both infectious and parasitic diseases components, whose specialty was more on parasitic diseases control. The Project also started without long-term experts to lead through OI and viral hepatitis. Hence, with the exception of research activities that continued from the last phase, the infectious diseases component was not implemented smoothly until 2003. As the long-term Experts for all the areas started their activities, momentum was built for intensified progress. After the separation from the other component (parasitic diseases control) until April 2005, Chief Advisor was not assigned at once. Although several provisions were made to address this issue, it was felt that the Chief Advisor was needed at the ground to sustain leverage over coherence and momentum in field-level operations, and oversee performance-based monitoring.

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Project management structure is considered mostly adequate both by Counterparts and Japanese Experts despite the fact that the Joint Coordination Committee (JCC) has not been conducted annually as stipulated in R/D. This is perhaps an improved communication among stakeholders through the regular progress review meetings put in place since October 2003. With the new JICA reporting guidelines in place, KEMRI core Counterparts and JICA Experts have organised a progress review sessions regularly, in which all the activities under the Project conducted in different KEMRI research centres were shared, consolidated and presented with recommendations. This forum dealt with regular monitoring of progress in light of PDM.

Securing sufficient time of Counterparts for the Project activities was often difficult. This has been largely influenced by KEMRI's institutional policy to encourage its staff members to pursue further degrees. Counterparts are often unavailable for study and annual leaves. Two researchers who received intensive training from JICA have also left the Project for other research projects or other organisations. This is related to a difference in incentive provisions between JICA and other cooperation agencies, which provide supplementary salary and allowances. JICA by regulation cannot cover this expense. Relating to this point, on the extent of motivation towards Project activities, 46% answered "rarely" or "more of less," in a questionnaire survey. Monetary incentives (16), technical and/or degree training (15), equipment and logistics support (8) were cited among the means to maintain Counterparts' motivation.

There was a case in which the lack of clarity over the ownership of data stirred conflicts among researchers, which required a significant amount of mediation efforts and energy of several Project stakeholders.

More than 70% of Counterparts said they rarely had communication problems with Japanese Experts, but eight specified that there was an issue of language proficiency. Experts were instrumental in networking researchers working under one theme across departments in KEMRI by initiating regular meetings and evaluation reviews, which was very much appreciated.

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