CHAPTER-2
INDIAN COUNCIL OF MEDICAL RESEARCH

National Institute of Malaria Research

Highlights

- **NIMR did not conduct Mosquito Fauna Surveys in the malaria endemic areas to know the prevalence of different mosquito species and to develop cost effective strategies to control malaria.**

  (Paragraph 2.6.1)

- **Malaria parasite bank established at a cost of Rs. 1.13 crore from the funding of Department of Bio-technology (DBT) was taken over by NIMR in October 1998 without the approval of Ministry of Health and Family Welfare. The objectives of malaria parasite bank were not fully achieved.**

  (Paragraph 2.6.2)

- **Of the 74 projects with potential for technology development, NIMR developed only two technologies during 2001-02 to 2005-06 and could not transfer any of these two technologies.**

  (Paragraph 2.6.5)

- **Collaboration among NIMR, National Vector Borne Disease Control Programme and State Programme Officer was inadequate.**

  (Paragraph 2.6.3)

- **In extramural projects, there was partial achievement of objectives (four projects), lack of follow up action (three projects) and midway closure (one project).**

  (Paragraph 2.6.4.1 and 2.6.4.2)

- **One third of the 51 scientists of NIMR were not involved in any project for a period ranging from one to five years.**

  (Paragraph 2.6.6)

- **Research project files containing preliminary survey/study progress reports and final reports and comments of monitoring bodies and action taken reports were not maintained for intramural projects.**

  (Paragraph 2.6.4.4)

- **Only 15 training programmes for State government health officials were conducted over a period of five years. No annual action plan for conducting training was prepared.**

  (Paragraph 2.6.8)

Summary of Recommendations

- *The fauna survey needs to be conducted for all areas of malaria incidence and ecological zones in a phased manner.*
- *Activities of Malaria parasite bank needs to be strengthened for effective utilisation of the facility for malaria research.*
- *NIMR should identify the areas where technologies could be transferred and target should be fixed for each field station of NIMR in coordination with appropriate authorities. Efforts should also be made to ensure patenting and commercialisation of the technologies developed.*
- *NIMR should strengthen its activities in the areas where malaria cases were higher in collaboration with State Programme Officers for effective control of malaria in the country.*
- *NIMR should formulate and adopt appropriate procedure for project-wise budgeting of intramural projects for effective financial control and monitoring.*
- *NIMR should undertake appropriate remedial measures to achieve the objectives of the projects fully, fix targets for health assessment and to undertake necessary follow-up action on the conclusion of the projects.*
- *NIMR should document research project files adequately as per available best practices in leading scientific institutions.*
- *There should be logical distribution of research projects to scientists with broad timeline and results peer reviewed before publication.*
- *Proper guidelines for achieving the objective of human resource development and preparation of annual action plan for the training and achievement thereof needs to be prepared.*

2.1 Introduction

Malaria is a serious public health problem all over the world and about 30 to 50 crore cases and 15 to 27 lakh deaths occur annually. Malaria is a vector[1] borne disease caused by a parasite[2] of genus Plasmodium and transmitted by anopheline mosquitoes. There are about 58 species of anopheles mosquitoes of

[1] Insects which transmit disease from one host to another
[2] The organisms which depend on others for food, shelter and survival

which only six are major vectors of malaria in India. The other vector borne diseases in India are dengue, chikungunya[3], filariasis[4] and kala-azar[5].

Malaria Research Centre (MRC), one of the permanent institutes of the Indian Council of Medical Research (ICMR) was established in 1977 and was renamed as National Institute of Malaria Research (NIMR) in November 2005. The primary task of NIMR is to find short term as well as long term solutions and support the National Vector Borne Disease Control Programme (NVBDCP) of the Ministry of Health & Family Welfare (Ministry) for control of malaria through basic, applied and operational field research. This apart, one project namely "Integrated Diseases Vector Control (IDVC) of malaria, filariasis and other vector borne diseases" was assigned to NIMR in 1985 by the Ministry to undertake research on basic aspects of transmission dynamics of malaria, evaluation of new insecticides and support NVBDCP. NIMR has 10 field stations in different states to conduct field operations to control malaria. However the major executing agencies for control of malaria are the State Governments.

NIMR is financed mainly by grants received from the Ministry through ICMR. Further, NIMR receives funds from other government departments and World Health Organisation (WHO) for specific schemes and from the Ministry for implementation of plan scheme namely IDVC through ICMR. NIMR also receives funds for consultancy services and contract research. During 2001-02 to 2005-06, against the revised estimates of Rs. 17.68 crore, Rs. 23.31 crore and Rs. 20.24 crore under plan, non-plan and IDVC plan heads, NIMR spent Rs. 12.02 crore, Rs. 21.92 crore and Rs. 18.98 crore respectively.

In India, malaria ranks at number one among vector borne diseases. The annual number of malaria cases is around 20 lakh for the last 10 years in India. In 2005, there were 13 lakh cases with 646 deaths reported. A study conducted by NIMR during 2004-05 however suggests that the actual number of cases of malaria and deaths is significantly higher than those reported by the State Health departments.

In the Tenth Five Year Plan (2002-2007), NIMR highlighted the primary task of finding short term as well as long term solutions to the problem of malaria through the following objectives:

[3] dengue and chickungunya are caused by viruses and transmitted by aedes mosquitoes
[4] filariasis is caused by a parasite and transmitted by culex and mansonia species of mosquitoes
[5] kala-azar is caused by *Leishmania donovani* parasite transmitted by sand flies

- Research activities on vector biology and control, genetics, cellular and molecular biology and epidemiology[6];
- Conducting mosquito fauna[7] survey in different zones of India to establish present day bio-diversity;
- Maintaining and utilising malaria parasite bank;
- Undertaking Geographical Information System (GIS) based study at micro level to digitise thematic maps and prediction of malaria using satellite remote sensing;
- Facilitating transfer of technology to state/district health departments and organising malaria control demonstrations in endemic areas; and
- Developing health education material and organising activities like trainings, health camps, exhibitions, audio-visual shows and meetings with the community.

NIMR undertakes intramural projects (i.e. projects/schemes funded by ICMR) and extramural projects (i.e. sponsored by other Government Departments/agencies and International agencies like WHO). NIMR implements one IDVC project having several sub-activities. It also provides consultancy services and executes contract projects. The details of these projects undertaken and completed during the period from 2001-02 to 2005-06 are indicated below:

TABLE 1

Type of project	Projects undertaken	Projects completed	Projects ongoing
Extramural	89	61*	28
Intramural	37	28	9
IDVC sub activities	89	69	20
Total	**215**	**158**	**57**

**** Includes one project of mid-way closure.***

2.2 Scope of Audit

The present performance audit covering the period from 2001-02 to 2005-06 was undertaken to review the outcome of activities of NIMR in the areas of project planning, implementation, monitoring, technology development and transfer, impact assessment and follow up action. The activities of mosquito

[6] The science which deals with transmission dynamics of disease in population
[7] Distribution of animal life in a particular region

fauna surveys, utilisation of malaria parasite bank, imparting trainings, organising health camps, exhibitions and meetings with the community were also reviewed. For the sake of completeness, periods prior to 2001-02 were also covered wherever pertinent and relevant.

Out of 158 completed projects, 46 projects i.e. 24 extramural (11 sponsored projects, seven contract/collaborative projects, six externally aided projects), seven intramural and 15 IDVC sub activities were selected by Audit. Further, eight out of 57 ongoing projects were also selected by audit. These projects were selected on the basis of their monetary value and significance of thrust areas of research and development (R&D) activities.

2.3 Audit Objectives

Performance audit of NIMR was conducted with a view to assess whether:

- NIMR conducted mosquito fauna surveys in the areas of high malaria incidence, malaria outbreaks and in all ecological zones of the country for planning sustainable vector control strategy for effective control of malaria;
- The envisaged objectives of the malaria parasite bank as a national repository were achieved;
- Effective co-ordination existed amongst NIMR, State Health Departments and NVBDCP for formulation of projects and sharing of feedback for further research and development activities;
- Proper system of formulating proposal, approval, progress reporting, monitoring of projects, evaluation/review of research results, proper documentation of research files existed;
- Technologies were developed and transferred;
- Trainings/workshops were organised for raising awareness of malaria;
- Adequate consultancy and collaborative projects were undertaken; and
- System of proper utilisation of scientific manpower in research projects existed.

2.4 Audit Criteria

The following criteria were adopted for assessing the performance of NIMR:

- Basis of selection of sites for mosquito fauna surveys and action plan to cover all high malaria prevalent areas in their surveys in different zones of the country during different seasons;
- Targets and achievements in collection, characterisation and adaptation of samples of malaria parasites from different zones of the country in order to meet the requirements of scientific community;
- Adherence to guidelines in regard to collaboration with State Government authorities and NVBDCP in implementing projects and getting feedback for effective control of malaria;
- Formulation of projects with specific aims and objectives after conducting feasibility study/survey, achievement of objectives, monitoring and evaluation and their documentation;
- Impact assessment of technology development and transfer;
- Achievement of trainings/workshops to be organised with reference to action plan for raising awareness on malaria and malaria control technologies;
- Adherence to procedures for consultancy and contract services; and
- Existence of norms for the number of projects that were to be undertaken by scientists at any one point of time.

2.5 Audit Methodology

The audit plan including the audit objectives and audit criteria was discussed in the Entry Conference held on 6 July 2006 with NIMR/ICMR. Project files, records and minutes of meetings of monitoring bodies were examined and discussions were held with the Director, NIMR and Project Investigators/Scientists concerned. The audit team visited villages/field sites where technologies were transferred by the NIMR's field stations, i.e Bangalore and Haridwar. The audit findings were presented and discussed with NIMR/ICMR in the Exit Conference held on 1 February 2007.

2.5.1 Acknowledgement

The co-operation of NIMR during the entry conference, course of audit and exit conference was satisfactory and the same is acknowledged with thanks.

2.6 Audit Findings

As a result of test check of records, audit observed inadequate mosquito fauna surveys, system deficiencies like non-documentation of project files in

intramural projects and IDVC projects and non-adherence of procedure in contract projects. Audit also observed partial achievement of objectives in sponsored projects including malaria parasite bank, externally aided projects, non-receipt of feedback information, lack of follow up action, besides midway closure. This apart, inadequate technology transfer and non-commercialisation of technology, improper utilisation of scientific manpower, inadequate system of publication of research results and organising of trainings were also noticed. These are all discussed in detail under appropriate topics of the succeeding paragraphs.

2.6.1 Inadequate Mosquito Fauna Surveys

One of the objectives of NIMR was to maintain parasite and vector repositories as a national facility for conducting research to control malaria in the country. In this context, mosquito fauna survey (survey) was essential to identify the prevalence of different mosquito species, especially vectors, in various parts of the country and during different seasons. The criteria used by NIMR for selection for surveys and collection of isolates[8] were the areas where malaria outbreaks had occurred and areas of high malaria endemicity. 450 malarial districts were identified by NIMR with varying prevalence of malaria in the country. The research activities for NIMR approved by the Ministry under the Tenth Plan (2002-07) provided for collection of isolates from 20 districts in the country located in four ecological zones.

Audit observed that States of Maharashtra, Karnataka, Madhya Pradesh, Andhra Pradesh, Gujarat, Tamil Nadu, Rajasthan, Orissa, Chhattisgarh and West Bengal were the top ten states where malaria positive cases reported were high. Malaria outbreaks had occurred in the districts of Kheda, Bhuj, Anand and Surat in Gujarat, Betul and Raipura districts of Madhya Pradesh, Haridwar district of Uttaranchal, Mazbat circle of Darrang, Sonitpur, Tinsukia, Lakhimpur and Golaghat districts of Assam and Bangalore district of Karnataka during 2001-02 to 2005-06. Thus, these districts were to be surveyed on priority basis.

Audit examination disclosed that:

- NIMR had not maintained any database to indicate districts that were surveyed so far in order to prepare the future survey plan effectively.
- Only seven districts of four states of top ten malaria affected states were covered in the surveys to be conducted during Tenth Plan.

[8] Single species of parasites picked up from a natural populations and established in culture

- None of the districts where malaria outbreaks occurred during 2001-06 were covered in the surveys under Tenth Plan.

- Of 20 districts targeted to be covered, the surveys were conducted in 18 districts as of January 2007. In two districts, survey had not been completed as yet.

This indicated that NIMR had not properly focused on high malaria prevalence areas for conducting surveys.

NIMR stated in December 2006 that there was no project exclusively for surveys and those undertaken so far were part of other projects undertaken in different ecological zones of the country. Further, it stated that it is not necessary to conduct survey in each and every district of India since sample from different ecological zones would provide the desired information. NIMR also stated that it was planning to submit a detailed project for funding to Department of Biotechnology / Department of Science and Technology/ Ministry of Environment and Forests for carrying out surveys to cover more districts in arid/semi arid and deciduous wet zones. The reply is not acceptable since as per the criteria used by NIMR, it was required to collect isolates from areas of high malaria endemicity. NIMR's reply confirms that it had not adequately planned to conduct surveys in highly malaria-affected states even though conducting fauna surveys was an important objective of NIMR.

However, ICMR stated in January 2007 that there was no target of 20 districts to be covered by March 2007 and that further surveys would be planned in a phased manner. The contention that there was no target for 20 districts to be covered is not correct as the target had been clearly mentioned in Tenth plan document of NIMR.

Recommendation

The mosquito fauna survey needs to be conducted in the highly malaria affected states and districts. NIMR should also plan to conduct mosquito fauna survey in all the ecological zones of the entire country in a phased manner.

2.6.2 Malaria Parasite Bank

Maintaining parasite and vector repositories as a national facility was one of the objectives of NIMR. In this context, the malaria parasite bank (Bank), a national resource for malaria research, was established during the year 1992-

93 at a total cost of Rs. 1.13 crore funded by the Department of Biotechnology (DBT). Its major objectives were:

- To collect and cryopreserve[9] isolates of human plasmodial[10] species, with an emphasis on parasites Plasmodium falciparum[11] and Plasmodium vivax[12];
- To characterise[13] isolates for drug sensitivity and genetic markers; and
- To supply biological material to the scientific community.

The observations of audit with regard to the functioning of the Bank are given below:

2.6.2.1 Non-approval of Malaria Parasite Bank Project

NIMR took over the malaria parasite bank in October 1998 from DBT and continued it as an extramural project with the funding of ICMR on ad hoc basis. A sum of Rs. 44.03 lakh had been incurred by NIMR during 1998-99 to 2005-06 on the project. A proposal to include the activities of the malaria parasite bank as a regular activity of NIMR was sent to the Ministry in March 2000. However Ministry's approval has not been received as of December 2006. Despite "maintaining and utilising malaria parasite bank" being one of the major objectives of NIMR as per Tenth Plan, delay of more than six years on the part of the Ministry to approve the project as a regular activity of NIMR was not justified.

ICMR stated in January 2007 that approval of its executive committee had been obtained for continuation of this project as an extramural project beyond five years with its funding on ad hoc basis. Therefore, there was no need to send the extension proposal to the Ministry. The reply does not address the audit comments related to the approval of the Ministry to include the activities of Malaria Parasite Bank as regular activity of NIMR. It is not related to extension of the project as contended by ICMR.

[9] Preservation of the malaria parasites (with cryopreservatives/ cryoproctent) in living condition at ultra low temperature (i.e. in liquid Nitrogen (-196^0 C)
[10] Species of genus Plasmodium causing malaria in human beings
[11] Plasmodium falciparum (P. falciparum) – Species of malarial parasite
[12] Plasmodium vivax – (P.vivax) – Species of malarial parasite
[13] Assessment of the character of a given parasite

2.6.2.2 Partial achievement of objectives

(i) The criteria of collection of malaria isolates had been one of the objectives in the malaria outbreak affected areas and high malaria endemicity. NIMR, in its long term plan proposed to cover all the states for collection of the isolates for mapping of genetic variation in malaria parasites. Under the short term plan, collection of isolates from out break affected areas was envisaged.

NIMR collected 636 species of Plasmodium falciparum, 68 species of Plasmodium vivax and five species of Plasmodium malariae[14] from 13 different states of the country during 1992 to 2006. However, among the top 10 states affected by malaria, only one district each of Andhra Pradesh, Chhattisgarh, Karnataka and Madhya Pradesh, two districts in each of Gujarat, Orissa, West Bengal, Assam, Tamil Nadu and three districts in Rajasthan were covered for collection of mosquito species upto April 2006. Maharashtra, which was one of the top ten states of malaria incidence, was not covered for collection of mosquito species. This apart, none of the districts except Anand and Kheda districts of Gujarat, where malaria outbreaks had occurred during 2001-02 to 2005-06 were covered for collection of mosquito species. Audit also observed that NIMR did not fix annual targets for the collection of isolates.

(ii) All the 709 species collected were to be cryopreserved, characterised for anti-malaria drug sensitivity and adapted[15]. It was observed that while all the 636 species of Plasmodium falciparum were cryopreserved, only 257 species were characterised and 180 were adapted. The rest of the species were not cryopreserved, characterised and adapted although these were collected between 1992 and 1996. Further, isolates characterised for anti-malarial drug sensitivity (257 species) were required to be further characterised/analysed to find out molecules which could be used as vaccine or as molecules for drug targeting. However, it was observed that these activities were not carried out by NIMR.

While accepting the facts, NIMR stated in July 2006 that due to non-availability of parasites, inadequate staff and non-availability of funds from ICMR, isolates from other states could not be collected and would be collected as early as possible. NIMR also stated that parasites collected could not be characterised fully due to technical reasons and target could be fixed only after

[14] A species of malarial parasite
[15] Cultivated in-vitro for a period of time

re-establishing the parasite bank in the new building at Pappan Kalan, New Delhi (expected to be completed by June 2007). However, ICMR stated in January 2007 that during the last five years, malaria outbreaks were rare in the country. Therefore, there was no scope of collecting isolates from such areas. ICMR further stated that characterisation/ adaptation had been done as per availability of human blood and sera as procuring blood and serum was difficult. Reply is not tenable as malaria outbreaks occurred in 13 districts of five states during 2001-02 to 2005-06 but the isolates were collected only in two districts. The reply also confirms that NIMR failed in its objectives of collecting and characterising of isolates for drug sensitivity and genetic markers.

(iii) Supplying biological material to the scientific community was also another objective of malaria parasite bank. Scrutiny revealed that NIMR supplied biological materials to 54 organisations during 2000-2006. However, it was observed that no guidelines for the supply of biological materials and for obtaining feedback from the Institutes to whom the species were supplied for research were formulated. Therefore, no feedback could be obtained from the institutes/organisations.

ICMR stated in January 2007 that biological materials were supplied for collaborative projects for which published results were in the nature of a feedback. The reply needs to be viewed in the light of the fact that procedure for supply of biological material and direct feedback from recipient institutes is essential to improve the services of the Bank, the quality of biological material maintained by NIMR and to serve as a reliable resource for further research to control malaria.

Thus, the objectives of the malaria parasite bank, established at a total cost of Rs. 1.13 crore, were not fully achieved 14 years after its establishment.

Recommendation

Activities of Malaria parasite bank needs to be strengthened to ensure effective utilisation of the facility for malaria research.

2.6.3 Inadequate Collaboration with the NVBDCP and State Health Departments

NIMR was required to provide solutions to the technical problems faced by NVBDCP of the Ministry and organise cost effective malaria control demonstrations in endemic areas. NIMR was also required to facilitate transfer

of technology to state/district health departments, to develop health education material and organise activities like health camps, exhibitions, audio-visual shows and meetings with the community in collaboration with the State Governments. In this regard, audit observed that:

2.6.3.1 Absence of action plans/targets

NIMR did not formulate any action plan/fix targets to conduct meetings regularly with the State Programme Officers (SPO). In this regard, NVBDCP also observed in November 2004, that there was no effective collaboration between the NIMR field stations and SPOs due to which the research priority of these field stations was not directed towards area specific needs of the programme. Therefore, NVBDCP issued instructions to NIMR (November 2004) and all SPOs to conduct monthly meetings to identify problematic areas for operational research by NIMR to provide evidence based technical support. However, monthly meetings were not held regularly after November 2004 despite clear instructions of NVBDCP.

NIMR stated in October 2006 that there was no fixed schedule of meetings between its field stations and SPOs. However frequent meetings had taken place. ICMR stated in January 2007 that NVBDCP never observed that there was no effective collaboration between NIMR field stations and SPOs. The reply was not correct as NVBDCP observed inadequate collaboration and ICMR by way of evidence could only produce schedules of some training programmes for one state.

2.6.3.2 Non receipt of feedback

As per the instructions of NVBDCP, NIMR was required to provide feedback of its activities/recommendations to SPOs to chalk out a detailed action plan for priority research areas in the State for improvement in the performance of the programme strategy. As a result of epidemic investigations carried out by NIMR in certain districts of 15 states during 1999 to 2001, field analysis in the context of roll back malaria[16] undertaken during 2000-01 to 2002-03 (expenditure Rs. 24.45 lakh) and investigation of reported deaths due to malaria in the district of Karbi-Anglong of Assam, NIMR made recommendations like strengthening surveillance systems, provide training to medical officers and technicians, establishment of malaria cells and inclusion of syrup medicines for children in the National Drug Policy etc. to SPOs and NVBDCP to improve the effectiveness of the programmes. It was observed

[16] WHO initiative to bring down malaria incidence

that NIMR did not evolve any system for impact assessment or getting feedback from states/NVBDCP.

ICMR stated in January 2007 that a system of obtaining feedback from the NVBDCP will be evolved.

Recommendation

NIMR should strengthen its activities in the areas where malaria cases were higher in collaboration with State Programme Officers for effective control of malaria in the country.

2.6.4 Project Analysis

Test check of 46 completed projects and eight ongoing projects revealed the following:

2.6.4.1 Partial achievement of objectives

There were partial achievements of objectives in three sponsored project whose expenditure was Rs. 83.68 lakh and one externally aided project whose expenditure was Rs. 24.76 lakh. In seven completed intramural projects test checked, it was observed that no project-wise budget was estimated and maintained. Due to non-achievement of the objectives, consequent remedial strategies could not be developed to control malaria despite total expenditure of Rs.1.08 crore. A few sponsored/externally aided projects with significant audit findings are discussed below:

(a) NIMR undertook a sponsored project **"Application of Remote Sensing (RS) & Geographical Information System (GIS) for decision support in malaria control"** in March 2000 and completed it in March 2003 at a total cost of Rs. 15 lakh. The objectives of the project were to map the distribution of India anophelines[17] with reference to ecological parameters, mapping of malaria receptivity in Koraput district of Orissa based on ecological profile and other attribute information, study spatio-temporal[18] evaluation of malaria in reference to recent epidemics: a case of Mewat region (Haryana and Rajasthan). The work was to be done on scale 1:50,000 for district and 1**:**2,50,000 for the state against which the work was carried out using topographical sheet on scale 1**:**60,00,000 resulting in insufficient projection of malaria receptivity and distribution area in the map. Further,

[17] Species of Anophelines in India
[18] Distribution in space time

necessary equipment were not procured for mapping of malaria receptivity and study spatio-temporal evaluation of malaria. This apart, study was undertaken in Mewat region of Haryana only. Thus the objective of preparing thematic maps for ecological parameters which mainly govern the distribution of malarial species - forest cover, rainfall, altitude, soil type and temperature could not be digitised even after an expenditure of Rs. 15 lakh. Thus, prediction of malaria using remote sensing and GIS remains to be achieved.

NIMR stated in October 2006 that when the work was started, the Survey of India was contacted and it was found that topographical sheets on scale 1**:** 50,000 and 1**:**2,50,000 were not available and hence the study was started with the scale 1**:**60,00,000. NIMR further stated that only Rs.15 lakh was made available by ICMR against the sanctioned project cost of Rs. 24.50 lakh. ICMR stated in January 2007 that the scale of 1**:**60,00,000 was taken after discussion with Indian Space Research Organisation (ISRO) experts and that equipment could not be purchased due to non-availability of funds. It further stated that the objective of the study was to cover only Mewat region. The reply is not tenable as the project had been taken up without proper planning and ascertaining the availability of specific topographical sheets. Further, funds were not provided and the state of Rajasthan was not covered as planned.

(b) NIMR undertook a sponsored project **"Process Development for production of a recombinant malaria vaccine based on Plasmodium Vivax Duffy binding protein**[19]**"** in July 2001 and completed it in 2004 at a total cost of Rs. 38.10 lakh. The objectives of the project were to develop protocols for production of Pv rII[20], to characterise Pv rII and test its immunogenicity[21] and to determine the sequence diversity. Scrutiny revealed that toxicology studies were in progress to achieve the objective of testing the immunogenicity of Pv rII. The evaluation of process for consistency and study of stability and potency of Pv rII were yet to be undertaken. Thus, the objectives of the project were not achieved.

NIMR stated in September 2006 that vaccine was produced for clinical trial and the toxicology studies of the vaccine were in progress at Bangalore and final report would be available in October 2006. ICMR stated in January 2007 that the points raised related to the collaborative institute International Centre for Genetic Engineering and Bio-Technology (ICGEB) and that the work of

[19] Protein which can bind to the duffy antigen of erythrocytes
[20] Pv rII – P.vivax region 2: a species of malarial parasite
[21] the property enabling a substance to provoke an immune response

NIMR was completed in 2004. The reply is to be viewed in the light of the fact that NIMR, being the lead centre of the project, should have collaborated with ICGEB effectively and ensured completion of the project and achievement of its objectives.

(c) NIMR undertook a collaborative sponsored project on **"Health impact assessment of Indira Sagar Dam and resettlement and rehabilitation colonies in Sardar Sarover Project (SSP) reservoir impoundment areas in Narmada Valley in Madhya Pradesh"** in 1999 for a period of seven years. The objectives of the project were to (i) raise data on the incidence of vector borne diseases (VBD), (ii) assess the adverse health impact of reservoir in the command area, (iii) assess risk factors related to malaria and other vector borne diseases, (iv) assess the quality of drinking water, and (v) make recommendations for mitigation measures for each component. The project was completed in 2006 after an expenditure of Rs. 30.58 lakh.

NIMR suggested developing mitigating measures like channelisation of pools into the main river, leveling of pools by filling, construction of mosquito-proof houses and spraying pyretheroids[22] as per NVBDCP guidelines to control the vector borne diseases and recommended the use of larvivorous fish[23] in the water stagnation and seepages areas. However, the assessment of adverse health impact of reservoir in the command areas was not undertaken. The microbial contamination in the canal drinking water sources was also not undertaken. Besides, the results of the cross-sectional survey of other vector borne diseases like dengue, japanese encephalitis and filaria conducted in December 2005 and January 2006 were also not recorded. Thus, the health impact assessment was not done fully.

Reply of ICMR in January 2007 stated that there was no delay on the part of NIMR in taking up the project, but did not deal with the issue of impact assessment.

(d) NIMR undertook an externally aided project **"Population genetic analysis of Anopheles culicifacies[24] species-A**" in May 1999 and completed it in October 2004 at a total cost of Rs. 24.76 lakh. The specific objective of the project was to develop molecular markers, microsatellite for species-A, to construct a genetic map[25] and to screen species-A populations from north,

[22] A group of insecticides
[23] A fish eating larvae of mosquitoes
[24] Anopheles culicifacies – vector of malaria
[25] A graphic representation of the arrangement of genes or DNA sequences on a chromosome

north-west and southern India for polymorphism[26] and hitherto unnoticed genetic barriers.

WHO reviewed the progress report in September 2003 and observed that no comments appeared in the report on the significance of the results or what the next steps of the project would be. WHO also observed that physical mapping by in-situ hybridisation[27] had been initiated but the procedure needed to be optimised. However, the final report of the project did not disclose whether the recommendations of WHO made in September 2003 were complied with by NIMR. Thus, it is evident that the objectives were not fully achieved despite an expenditure of Rs. 24.76 lakh.

ICMR stated in January 2007 that the technique was standardised and could be used as foolproof technique for studies on in-situ hybridisation. It further stated that more studies could not be conducted as the term of project had been over and that the objective of the project was to ascertain the diversity in the genetic structure of the population. The reply is not tenable since the objective was to screen species-A population to construct a genetic map.

2.6.4.2 Lack of follow-up action

In the following projects, follow up actions as suggested in the final report were not undertaken resulting in non-fulfillment of objectives of the projects:

(a) NIMR completed a project titled **"Phase II evaluation of Bifenthrin[28] 10 per cent and Fipronil[29] 80 per cent WDG[30] indoor residual spraying for malaria vector control in India"** in March 2000 in collaboration with the WHO Pesticide Evaluation Scheme (WHOPES), after incurring an expenditure of Rs. 71.94 lakh. The project aimed to test efficacy of Bifenthrin 10 per cent and Fipronil 80 per cent WDG against An. culicifacies, the most important vector of malaria in rural India to determine the best application dose for the future. The trial was to be carried out in an area in central Gujarat where An. culicifacies was the major vector. The completion report revealed that since Bifenthrin was highly effective against mosquitoes, houseflies and other domestic insects, more detailed studies such as nerve conduction test, lung function test, haematological and urological tests were required to be conducted for the spray men and occupants of sprayed rooms. However, no follow-up action was taken on the conclusion of the project resulting in non-

[26] many forms of any species
[27] to make hybrids of any animal/plant species at their native location
[28] Name of insecticide
[29] Name of insecticide
[30] WDG – Water Dispersible Granules of bio-larvicide

achievement of some of the important objectives of the project.

ICMR stated in January 2007 that follow up action was not part of the objectives. The reply is not acceptable as one of the objectives of the project was to record perceived side effects on spray men and occupants of the sprayed rooms, which was not achieved.

(b) NIMR undertook a project **"Operational activity for the assessment of therapeutic efficacy of chloroquine[31] and/or sulfa pyrimethamine[32] in uncomplicated falciparum malaria in Orissa, Rajasthan and Goa"** funded by WHO from 2003 to 2005 at a total cost of Rs. 9.60 lakh. The specific objective of the project was to evaluate therapeutic efficacy of chloroquine and/or sulfa-pyrimethamine in P.falciparum malaria in India using standard methodology.

The final report revealed that in Orissa, the treatment of chloroquine was not effective. All patients responded to the second line drug namely sulfa-pyrimethamine (SP). As chloroquine was still effective in Rajasthan and was ineffective in Goa, immediate change of drug policy was suggested. Further, therapeutic efficacy of SP after its introduction was required to be monitored to ascertain resistance. The suggestions have however not been implemented so far.

NIMR stated in September 2006 that further monitoring could be taken as a new project after approval by Scientific Advisory Committee. The reply confirmed that no project proposal to this effect was prepared even after completion of the project in 2005. However, ICMR stated in January 2007 that the study would be planned only if state authorities or NVBDCP requested NIMR. The reply is not acceptable since no follow up action was taken to monitor the therapeutic efficacy of SP resulting in non achievement of the objectives of the project fully.

(c) NIMR undertook a project **"Assessment of therapeutic efficacy of anti-malarial drugs against uncomplicated P. falciparum malaria in West Bengal as part of Indo-Nepal cross border activity"** in October 2003 and completed it in February 2004 at a total cost of Rs. 18 lakh. The objective of the project was to assess therapeutic efficacy of chloroquine and sulfa-pyrimethamine (SP) in uncomplicated P.falciparum malaria in district Darjeeling of West Bengal.

[31] Anti malarial drug
[32] Anti malarial drug

The study proved that the first line drug chloroquine was no longer effective in this border district. Although the drug policy had been changed in some PHCs of the state, the project report suggested that there was an urgent need to review the policy for additional sites also. To prevent further spread of resistance, issue of introduction of artemisinin[33] based combination therapy should be seriously considered and debated. The conclusion of the completion report revealed that there was a need to monitor the efficacy of SP for 28 treatment days to detect late failures. It was observed that NIMR did not take follow up action on the conclusion of the project.

ICMR stated in January 2007 that deployment of additional staff for two months was required. It further stated that the main objective of the study was achieved. The reply revealed that no follow up action was taken by NIMR to monitor efficacy of SP to detect late failures.

Recommendation

NIMR should undertake appropriate remedial measures to achieve the objectives of the projects fully, fix targets for health assessment and to undertake necessary follow-up action on the conclusion of the projects.

2.6.4.3 Midway closure of Project

NIMR undertook a project entitled **"Genetic polymorphism of T-helper cell[34] epitopic regions of circumsporozoite protein of Plasmodium falciparum isolates from India: Relevance for Vaccine development"** sponsored by the Council of Scientific and Industrial Research (CSIR) between January 2002 and January 2005 at a total expenditure of Rs. 8.69 lakh. The objectives of the project were to study the extent of genetic variation in T-helper cell and its relevance for vaccine development.

Although the research fellow associated with the scheme left NIMR in November 2004, NIMR undertook the same project as a new project in the name of same research fellow in February 2006 for a period of three years at a total cost of Rs. 16.56 lakh sponsored by Department of Science and Technology (DST) which was irregular. NIMR received Rs. 8.50 lakh from DST in March 2006 and discontinued the project after incurring an expenditure of Rs. 0.33 lakh in August 2006 as the research fellow had already left NIMR, with the result that the important work of vaccine development

[33] plant based anti malarial drug
[34] a kind of white blood cells derived from thymus and are able to provide defence mechanism to the body

could not be undertaken. Thus, the entire expenditure of Rs. 9.02 lakh (Rs. 8.69 lakh + Rs. 0.33 lakh) proved unfruitful. NIMR did not surrender the balance of Rs. 8.17 lakh as of September 2006.

NIMR stated in October 2006 that the two projects had relevance for vaccine development and accepted that the project funded by DST could not be completed.

2.6.4.4 Systems Deficiencies

(a) Non-maintenance of project-wise budget in intramural projects

In seven completed intramural projects test checked, it was observed that no project-wise budget was estimated and maintained. NIMR booked expenditure of the projects in its common heads like research contingencies, travelling allowance and pay and allowances. In the absence of project-wise budgeting, the control management exercised on individual projects was not clear and the fruitfulness of the expenditure for each project could also not be vouchsafed in audit.

ICMR stated in January 2007 that project-wise budgeting for intramural projects would be done for effective financial control.

(b) Inadequate Project Documentation

(i) Intramural Projects/IDVC sub-activities

Test check of records of seven completed projects, 15 IDVC sub-activities and two on-going projects revealed that documents like project proposal and approval of the project by the competent authority and comments of monitoring body alongwith action taken report, evaluation of the final report of the project were not kept in the project files. Only a copy of the progress report or final report was kept in the project file.

In the absence of proper documentation of project files, it could not be ascertained as to whether (i) feasibility study/survey was conducted, (ii) the activities planned in the plan document were covered, (iii) justification for extension of project, if any, was presented and approved by the competent authority, (iv) comments of monitoring body were acted upon and proper implementation of the project as a whole were carried out, (v) objectives of projects were achieved, and (vi) follow-up action on the conclusions/suggestions made in the reports was promptly taken. In the absence of these documents and their review, the adequacy of management control cannot be vouched.

In this connection, it is pointed out that other scientific and research organisations like Indian Council of Agricultural Research (ICAR) had prescribed formats for presentation of project proposal, annual progress report of the project and final report for strict compliance. No such instructions/ procedures/ norms were in existence in NIMR.

ICMR, while accepting the fact, stated in January 2007 that project files would be maintained properly in future for appropriate financial controls.

(ii) Contract Projects

In terms of guidelines of contract research issued by ICMR, for every contract project, approval of ICMR is to be obtained after approval of SAC of NIMR by furnishing project details in the prescribed format. Also, an agreement was required to be signed with the sponsor. Scrutiny of four contract projects revealed that neither the approval of SAC or ICMR was obtained nor was agreement signed with the sponsors of the project.

ICMR stated in January 2007 that the matter would be reviewed.

Recommendations

- *NIMR should formulate and adopt appropriate procedure for project-wise budgeting of intramural projects for effective financial control and monitoring.*
- *NIMR should document research project files adequately as per available best practices in leading scientific institutions.*

2.6.5 Inadequate technology transfer and commercialisation

NIMR, during 2001-02 to 2005-06, completed 61 extramural projects, 28 intramural projects and 69 sub-projects/sub-activities of IDVC project. Out of these, 74 projects were identified by NIMR as potential for technology development and transfer. However, it was observed that NIMR developed only two technologies and evaluated eight technologies during 2001-02 to 2005-06.

2.6.5.1 Inadequate technology transfers

Neither of the two technologies developed during 2001-02 to 2005-06 was transferred resulting in unfruitful expenditure of Rs. 36.62 lakh**.** NIMR replied in October 2006 that there was no need for transfer of technology for the research work that had been published. The contention of NIMR was contrary to its own identification of 74 projects as potential for transfer of technology

and as one of its objectives to control malaria in addition to publishing research papers.

Inadequate transfer of technologies developed prior to 2001, was also observed in following cases:

(i) The Field station of NIMR at Bangalore transferred the technology **"Use of larvivorous fish to control malaria"** in the year 2002-03 to four districts in Karnataka, namely, Tumkur, Hassan, Chickmagalur and Chitradurga. Although the technology was effective, it was not transferred in the whole state, nor was it transferred to the state of Andhra Pradesh (A.P.) which is also to be covered by this field station. Thus, transfer of technology was confined only to the areas around Bangalore.

ICMR stated in January 2007 that the State Government was planning to extend the technology transfer in a phased manner throughout the State.

(ii) Field station of NIMR at Goa undertook a project '**Bio-environmental Control of Mosquitoes in Mormugao Port – A Transfer of Technology Project'** in February 1998 with the primary objective to transfer bio-environmental control technology to the Mormugao Port. In 2001, bio-environmental control technology was transferred to the Port medical and civil engineering departments. Port personnel, including doctors and engineers were trained (November 2001 to Feb 2002) in the field by NIMR on all the necessary technical aspects of the programme. The impact assessment carried out (August 2001 to Feb 2002) showed that the number of malaria cases in 2001 was almost double the cases of the year 2000 (from 19 in 2000 to 36 cases in 2001). The project was completed in January 2002 at a total cost of Rs. 29.09 lakh sponsored by Mormugao Port Trust, Goa. However no further impact assessment was carried out by NIMR after completion of the project in January 2002.

ICMR stated in January 2007 that the increasing trend was due to transmission period from 2001 to 2002 when the technology was transferred to the Port.

2.6.5.2 Non-commercialisation of technology

During 2001-02 to 2005-06, NIMR patented two technologies of which final patenting was under process for one technology and the other technology was not commercialised as yet as discussed below:

NIMR undertook an in-house project "**Studies on larvicidal properties of leaf and seed extract of Solanum nigrum"** in 2000 and completed it in 2002.

The objective of the project was to assess the mosquito larval efficacy of different extract of plant part of Solanum nigrum[35]. The report produced to audit revealed that Solanum nigrum seed powder, when mixed in water for spray, was effective in causing 100 per cent mortality in the mosquito larvae. Accordingly, the technology **"use of Solanum nigrum extract as larvicidal agent"** had been patented in June 2004. However, this technology has not yet been commercialised for use of malaria control.

NIMR stated in October 2006 that commercialisation of technology would be done with an accepting sponsor, for which attempt would be made. The reply showed that no efforts had been made to commercialise the technology though the technology was patented in 2004. ICMR stated in January 2007 that efforts would be made to commercialise the technology.

Recommendation

NIMR should identify the areas where technologies could be transferred and target should be fixed for each field station of NIMR in coordination with appropriate authorities. Efforts should also be made to ensure patenting and commercialisation of the technologies developed.

2.6.6 Improper utilisation of scientific manpower

Scrutiny of the records of the projects undertaken by all 51 scientists of NIMR during 2001-02 to 2005-06 revealed the following differential in the number of projects being handled by scientists:

- Two scientists did not undertake any project during the last five years;
- 15 scientists were not having any project for a period ranging from one year to four years;
- Nine scientists were having only one project each;
- Eight scientists were handling two projects each; and
- 14 scientists were engaged in four or more projects, of which seven scientists were handling seven to 11 projects at one time in a year.

A system for monitoring of involvement in the projects and percentage of time spent for each project by the project investigator and project associate as it exists in the other organisation like Indian Council of Agricultural Research (ICAR), did not exist in NIMR, resulting in some of the scientific manpower

[35] Raspberry plant weed

remaining idle. Thus, one third of the 51 scientists of NIMR were not involved in any project for a period ranging between one to five years. This indicated that the distribution of projects among scientists was not rational or optimised.

ICMR stated in January 2007 that the issue needed to be discussed and finalised in the SAC meeting.

Recommendation

There should be logical distribution of research projects to scientists with broad timeline and results peer reviewed before publication.

2.6.7 Inadequate system of appraisal for publication of research papers

The Institute did not have any measurable targets for the number of research papers to be published by scientists for projects undertaken. It was observed that:

- Prior approval of Director General (DG) of ICMR for publishing the papers was not found on record. Further, in other organisations like ICAR, research papers are published first in the journals of ICAR with the approval of DG and only then they are published in other journals. This is essential to ensure that the research papers involving technology development and new scientific innovation are not published before patenting. In NIMR, none of the research papers were published in ICMR/NIMR journals. They were published only in other journals.

- Peer review system of research papers which is an independent scrutiny of scientific research papers by other qualified scientific experts (peers) before they are made public, was not found on record in NIMR.

NIMR stated in October 2006 that scientists themselves decided the publication of research papers in Indian or Foreign journals. It further stated the research papers were peer reviewed and the comments were kept confidentially between the authors and editors of the journals. The reply is not tenable as there should be a system for appraisal of research papers before their publication. Comments of the peer review should also be kept on record for ensuring transparency.

2.6.8 Training

(i) Establishing linkages and networking with the national and international laboratories for advance research and training and participating in the human resource development by organising training course, workshops and meeting with personnel were among the objectives of NIMR. However it was observed that NIMR did not formulate any annual action plan or fix any targets for training courses. NIMR did not conduct training courses during the years 2002 and 2003.

Further, as per the instructions of NVBDCP, integrated vector borne diseases control was to be implemented in areas where more than one disease was prevalent. Hence, there was a need to reorient the training schedules not only to cover malaria but also other vector borne diseases endemic in such areas. The existing training modules for different tiers of personnel were to be modified suitably. The task was to be undertaken by NVBDCP, National Institute of Communicable Diseases, NIMR, Vector Control Research Center (VCRC) and other central and state training institutions. The revised training modules were to be field-tested and capacity building was to be augmented to meet the needs of the programme for integrated control of vector borne diseases. However, no information on fulfillment of this need was on record. In the absence of the information, the achievement of objectives of NIMR in this context could not be verified in audit.

(ii) In 24th SAC meeting held in March 2004, it was stated that there was a need for training of scientists in their respective and related fields. The Director, NIMR was empowered to decide the need and accord approval for short term training at national and international levels and the matter was to be referred to ICMR for approval. However, this was not acted upon and as a result, training could not be imparted to the scientists. Further only 15 training programmes were held for State Government officials during the period 2001-06.

ICMR stated in January 2007 that presently NIMR is not able to develop action plan for training programmes, as there is no infrastructure for training and hostel facility. Once NIMR's own building is ready, annual plans for training would be developed.

Recommendation

Proper guidelines for achieving the objective of human resource development and preparation of annual action plan for training and achievement thereof needs to be prepared.

2.7 Conclusion

R&D projects undertaken by NIMR revealed partial achievement of objectives, non-receipt of feedback information and lack of follow up action besides midway closure. Mosquito fauna survey, one of the important activities of the NIMR to establish present day bio-diversity was not carried out in all the states where malaria incidences had occurred during 2001-02 to 2005-06.

The functioning of malaria parasite bank, a national facility for malaria research, was ineffective as its objective of collecting, characterising, cryopreserving and adaptation of malaria isolates was not achieved fully due to lack of infrastructure facilities. There was no proper planning in GIS based study at micro level to digitise thematic maps and prediction of malaria using satellite remote sensing. Consequently the objectives of mapping malaria receptivity were not achieved fully.

Only two technologies were developed during 2001-06 and there was no technology transfer. Two viable technologies patented were not commercialised. Collaboration among NIMR, NVBDCP and SPOs was inadequate as meetings were not held regularly. Further, there was no exchange of feedback and follow up action on the recommendations of NIMR.

Keeping in view the prevalence of malaria in the country, NIMR should strengthen its activities in priority research areas for development of effective strategies for control of malaria.