EXTENSION OF NEONATAL SCREENING PROGRAMME TO RURAL AREAS (THA/6/029) E1

MODEL PROJECT

CORE FINANCING

YEAR	Experts		Group Activity	Equipment	Fellowships		Scientific Visits		Group Training	Sub-Contracts	Misc. Comp.	TOTAL
	m/d	US $	US $	US $	m/d	US $	m/d	US $	US $	US $	US $	US $
1997	1/0	13,200	0	81,500	4/0	12,600	0/0	0	0	0	0	107,300
1998	1/14	20,460	0	18,500	0/0	0	0/14	4,760	0	0	0	43,720

First Year Approved: 1995 Total expenditure to 30 September 1996: $109,746 (TCF)

OBJECTIVES: This project relates to the development goal of improving child health care throughout the country. Specifically, the project will help establish the capability for local production of radioimmunoassay kits for a nationwide neonatal hypothyroidism screening programme.

BACKGROUND: Iodine deficiency disorders are a major threat to the health of newborns in rural areas of Thailand. The problem is especially severe in the north and northeast regions where the long distance to the sea results in low consumption of seafood. In some provinces of these regions, the incidence of neonatal hypothyroidism is alarmingly high, reaching 1 in 900 births in Nan Province, for example. The Government plans to expand a screening program that already reaches about 80% of newborns. The national initiative "Health for All in the Year 2000" includes the objective of screening all one million newborns by the turn of the century. In addition to providing follow-up treatment when diagnosis is positive, the Government has begun to fortify fish oil for cooking and salt with iodine as a preventive measure. Self-reliance is a key feature of the Government's development plans in the health sector and elsewhere. The earlier phase of the neonatal hypothyroidism programme under THA/6/029 reached completion in 1996. It led to the creation of a technical capacity for the local production of diagnostic reagents, with a current output of 300,000 test kits per year. At the same time, the Ministry of Health established a pilot screening programme and articulated a national policy for comprehensive neonatal diagnosis. For the 1996-98 biennium, the Government has requested assistance in expanding local reagent production facilities to meet the nationwide demand at the lowest possible cost, and in setting up the logistics of the screening programme. Extension of the programme to the entire country will take place in 1998-2000.

PROJECT PLAN: The project's major activities will consist of (i) expanding the capacity for reagent production using bioreactor technology to produce the required monoclonal antibodies, replacing the slower and more costly cell expression in mice; (ii) adding rural laboratories to the existing network until all 37 provinces have at least one; (iii) setting up a quality assurance scheme for reagents and kits; and (iv) arranging the methodological and organizational aspects of network operation, including sample tracking, and follow-up treatment procedures. The National Reference Laboratory will be responsible for managing quality assurance, handling both laboratory standardization and technology transfer. It will also undertake research and development. Several regional laboratories will be in charge of quality control assessment and will oversee provincial laboratories. The provincial laboratories will supervise and coordinate the activities of the rural area laboratories and offer confirmatory testing. Rural area laboratories will conduct routine testing and act as the point of contact for any follow-up actions. Similarly detailed plans exist for a national report and data management system, and for a follow-up and treatment framework.

NATIONAL COMMITMENT: Current Government expenditures on this programme are about US $400,000 annually. The programme has a first-class reference laboratory, built with bilateral assistance. The laboratory staff consists of 16 permanent, full-time scientists, six technicians, and seven clerical workers, with salaries totalling more than US$ 120,000 annually. The monoclonal antibody production facility now includes a semi-industrial scale bioreactor, as well as the pre-existing colony of SPF balb c mice. The Government supplied US$ 60,000 in consumables for reagent production in 1996, and this will rise as demand increases. The Government will defray all operating costs associated with the project. The Minister of Health has made a firm commitment to have a nationwide screening programme in place by year 2000.

AGENCY INPUT: The Agency will provide expertise and expert services to support reagent production, design the quality assurance scheme, and plan the comprehensive nationwide screening programme. It will also furnish a gamma counter and associated supplies, along with the necessary training.

PROJECT IMPACT: Because of the high incidence of neonatal hypothyroidism in rural Thailand, the nationwide screening programme can expect to uncover as many as 1000 cases among the one million live births annually. Effective follow-up and treatment will avoid the large monetary and social costs associated with the condition's effects on mental and physical development. Successful operation of the semi-industrial scale bioreactor for monoclonal antibody production will potentially make low cost diagnostic reagents available throughout the region. Already, many other countries have sent representatives to Thailand to study their model for extending diagnosis and treatment to large rural areas.