RADIATION STERILIZATION OF BIOLOGICAL TISSUE GRAFTS (ZAM/7/003) E2 New

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	50,000	3/0	9,450	1/0	9,600	0	0	0	82,250
1998	1/0	13,950	0	10,000	3/0	9,900	0/0	0	0	0	0	33,850

First Year Approved: 1997

OBJECTIVES: The major development goal this project addresses is to improve patient care in burn cases and make the improved care available throughout the country. The specific goal is to establish a tissue bank that will make low-cost skin grafts prepared from radiation sterilized pigskin widely available.

BACKGROUND: Tissue bank facilities, while relatively common in developed countries, are not generally available in developing parts of the world. This situation compels the use of expensive imported tissue grafts. Most of the population cannot afford these materials. They also are a drain on limited foreign exchange. The national referral hospital in Zambia is the University Teaching Hospital (UTH), Lusaka. It admits approximately 600 burn patients every year, which represents 20% of the bed capacity. Thousands of others suffer severe burns every year but receive no treatment. In co-operation with the University of Zambia, the UTH trains medical personnel and undertakes research in an attempt to lower the morbidity and mortality rate of burn victims. The project ZAM/7/002, initiated in 1991, helped set up a tissue processing laboratory at the UTH. Zambia has now acquired the basic know-how for producing amnion allografts for the treatment of human burn wounds. The superior performance of amnion tissue allografts compared with significantly more expensive surgical pharmaceutical dressings has been clearly demonstrated with regard to infection rate, healing rate and healing quality. The demand for such dressings is very high, and current production does not meet the requirements of the UTH and other hospitals. The HIV pandemic has drastically reduced the production of amnion membrane dressings. Alternative biological sources need to be found. Preliminary results have indicated that pigskin is a viable option because the risk of transferring infection is lower than with amnion allograft. The Government has requested the Agency to assist in developing production of radiation-sterilized tissue grafts from pigskin. Zambia has some advantages over other countries in the sub-region for the establishment of a tissue bank. The National Council for Scientific Research (NCSR), Lusaka, has been operating a Co-60 irradiator since 1987 and has developed considerable expertise in radiation processing technology. Moreover, NCSR has some experience in producing dressings from pigskin. Dressings are currently under evaluation for quality, shelf-life and sterility.

One staff member of the NCSR was trained in Hungary in the production of pigskin dressings and is now involved in procurement, processing and quality control tests.

PROJECT PLAN: The main project activities in 1997 will include (i) identification of pigskin sources; (ii) production process optimization; (iii) quality assurance and sterility studies; (iv) development of protocols and guidelines for use; and (v) release of the first pigskin grafts for clinical trials. In 1998, activities will consist of (vi) continued sterility testing; (vii) expanded clinical trials; (viii) initiation of tissue banking; and (ix) mid-term analysis and evaluation by external experts of production and quality control leading to certification that the grafts and banking procedures meet international standards for full clinical use in Zambia. The third year will see activities that include (x) setting up pilot scale production facilities to prepare the technology for transfer to entrepreneurs; (xi) identification of other tissues for inclusion in the tissue bank; and (xii) a public awareness campaign to promote the use and acceptance of pigskin dressings. Staff from UTH and NCSR will operate as a team to provide overall project management and co-ordination.

NATIONAL COMMITMENT: NCSR will supply the irradiation facility. UTH will provide equipment and facilities, including those from the previous project as well as additional premises. The Government has made financial provision for consumables, transport and maintenance. The project team will consist of staff from UTH and the University of Zambia (clinical evaluation), and from the NCSR (sterilization and production). The plan calls for including these dressings in the Primary Health Care (PHC) kits of drugs and other medical supplies that are sent to all district hospitals, health centres and clinics under the decentralized health care system of the ongoing national health reforms. There is at present no legal framework pertaining to the use of biological dressings, but each major hospital has a medical ethics committee which approves patient care practices, using guidelines from the Medical Council of Zambia. Consultations are under way to draft legislation on the use of biological tissue grafts.

AGENCY INPUT: The Agency will provide expertise in the production of pigskin tissue grafts and in quality control and clinical application of biological dressings; overall technical advice and backstopping; equipment including a freeze dryer, incubator and colony counter; and training.

PROJECT IMPACT: The project's major impact will consist of eventual nationwide availability of sterile pigskin burn dressings to the several thousand people who are burned annually but now receive no treatment. The tissue bank will allow their needs to be met without recourse to expensive imported materials, as the grafts become widely available through the decentralized health care system that is part of ongoing national health reforms. The existence of the tissue bank should stimulate other countries in the region to adopt similar strategies.