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GLOBAL WHO STRATEGY FOR THE
 PREVENTION AND CONTROL OF
 ACQUIRED IMMUNODEFICIENCY SYNDROME

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PROJECTED NEEDS FOR 1986 - 1987

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I INTRODUCTION

The Acquired Immunodeficiency Syndrome (AIDS) and the entire spectrum of disease associated with lymphadenopathy-associated virus/human T-lymphotropic virus type III (LAV/HTLV-III) infection has recently and rapidly become a problem of intense international interest and concern. LAV/HTLV-III disease is not simply one of a series of newly emerging diseases during the past decade, but has several biological and epidemiological features which together justify a unique sense of urgency among public health officials, physicians, political leaders and the general public.

II STATEMENT OF THE PROBLEM

The etiologic agent of AIDS, the LAV/HTLV-III virus, differs in important ways from more traditional human viral pathogens such as hepatitis B, poliovirus or measles virus. LAV/HTLV-III infects the immune system and the nervous system (brain) and literally incorporates its genetic material into the genetic material of the infected person. This results in an infection most virologists believe to be lifelong. The factors influencing the viral activity level are currently unknown, but it is clear that the virus can move readily from a resting or dormant state to intense activity which results in disease manifestations of varying severity. Therefore, the LAV/HTLV-III infected person probably remains susceptible to virus-caused illnesses throughout life.

The full range of disease expressions of LAV/HTLV-III infection are not yet fully known. AIDS, the most severe currently recognized consequence of LAV/HTLV-III infection, is characterized by destruction of key elements in the host immune system, resulting in a series of severe and ultimately fatal opportunistic infections and malignancies. Available evidence predicts that at least 1-2% of LAV/HTLV-III infected persons will develop AIDS each year.

A series of severe yet lesser clinical manifestations of LAV/HTLV-III infections are classified as the "AIDS-related complex", or ARC. Persons with ARC suffer ill health e.g., chronic fever, diarrhoea, weight loss, night sweats and swelling of lymph glands. Current data suggest that approximately 5-10% of LAV/HTLV-III infected persons will develop ARC each year. ARC cases are also at increased risk of progressing to frank AIDS: 5-10% per year.

LAV/HTLV-III also behaves like a "slow virus" infecting the central nervous system. The LAV/HTLV-III virus appears responsible for a variety of neurologic syndromes, ranging from acute inflammation of the brain to chronic dementia. The relatively recent discovery of LAV/HTLV-III virus and the short observation period of known infected persons limits the ability to predict the eventual neurological burden associated with LAV/HTLV-III. The ultimate manifestations of sub-acute and chronic LAV/HTLV-III infection of the brain will only become evident during the next 10-30 years. Nevertheless, the possibility clearly exists that neurological damage may represent the most destructive aspect of LAV/HTLV-III infection.

Finally, other adverse consequences of LAV/HTLV-III are likely to emerge during the next decade. Given the central role of the immune system in a wide range of disease states, especially malignancies and "autoimmune" diseases,

the results of LAV/HTLV-III-associated immunologic dysfunction may be far-reaching. In summary, the ultimate health impact of LAV/HTLV-III infection, including effects on future generations, is unknown, and the currently recognized syndromes constitute an unknown portion of the LAV/HTLV-III problem.

As a result, the LAV/HTLV-III infected person, even when he feels healthy, faces a distinctly uncertain future, with a risk of approximately 10% of developing AIDS, a 25% risk of ARC, and an unknown risk of nervous system affections during the initial 5 years. The annual risk for infected persons of developing AIDS or ARC does not appear to change during the first 5-7 years after infection and the ultimate cumulative risk for infected persons is unknown. In population terms, therefore, the scope of the LAV/HTLV-III problem cannot be measured in terms of current AIDS cases. As more years of observation accumulate, a clearer picture will emerge. Current estimates suggest that in the developed and developing world, there are approximately 50 to 100 (or more) LAV/HTLV-III infected persons for each case of frank AIDS. Thus, between 500,000 and 1 million residents in the United States are thought to be infected, and therefore susceptible to LAV/HTLV-III-associated health problems.

AIDS and ARC are costly diseases in human and financial terms. Due to its modes of transmission (predominantly sexual), approximately 90% of cases in developed and developing countries are between 20 and 49 years of age. The particular impact on younger persons is reflected in New York City (Manhattan) and San Francisco, where AIDS has become the most important cause of premature mortality (years of expected life lost) among single men 25-44 years old. Thus, the loss of human potential must be added to the extraordinary financial burden of an incurable disease. In the United States, the average in-hospital treatment of each AIDS patient has been estimated to cost as much as US \$150,000. In developing countries, AIDS patient care depletes the already limited health care resources. Finally, the lack of any recognized effective treatment for LAV/HTLV-III associated immunosuppression limits medical care to treatment of secondary effects (infections, cancers) and palliation.

The person-to-person transmission of LAV/HTLV-III is dominated by the role of the apparently healthy yet infected person ("carrier"), who is clearly capable of transmitting the virus, and of whom there may be, as mentioned above, 50-100 or more for each recognized AIDS case. Regardless of the area of the world studied, the modes of LAV/HTLV-III transmission are fundamentally the same: (1) sexual; (2) contact with blood and blood products; and (3) perinatal (before, during, or shortly after birth). Two "classic" epidemiological patterns have been recognized in the developed and developing world. In the developed world, transmission is most important among male homosexuals and bisexuals and intravenous drug users. Thanks to screening programmes and other measures, blood transfusions and clotting factors have virtually ceased to be a mode for LAV/HTLV-III transmission in these areas. In parts of the developing world (e.g., Africa), heterosexual transmission dominates the epidemiological scene; persons receiving injections or other treatment with contaminated needles and other skin-piercing instruments; infants born to infected mothers and recipients of non-screened blood transfusions are also at risk of LAV/HTLV-III infection.

Throughout the world, sexual contact is of primary importance in LAV/HTLV-III transmission. This mode of transmission creates extraordinary problems for control efforts as sexually transmitted diseases have demonstrated ability to spread rapidly and efficiently within countries as well as internationally. Sexuality and related issues are generally difficult to discuss openly due to complex social and religious factors. Nevertheless, in the absence of a vaccine, prevention of sexual transmission depends upon educational strategies which will require a strong focus and a creative approach to be successful.

Several areas of the world are now experiencing substantial endemic or epidemic LAV/HTLV-III associated disease, particularly North America, Europe, South America, Africa and Australia. With the exception of North America, Europe and Australia, which together reported 22,404 AIDS cases as of 5 May 1986 (87% from the United States), the numbers of reported cases do not reflect the actual AIDS situation. For example, while only nine African countries have officially reported a total of 378 AIDS cases, the AIDS incidence in several Central African cities is known to equal or exceed incidence rates in New York and San Francisco.

The African AIDS situation illustrates the scope and dramatic nature of the current LAV/HTLV-III pandemic. Studies from several Central African countries have documented a 2-20% rate of LAV/HTLV-III infection (seropositivity to LAV/HTLV-III by ELISA and immunoblot methods) among healthy adults in the general population. In one Central African city, 1/500 (0.2%) healthy mothers were LAV/HTLV-III seropositive in the mid-seventies. In 1984, seroprevalence in a sample of women 20-39 years old from the same city was 8%, or a 40-fold increase compared with the seventies. The consequences of this recent dramatic increase in LAV/HTLV-III infections in Central African countries include a substantial number of AIDS cases, an increasing number of children infected at birth by LAV/HTLV-III (estimated 2-4% of all newborns infected in those areas where 8% of pregnant women are seropositive), complex interactions between LAV/HTLV-III infections and endemic diseases of public health importance such as tuberculosis, measles, malnutrition and malaria, and presumed LAV/HTLV-III infection of 6-16% of the blood donor population.

In addition to evidence that the LAV/HTLV-III problem has been increasing in those areas (presumably affected since the mid-to-late 1970s) the geographic extent of LAV/HTLV-III infection in Africa is rapidly increasing. For example, seroepidemiological studies among prostitutes in an East African city suggest that LAV/HTLV-III was introduced into that population in the early 1980s. The high percentage of these prostitutes infected by 1985, combined with the now measurable seroprevalence among healthy mothers in the same area and the virtual absence of recognized AIDS cases in that country until very recently (1985) illustrates that viral penetration into the community will be substantial by the time the first clinical AIDS cases are recognized. The recent report that 20 of 289 (7%) prostitutes in a West African country were LAV/HTLV-III seropositive is also of concern, although the extent of viral dissemination in West, East and Southern Africa is currently unknown.

Despite difficulties in generalizing about an entire continent, an estimated one to two million or more persons may be infected with LAV/HTLV-III in Africa. If one million persons are assumed to be infected and the most conservative rate of annual progression to clinical AIDS is utilized (1% per year), a minimum of 10,000 AIDS cases annually may be occurring in Africa.

The world can be divided into three areas, according to their current LAV/HTLV-III problem. The first group includes the developed countries which have been dealing with AIDS during the past several years. These countries recognize the public health importance of LAV/HTLV-III infections and command sufficient resources to address many aspects of this problem. The second group of countries includes those that are apparently free, or nearly free, of LAV/HTLV-III infection. These include both developed and developing countries, who currently have the enviable opportunity to take rational steps to protect themselves against the LAV/HTLV-III pandemic. Some of these countries have the resources needed to undertake surveillance and other sentinel activities, yet others do not. Finally, in the third group are the many countries in the developing world which currently face an AIDS crisis. As mentioned above, some of these countries are characterized epidemiologically by heterosexual transmission, transmission by nonsterile needles, syringes and other skin-piercing equipment, perinatal transmission and spread through uncontrolled and unscreened blood transfusions. These countries must confront a complex LAV/HTLV-III problem superimposed upon the already severe public health problems of the developing world, such as malnutrition, diarrhoeal disease, measles and malaria.

The alternative to concerted public health action to control AIDS is the unchecked progression of LAV/HTLV-III infections throughout the world, ultimately reaching all segments of the population. The particular biological and epidemiological features of this infection require that the LAV/HTLV-III pandemic be seen as a unique public health problem, and not just as another of many communicable disease problems facing the world today. Uninfected populations must be protected, as LAV/HTLV-III infection in itself is an adverse health outcome of profound personal and public health importance. The apparently healthy infected person is not only at substantial risk of severe illness at a later date, but creates a public health risk because of higher ability to infect others. The challenge to public health control of LAV/HTLV-III cannot wait for the possible development of effective antivirals and vaccines. The solutions to pandemic health problems require international cooperation and global coordination.

III PROGRESSION TOWARDS A GLOBAL PROGRAMME

In November 1983, the first WHO headquarters meeting on AIDS was held in Geneva. During 1983 and 1984, regional meetings were also organized in Europe and the Americas. Following the First International AIDS Conference in Atlanta (USA) in April 1985, a WHO consultation group recommended that WHO establish a network of collaborating centres on AIDS, coordinate the global surveillance of AIDS, and assist in the development of effective control strategies. The first Meeting of the Collaborating Centres on AIDS, held from 25-26 September 1985, concluded that WHO has an important role in the prevention and control of AIDS, especially in the developing world, and recommended that WHO should institute a global AIDS programme in WHO headquarters. A second Meeting of the Collaborating Centres on AIDS held from 16-18 December 1985, delineated a programme for the further development of collaborative activities among the Organization, its network of collaborating centres, and Member States.

Discussions in the Programme Committee of the Executive Board in October 1985, and the Executive Board in January 1986 led to approval of a resolution (EB77.R12) requesting the Director-General to further develop activities within the WHO Programme on AIDS and to seek additional funds from extrabudgetary sources for the support of national and collective programmes of surveillance and epidemiology, laboratory services, clinical support, and prevention and control. These funds were intended to supplement funding provided to the Division of Communicable Diseases from the Director-General's Development Programme for the 1986-87 biennium.

During 1985, AIDS was discussed at the six WHO Regional Committees. Member States requested WHO to take an active role in coordination of regional and global AIDS control activities. In addition, within the past 6 months, five of the six regions have convened special workshops to discuss AIDS. The African Regional experience is illustrative of the developments in the other regions. A workshop on AIDS in Central Africa was held in Bangui, Central African Republic, from 22-25 October 1985, with representation from nine Central African countries. The workshop recommended that WHO assist countries in dealing with AIDS and discussed specific areas where WHO could collaborate with Member States. Subsequently, during a meeting in Brazzaville from 3-7 March 1986, a set of "Recommendations for a Plan of Action for AIDS Control in the African Region of WHO" were unanimously approved following extensive plenary discussions. All countries within the African Region of WHO were represented at the meeting.

In summary, from WHO's first official involvement with AIDS in 1983 to the present, a consensus has emerged among Member States, expert groups, and collaborating centres on AIDS regarding the role of WHO in global AIDS control, the essential components of the headquarters Control Programme on AIDS (CPA), the role WHO Regional Offices should play, and the recommended approaches to AIDS prevention and control at the country level.

In establishing the WHO CPA within the Division of Communicable Diseases at headquarters, WHO is making a long-term commitment to AIDS prevention and control. WHO believes that AIDS is indeed an exceptional public health problem and challenge, and that AIDS illustrates the great lesson of our time: that we are, in the words of the Director-General, travellers on one spaceship, our Earth. WHO is uniquely suited to coordinating AIDS control activities.

As a reflection of this commitment, WHO has provided the necessary financial support to staff the CPA with two full-time staff members. In addition, human resources from a number of related technical areas of the Organization, equivalent to an estimated 6 person-years, will be made available during this biennium to assist in this effort. Globally, WHO provided support for AIDS activities in the 1984-1985 biennium from various regular budget headquarters and regional allocations. An estimated US \$1,150,000 in regular budget allocations as well as human resource contributions has been made available for this effort for the 1986-87 biennium.

IV GLOBAL AIDS CONTROL

A consensus regarding the fundamental components of AIDS control has emerged from consultations with Member States, collaborating centres, expert groups, the World Health Assembly and Regional Committees. This approach to AIDS control requires coordinated and complementary activity at the headquarters, regional and country levels.

A. Overview

1. The primary headquarters/regional responsibility is coordination, involving:

- (1) exchange of information on AIDS epidemiology and sero-epidemiological studies of LAV/HTLV-III infection, legislation and policies introduced by Member States to control spread of the infection;
- (2) preparation and distribution of guidelines for the diagnosis, surveillance, prevention and control of LAV/HTLV-III infection directed towards the general public, groups at high risk, and health care workers;
- (3) assessment of commercially available antibody (or other) test kits, stimulation of research towards development of a simple and inexpensive test for field application, particularly in the developing world, and establishment and distribution of WHO reference reagents;
- (4) cooperation with Member States in the development of national programmes/actions for the containment of LAV/HTLV-III. The important role of non-governmental organizations, especially in the health, social service, and women's and children's areas will be stressed;
- (5) advice to Member States on the provision of safe blood and blood products;
- (6) coordination of research on therapeutic agents, vaccines, and simian retroviruses.

NOTE: details of the proposed 1986-87 activities and associated extra-budgetary needs are presented in Annex A.

2. At the national level, a plan of action for AIDS control is required. This plan represents a strategy for addressing control and prevention of AIDS and LAV/HTLV-III infection over a 1-3 year period. Once the epidemiology is clarified, the surveillance system and laboratory capability established, the clinical picture defined and the initial public education efforts underway, the focus of activity at the national level will likely shift to expanded public education programmes and control of specific problem areas such as blood transfusions, injections and perinatal transmission. Therefore, the outline presented in the following section represents the initial phase of a long-term national commitment to AIDS control.

B. Major components of the national programme

The first step is explicit national willingness to confront the complex problems associated with LAV/HTLV-III infection.

A comprehensive plan at the national level begins with creation of a National AIDS Committee (or the equivalent), most often organized under the auspices of the Ministry of Health, and includes representatives from health,

social service, education and other relevant sectors. Close collaboration with WHO should be encouraged through the WHO Representative's participation in the Committee's deliberations. The National Committee would coordinate AIDS activities, collect and maintain documentation on LAV/HTLV-III in the country, and define, design and evaluate the key components of the control programme.

In order to design the national programme, an initial epidemiological and resource assessment is necessary. The initial assessment is designed as a "package" to be conducted within a relatively brief (4-8 week) period and has two main components: (a) the epidemiological assessment to determine the prevalence of LAV/HTLV-III in selected areas and review and summarize all existing data on LAV/HTLV-III in the country; and (b) the resource/infrastructure assessment to determine the ability of the existing health system to support epidemiological, laboratory, clinical and prevention components of the national AIDS programme.

Based on findings of the initial assessment, a surveillance system will be established to provide timely and useful epidemiological information regarding LAV/HTLV-III infections, including AIDS, to the National AIDS Committee. In addition, serosurveys may be conducted among designated populations, and based on initial analysis of the national epidemiological situation, serosurvey monitoring of selected populations and specific epidemiological studies could be considered.

Laboratory support will be required for epidemiological, clinical and prevention activities. Based on results of the initial assessment, decisions will be made regarding the need for an in-country serodiagnostic capability. In-country laboratory capability would be established where appropriate and feasible.

National health systems will be assisted in the recognition, diagnosis, and management of LAV/HTLV-III associated disease, to include hospital and community management of LAV/HTLV-III infected persons. Counselling of LAV/HTLV-III infected persons, confidentiality, and the ethical dimensions of LAV/HTLV-III infections are vitally important for appropriate individual management and public health action.

The principal goal of the national AIDS programme remains to be the prevention of LAV/HTLV-III transmission to uninfected persons. Prevention activities will be primarily educational and will be directed towards the general public, specific risk groups identified through epidemiological analysis, and health care workers at all levels. The desired outcome of education is behavioural modification, and considerable use of grassroots (non-governmental) organizations will be required to achieve these objectives. In addition to educational strategies, specific attention will be focused in some areas upon blood transfusions, injections, and perinatal transmission issues.

The implementation of a national programme requires willingness by the Member State to recognize AIDS and LAV/HTLV-III infections as a health issue warranting a short and long-term personnel, fiscal and political commitment.

NOTE: an expanded description of the principal components of the national strategy is provided in Annex B.

C. Cost of national AIDS control programmes

The cost of this initial phase of a national programme clearly depends upon a variety of country-specific issues, especially regarding epidemiological surveillance and laboratory infrastructure. Nevertheless, the budget estimates for a 1-2 year initial phase country programme including estimates of the anticipated national contributions are presented in Annex C. The more detailed costing of components, including key assumptions and options regarding levels of laboratory support is presented in Annex D.

V COORDINATION OF GLOBAL ACTION

A. Organization

The organizational structure of the Control Programme on AIDS (CPA) reflects the need to provide global coordination as well as assistance to the national (operational) level. The first objective, global coordination, necessitates strong linkages with five principal groups: (1) the interested parties (donors and aid recipients); (2) the WHO collaborating centres on AIDS; (3) WHO headquarters/regional programmes (e.g., EPI, public information services, health legislation); (4) other international organizations, including UN agencies (e.g., UNICEF); and (5) other expert groups and institutions.

A steering committee, with representatives from each of these principal groups, will be asked to provide guidance on policy and programme strategies, review progress towards preset targets and ensure coordination of bilateral and multilateral AIDS prevention and control activities. In this manner, the CPA will benefit from a broad level of participation and experience in an efficient and timely manner. This steering committee is designed to represent the collective experience and perspectives of the above-mentioned groups but does not replace the need for systematic communication and direct interaction between the CPA and individual organizations and Member States with direct interest and involvement in AIDS prevention and control.

In addition to the steering committee, relationships within WHO and with the collaborating centres on AIDS require additional organization. Within WHO, a task force will be formed to coordinate CPA action with other WHO programmes at the headquarters level. Representatives to this task force would include: public information services, laboratory development, biologicals, sexually transmitted disease control, health legislation, health education, mental health, and EPI. In addition, the wide-ranging repercussions of LAV/HTLV-III infection will necessitate flexibility in the membership of this task force, so that emerging problems can be approached in a coordinated manner.

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(5) coordination of research, in particular on therapeutic agents, vaccines, simian retroviruses, and the epidemiological and behavioural aspects of AIDS and LAV/HTLV-III infection.

These activities necessitate collaboration, support and guidance from all levels of WHO, other UN agencies, Member States, participating parties in assistance programmes, WHO collaborating centres on AIDS, and outside experts, as described in Section A.

In order to assist Member States to establish national AIDS control programmes, extrabudgetary resources will be required, although the support of national AIDS control programmes can be bilateral or multilateral. Three levels of CPA involvement are envisaged.

(1) The minimal CPA role would involve communication and information exchange with the bilateral partners regarding the design, targets, results achieved and evaluation of the national programme. In this manner, the CPA can fulfill its coordination responsibility for global AIDS control activities.

(2) CPA can assist bilateral programmes in the design, implementation and evaluation of component parts of the national AIDS control programme through provision of specific technical consultancies, organization of workshops and training courses, purchase of equipment and supplies and assistance in programme review and evaluation.

(3) CPA can undertake the entire range of technical assistance required by a Member State to implement the key components of a national AIDS control programme, utilizing resources from single or multiple interested parties. This approach may be a desirable alternative for the coordination of simultaneous bilateral support to different components of a control programme (e.g., laboratory support from one interested party and epidemiological/surveillance support from another interested party).

A priority system will be essential to allocate limited resources in an optimal manner. Three major criteria are proposed for resource allocation:

Major criteria

(1) Recognition by national authorities of the importance of AIDS and LAV/HTLV-III infections and expressed commitment to create and maintain a national AIDS control programme.

(2) Apparent gravity of the LAV/HTLV-III situation, based on available national data and knowledge of the regional epidemiological situation.

(3) A strong preference for complete national programmes rather than unplanned implementation of individual components (e.g., purchase of laboratory equipment prior to evaluation of the extent of the LAV/HTLV-III problem, assessment of need for in-country serodiagnostic services, or potential for inter-country or regional collaboration). Priority will be given to support complete, well-designed, national AIDS control programmes or programmes requiring assistance in well-defined areas (e.g., laboratory services) in order to upgrade an otherwise structurally sound national AIDS control programme.

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ANNEX A

I. PROPOSED ACTIVITIES OF THE WHO CONTROL PROGRAMME ON AIDS -
1986 - 1987

A. Exchange of information

1. Establish WHO individual case report and monthly/quarterly national reporting forms for AIDS.
2. Collect and disseminate AIDS surveillance data.
3. Collect and distribute seroepidemiological data on LAV/HTLV-III infections, with emphasis on sufficient standardization to permit geographic and temporal comparisons.
4. Collect and distribute information on the operational status - including laboratory test capability - of national AIDS control programmes.
5. Collect and distribute information on legislation and policies introduced by Member States to control the spread of LAV/HTLV-III.
6. Convene at least one meeting of all WHO collaborating centres on AIDS for information exchange (and programme review) per biennium.
7. Collect and make available information regarding bilateral and multilateral AIDS research and control programmes.
8. Provide rapid updates as needed through the Weekly Epidemiological Record (WER), facsimile or telex (including automatic telex reply service).
9. Collaborate with WHO Media Services in the periodic revision of press information kits on AIDS.
10. Ensure up-to-date information availability to Ministries of Health via the WHO Media Service "In point of fact".
11. Provide Ministries of Health with updates on scientific, technical or programmatic information directly relevant to AIDS prevention and control.
12. Collect and distribute information on LAV/HTLV-III diagnostic test kits (see section 3).
13. Engage media in active dialogue regarding global AIDS prevention and control, with emphasis on credibility and speed of information transfer to the general public.
14. Convene a workshop on legislation/public policy aspects of LAV/HTLV-III.

B. Preparation and distribution of guidelines

1. Develop and distribute guidelines for:
 - (a) health care workers at all levels regarding prevention of LAV/HTLV-III transmission;
 - (b) counselling and guidance of asymptomatic LAV/HTLV-III infected persons;
 - (c) the general public regarding prevention of LAV/HTLV-III transmission.
2. Develop and distribute technical manuals and monographs on AIDS surveillance, clinical evaluation of LAV/HTLV-III infected persons, clinical manifestations of AIDS in different geographical settings, and public education for AIDS prevention.
3. Coordinate development of prototype educational materials for high-risk groups and the general population.
4. Develop and distribute guidelines on use of serologic testing for LAV/HTLV-III.

C. Assessment of diagnostic methodology for LAV/HTLV-III infection

1. Establish international reference sera for use in evaluating existing and new diagnostic kits (panels of sera from different geographic areas will be necessary).
2. Collect and distribute information regarding test kit performance characteristics.
3. Facilitate distribution of LAV/HTLV-III or other relevant viruses in order to assist development of more simple and less expensive screening and diagnostic tests.
4. Coordinate collection and characterization of additional virus isolates and their free exchange through the WHO collaborating centres on AIDS.
5. Coordinate development and characterization of panels of monoclonal antibodies to specific epitopes of LAV/HTLV-III and cDNA clones of reference for diagnostic and research work on AIDS.
6. Stimulate assessment of test kits under varying field conditions and in various geographical areas.
7. Negotiate with test kit manufacturers regarding bulk purchase of kits at favourable rates on behalf of developing countries.
8. Stimulate research and development of reliable, sensitive, specific, simple to perform, inexpensive and thermostable diagnostic and screening methods.

D. Cooperation with Member States

1. Coordinate and support regional, intercountry and national workshops and training courses in epidemiology/surveillance, laboratory testing, and education/prevention.
2. Assist Member States by distributing guidelines for the key components of a national AIDS control programme (e.g., initial assessments, epidemiology/surveillance, laboratory services, education of health care personnel, prevention/education).
3. Assist Member States directly in establishing national AIDS control programmes through provision of specific technical consultancies and training, resource to support establishment and maintenance of surveillance, laboratory, and prevention activities for AIDS control, and coordination of additional or future bilateral or multilateral support. Two additional options are proposed in this area, according to the extent of extrabudgetary support: (a) development of pilot projects to establish national AIDS programmes in two countries; and (b) assignment of WHO country advisers to assist national AIDS programme development in selected countries. The pilot projects would provide funding for the initial phase of two national programmes (initial assessment, surveillance/serosurveys, laboratory (option 2), clinical and prevention components) along with a country adviser assigned to the programme and a P.4 technical officer assigned to the CPA (headquarters) to work closely with the two national programmes. The pilot areas would be selected following consultation with the Steering Committee with particular attention to the national programme's potential for evaluation as a model project (see other criteria No. 2, 3 and 5 page 12). The in-country advisers could be assigned to the national programme through the WHO Representative's Office in order to assist in programme design and implementation, coordination with non governmental organizations and evaluation.
4. Assist Member States who are establishing national AIDS control programmes with involvement ranging from information exchange to technical cooperation and coordination of additional or future bilateral or multilateral support.
5. Ensure information exchange regarding practical experience and evaluation of key components of the national AIDS control programme.
6. Stimulate operational research regarding prevention of sexual transmission, transmission through contaminated needles, syringes and other skin-piercing instruments.

E. Advice to Member States on the provision of safe blood and blood products

Blood transfusion and blood products have played only a minor role in the AIDS epidemic, and control measures are available to further reduce the risk of transmission. Programmes to inform and educate persons at increased risk of AIDS to refrain from giving blood and to screen for virus antibody have been successful. Other measures include strategies to reduce the demand for blood, replacement of whole blood or plasma with blood components and derivatives when available; and to transfuse whole blood or plasma only when medically justified. Decision on laboratory screening requires careful consideration concerning information and education for donors, confirmation of initial test results, confidentiality of test results, counselling and medical follow-up. National AIDS control programmes should be assisted in evaluating the role of blood transfusions in LAV/HTLV-III transmission at the country level. National AIDS control programmes should assess the options available to reduce LAV/HTLV-III redundant risks associated with blood transfusion within the larger context of national AIDS prevention and control.

The WHO Control Programme on AIDS and the Blood Programme of the League of Red Cross and Red Crescent Societies have agreed to collaborate closely in this endeavour.

F. Coordination of research

1. Coordinate collaborative action and information exchange regarding:
 - (a) antiviral research;
 - (b) vaccine research;
 - (c) t-lymphotropic simian retroviruses.
2. Coordinate discussions regarding preparations for eventual vaccine field trials.
3. Convene a workshop on antivirals and international clinical collaboration in testing of antivirals in varying geographic areas.
4. Act as a clearing-house for information on behavioural research in risk reduction for LAV/HTLV-III transmission.

II. EXTRABUDGETARY RESOURCES FOR GLOBAL CONTROL ACTIVITIES

A. <u>Exchange of information</u>	
Printing and materials	30,000
Meeting of WHO collaborating centres	62,500
Support for workshop on legislation/public policy aspects	20,000
SUB-TOTAL	112,500
B. <u>Preparation and distribution of guidelines</u>	
Technical consultation with expert groups	50,000
Preparation of 2 manuals and 2 monographs	80,000
Prototype materials for education	30,000
SUB-TOTAL	160,000
C. <u>Assessment of diagnostic methodology</u>	
Seed money for field evaluations	40,000
Support to WHO Collaborating Centres for laboratory reference and other services, at 15,000/centre	375,000
SUB-TOTAL	415,000
D. <u>Cooperation with Member States</u>	
Support for epidemiology/surveillance workshops at international, regional, or subregional level	50,000
Support for laboratory workshops	100,000
Support for prevention/education workshops	100,000
Country advisers assigned to national programmes (65,000 x estimated 10)	650,000
Pilot projects for two national programmes	911,000
SUB-TOTAL	1,811,000
E. <u>Coordination of research</u>	
Support for workshop on antivirals and international clinical collaboration	20,000
SUB-TOTAL	20,000
F. <u>Administrative support for Control Programme on AIDS</u>	
One P-3, one G-3	78,000
TOTAL BUDGET ESTIMATE (extrabudgetary resources) FOR 1986-87 BIENNIUM	
	US \$2,596,500

ANNEX B

PRINCIPAL COMPONENTS OF THE NATIONAL AIDS CONTROL PROGRAMME

A. FORMATION OF A NATIONAL AIDS COMMITTEE

A comprehensive plan on AIDS begins at the operational level with creation of a National AIDS Committee, including representatives from health, social service, education and other relevant sectors. The Committee would coordinate AIDS activities, collect and maintain documentation on LAV/HTLV-III in the country, and select, design and evaluate the key components of the control programme: epidemiology, laboratory, clinical, and prevention. In order to design this national programme, an initial assessment must first be performed to examine the actual epidemiological and resource/infrastructure situation.

B. INITIAL ASSESSMENT

1. Purpose

The initial assessment is designed as a "package" to be conducted within a relatively brief (3-8 week) period. The assessment is divided into two parts: epidemiological and resource/infrastructure.

The epidemiological assessment would determine the prevalence of LAV/HTLV-III in the country, or in selected areas. This would involve:

- Confirming the presence of indigenous LAV/HTLV-III infection;
- Verifying the usefulness of existing definitions (CDC/WHO and clinical) and further refinement of clinical definition as needed;
- Reviewing and analyzing already existing clinical, laboratory and epidemiological data on AIDS;
- Performing surveys for clinical AIDS cases in selected medical facilities;
- Performing serological surveys of selected populations (e.g., blood donors, prostitutes);

The resource/infrastructure assessment would determine the ability of the existing health system to support epidemiological, laboratory, clinical and prevention components of the national AIDS programme. This would involve:

- Assessing national epidemiological systems and resources, and identifying resource needs for surveillance, serosurveys, and studies (including personnel, training, equipment)
- Assessing national laboratory systems and resources, and identifying resource needs for LAV/HTLV-III serological testing adequate for existing and anticipated demand (includes specimen collection and transport, personnel, training, equipment, supplies, laboratory safety and quality assurance programmes)

- Assessing national clinical resources and systems for continuing education, training, and guideline development and distribution
- Assessing national health educational, informational and media resources and systems
- Assessing blood banking and transfusion systems
- Assessing injection/instrument sterilization practices

2. Resource Requirements

The resource requirements for epidemiological assessment include:

- Two consultants (epidemiologist, laboratory)
- Laboratory support (in-country, to be brought with consultants, or provided by outside reference laboratory)

C. EPIDEMIOLOGY/SURVEILLANCE

1. Purpose

Based on findings of the initial assessment, a surveillance system should be established to provide timely and useful epidemiological information regarding LAV/HTLV-III infections, including AIDS, to the National AIDS Committee.

In order to initiate AIDS surveillance:

- Suitable sites should be selected
- Surveillance methodology identified (passive, active; hospital-based, sentinel physician, etc.)
- National surveillance form developed
- Develop plan for analysis and dissemination of surveillance data
- Distribute information about LAV/HTLV-III and AIDS surveillance to health care providers, including adult and pediatric case definition
- Make arrangements for reporting of AIDS cases to WHO Regional Offices
- Evaluate surveillance system (e.g., completeness and accuracy of forms, geographic distribution of reported cases)

Serosurveys should be performed on selected populations:

- Select "high risk" and target groups as identified by known modes of LAV/HTLV-III transmission and results of initial assessment
- Based on initial results and analysis of national epidemiological situation, design plan for serosurvey monitoring of selected populations

Epidemiological studies should be designed to address research issues of priority interest and importance (e.g., risk factors, modes of transmission, natural history).

2. Resource Requirements

- National staff for surveillance and serosurveys
- Technical consultation (epidemiology)
- Training for surveillance staff and participants
- Computer hardware and software
- Printing of forms and related documents
- Vehicles/transport
- Radios/communications

D. LABORATORY

1. Purpose

Laboratory support will be required for epidemiological, clinical and prevention activities. Based on results of the initial assessment, in most cases, an in-country laboratory capability for LAV/HTLV-III serological testing using ELISA techniques should be developed. This will involve:

- Determining sites for laboratory testing
- Hiring and training of national laboratory personnel
- Procuring necessary laboratory equipment and supplies
- Strengthening of specimen collection and transport systems
- Determining source(s) for reference laboratory support (e.g., confirmatory testing)
- Developing laboratory safety and quality assurance programmes

2. Resource Requirements

- National staff
- Technical consultation
- Training programmes for laboratory staff
- Laboratory equipment, both generic (refrigerator, centrifuge) and ELISA-specific (dilutor, reader)
- Laboratory supplies, both generic (blood collection equipment, tubes, serum storage vials, pipettes) and ELISA-specific (pipettes, kits)
- Miscellaneous laboratory support, including specimen handling and shipping within country to the laboratory and for confirmatory testing

E. CLINICAL

1. Purpose

National health systems should be assisted in recognizing, diagnosing, and managing LAV/HTLV-III-associated disease, including hospital and community management of LAV/HTLV-III-infected persons. Counselling of LAV/HTLV-III infected persons is vitally important both for individual management and for public health reasons.

Important clinical activities will include:

- Providing guidelines, education and training on LAV/HTLV-III diagnosis for health care personnel at all levels
- Providing guidelines, education and training on in-hospital, outpatient and community management of LAV/HTLV-III-infected persons
- Providing guidelines, education and training on counselling of LAV/HTLV-III-infected persons
- Designing outreach programmes for traditional providers

2. Resource Requirements

- Translation or development of guidelines and other materials
- Printing and distribution of guidelines and other materials
- Educational seminars for health care personnel, including traditional providers

F. PREVENTION

1. Purpose

The principal goal of the national AIDS programme is preventing transmission of LAV/HTLV-III to uninfected persons through programmes integrated within, and strengthening to the maximum extent possible the national health infrastructure. Prevention activities must focus on educational programmes directed towards the general public, high risk groups, and health care providers.

For the general public, available scientific knowledge regarding risk factors and modes of LAV/HTLV-III transmission must be converted into messages and materials suitable to the national audience and designed to result in behaviour modification. Behaviour modification should focus upon sexual activity and practices and (in many areas of the developing world) upon attitudes towards injections. A "Meeting on Educational Strategies for the Prevention and Control of AIDS" has been scheduled in Geneva on 17-19 June 1986. Health educational and social marketing approaches and strategies emerging from that meeting will be considered.

High risk groups for sexual and parenteral LAV/HTLV-III transmission must be identified. Behavior modification in these groups may be even more complex than among members of the general public.

Health care providers must be educated regarding clinical aspects of LAV/HTLV-III (described in the clinical section) and also about their role in prevention of transmission through blood transfusions and use of contaminated needles/syringes or other skin-piercing instruments.

In addition to educational approaches, LAV/HTLV-III transmission through parenteral and perinatal routes can be addressed. Prevention of LAV/HTLV-III transmission through blood transfusions may require modification of the blood collection and transfusion system, possibly including screening of donors or donated blood for antibodies to LAV/HTLV-III. Prevention of transmission through injections may require programmes to prevent reuse of single-use syringes/needles or methods to ensure reliable sterilization of reusable injection material. Programmes may also be directed towards sterilization of other instruments which pierce the skin or contact mucous membranes (e.g., scarifications, circumcision knives, ear-piercing). Perinatal transmission would require identification and screening of women considered at higher risk of LAV/HTLV-III infection, with subsequent counselling and possible provision of birth control assistance.

2. Resource Requirements

- Educational (social marketing) materials: visual, aural, printed
- Technical consultation on social marketing packages and strategies
- Technical consultation on blood banking
- Suitable sterilizers for needles/syringes; self-destructing needle/syringe units; provision of high-quality plastic or glass reusable syringes; other material
- National personnel for educational programmes and associated costs

ANNEX C

BUDGET ESTIMATE FOR INITIAL PHASE OF
NATIONAL AIDS CONTROL PROGRAMME

I Extrabudgetary contribution

<u>COMPONENT</u>	<u>ESTIMATED COST (US \$)</u>	<u>PERCENT OF TOTAL</u>
Initial assessment	55,000	14
Epidemiology/surveillance	93,600	24
Laboratory (option 2)	140,800	37
Clinical	21,900	6
Prevention	71,200	19
TOTAL	<u>US \$ 382,500</u>	100

II Anticipated national contribution

The national contributions to the initial 1-2 year phase of the national AIDS control programme would generally include personnel, supplies, transportation, fuel, utilities, furniture, rent, and maintenance. Estimated national contributions and their relationship to contributions by interested parties are shown below

<u>PROGRAMME COMPONENT</u>	<u>ESTIMATED COST (US \$)</u>	<u>RATIO</u>
Initial Assessment	20,000	1:2.8
Epidemiology/surveillance	24,000	1:3.9
Laboratory	30,000	1:4.7
Clinical	15,000	1:1.5
Prevention	25,000	1:2.8
TOTAL	<u>US \$ 114,000</u>	1:3.4

* - ratio of national contribution to interested party contribution

ANNEX D

DETAILED BUDGET ESTIMATES FOR
NATIONAL AIDS CONTROL PROGRAMME

INITIAL ASSESSMENT

(a) Epidemiological assessment

1. Consultants, including international
and in-country travel.....US\$ 24,500
 2. Laboratory support for serological testing
of up to 1,000 specimens.....12,000
- TOTAL.....US\$ 36,500

Key Assumptions

1. Laboratory testing to be done outside the country,
so that only serum collection, storage and shipment
supplies are required
2. Laboratory in country is equipped with centrifuge

(b) Resource/infrastructure assessment

1. Consultants, including international
and in-country travel.....US\$ 18,500
- TOTAL ESTIMATED COST FOR INITIAL ASSESSMENT.....US\$ 55,000

EPIDEMIOLOGY/SURVEILLANCE

(a) Surveillance system

1. Consultant, including international and in-country travel.....US\$ 8,000
2. National staff.....7,000
3. Training seminars (in-country).....5,500
4. Computer hardware and software.....11,500
5. Printing of forms, gasoline/oil, assorted supplies.....8,000
6. Vehicles (2 Land Rover-type vehicles).....17,500
7. Radios/support of communication network.....5,500
- Total surveillance system costs.....US\$ 63,000

(b) Serosurveys

1. Consultant, including international and in-country travel.....US\$ 9,200
2. National staff.....3,400
3. Supplies (laboratory, printing).....14,700
4. Travel for national staff.....2,300
5. Miscellaneous.....1,000
- Total serosurvey costs.....US\$ 30,600

Key Assumptions

1. Serosurvey assumes that in-country ELISA testing is available, that up to 2,500 sera will be tested, and that confirmatory testing is available without charge in a reference laboratory
2. No costs included for epidemiological research on risk factor, route of transmission, natural history

TOTAL ESTIMATED COST FOR EPIDEMIOLOGY.....US\$ 93,600

LABORATORY

1. National staff.....	US\$ 6,700
2. Consultant, including international and in-country travel.....	8,000
3. Training seminars (in-country).....	2,000
4. Shipping (in-country and to reference laboratory).....	3,000
5. Laboratory Equipment:	
a. generic.....	14,700
b. ELISA-specific.....	27,300
6. Laboratory Supplies:	
a. option #1: 2,000 ELISA tests annually:	
1. generic supplies.....	4,500
2. kits.....	<u>11,300</u>
Total for option #1.....	US\$ 15,800
b. option #2: 10,000 ELISA tests annually:	
1. generic supplies.....	22,600
2. kits.....	<u>56,500</u>
Total for option #2.....	US\$ 79,100
c. option #3: 50,000 ELISA tests annually:	
1. generic supplies.....	113,000
2. kits.....	<u>282,500</u>
Total for option #3.....	US\$ 395,500
TOTAL ESTIMATED LABORATORY COSTS:	
- Option #1 (2,000 tests annually).....	<u>77,500</u>
- Option #2: (10,000 tests annually).....	<u>140,800</u>
- Option #3: (50,000 tests annually).....	US\$ <u>457,200</u>

Key Assumptions

1. Training assumes that at least one national laboratory person has attended an ELISA workshop
2. Generic laboratory support includes: refrigerator, centrifuge, air conditioner, freezer, autoclave, incubator, surge protectors
3. ELISA-specific laboratory support includes reader, automatic dilutor, special pipettes for manual dilution
4. Generic laboratory material estimated at US\$ 2 per test, and includes blood-drawing equipment, tubes, vials for serum, pipettes
6. ELISA kits estimated at US\$ 5 per test, including shipping
7. Laboratory support costs outlined above intended for diagnostic and epidemiology support. If ELISA testing is desired for blood bank or other screening programmes, the number of these tests should be added.

CLINICAL

- Guideline translation, printing and distribution...US\$ 5,600
 - Seminars for education of health care personnel.....11,300
 - Purchase/production of educational materials.....5,000
- TOTAL ESTIMATED COST FOR CLINICAL.....US\$ 21,900

PREVENTION

1. National staff.....US\$ 6,800
 2. Consultant, including international and in-country travel.....7,900
 3. Material preparation, reproduction, distribution.....28,300
 4. Blood banking: consultant, including international and in-country travel.....7,900
 5. Laboratory support to evaluate blood banking.....9,000
 6. Syringe/needle pilot project.....11,300
- TOTAL ESTIMATED PREVENTION COST.....US\$ 71,200

Key Assumptions

- a. Health education/social marketing strategies are expected to be developed at meeting in early June 1986
- b. Laboratory support to evaluate blood banking would require in-country ELISA testing, so that only generic and ELISA-specific supplies (kits) would be required
- c. Pilot projects using reusable syringes/needles, single-use units, or self-destructing single-use units are projected