for added warnings and precautions. This is particularly important when the recommended
agent is a new and/or infrequently employed drug.

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Printed in Switzerland on acid-free paper by Thür AG Offsetdruck, Prattein
ISBN 3-8055-5485-0

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Preface
The Italian Experience in the Global Challenge against AIDS
Hon. Francesco de Lorenzo
Minister of Public Health, Italy

It is my pleasure to introduce this book containing the master lectures, state-of-the-art plenary lectures, the best papers selected and the summary reports from the VIIth International Conference on AIDS that was held in
Florence in June 1991. The conference represented the major international forum on AIDS, and constituted a meeting place for initiatives on a problem that in a short time has had a dramatic global impact.

In addition to the scientific observations presented during the conference, discussion focused also on important questions relating to the war against AIDS - not only as a war against the disease, but also as a concrete prospect of human solidarity towards the persons suffering.

We obtained maximum benefits from these presentations in terms of exchange and collaboration between the different people, professional and nonprofessional, fighting against HIV infection. This is an extraordinary opportunity to unite efforts at all levels - whether they be researchers, clinicians, health care workers, NGOs or representatives of the mass media.

In Italy, the fight against AIDS is very long and became fully operational in March 1987, when the Ministry of Health, faced with the evolution of the AIDS epidemic in this country and the rest of the world, set up a national commission of experts. This group helped to provide guidelines and expertise to the Minister, who is also the chairman of the commission, in order to coordinate the efforts already underway in some regions which were hard hit by the HIV infection. This initiative was well integrated with the development of the AIDS policy at the European level: in November 1987, the European committee of Health Ministers declared the fight against AIDS to have priority at a national level.

Preface VIII

The Italian National Commission has always worked in conjunction with the WHO document 'Guidelines for the Development of National AIDS Prevention and Control Program' in order to fully implement the global fight against AIDS. This policy has focused since the beginning on international collaboration and the exchange of information at a national level, in both AIDS research and the struggle against discrimination. As regards the Italian situation, the activity of the national commission has recently been enriched by the participation of NGOs aiming to harmonize legislative and social decisions.

I wish to emphasize this serious and important point. The resolution adopted on November 13th 1989 by the Council of the European Community and by the Ministers of Health of the member states, stressed the concept that 'the free movement of people ... in the community and the equity of treatment defined by the treaties are guaranteed and will continue to be so'. This concept was developed and ultimately elaborated in 1990, during the semester of the Italian presidency of the Community. In
that context, several measures were adopted for an effective fight against AIDS and drug addiction, the most serious and rapidly increasing risk behavior.

A resolution adopted on December 3, 1990 underlined the need to improve home care and study of prevention interventions to counteract the increasing use of needles and syringes.

On the 4th of June 1991 in Luxembourg, the Council of the Ministers of Health of the member states approved a 3-year plan of action called Europe against AIDS.

As already stated, the main purpose of the Italian activities against AIDS is the tenacious pursuit of the most extensive international collaboration, especially with EEC countries and WHO. In fact, rejecting all discriminatory aspects, the Ministers of Health of the EEC countries unanimously agreed in the spring of 1990 to take a united stand against the restrictions regarding the entry of HIV-positive persons at national borders, to the point of not participating at the San Francisco Conference.

Today, there is no scientific basis to justify such a restriction on the free movement of HIV-positive individuals from country to country. That resolution was intended to convey a message to the US government to review its policy that is in serious conflict with the great democratic traditions of that country, with which we are closely associated. At the time of the Florence Conference, taking place in a country of free movement, to our regret the US had not yet found a solution based on the principle of freedom, as well as scientific knowledge. Therefore, we hope the US government will change its policy. This will allow everyone to meet in Boston in 1992. It is in a spirit of cooperation and brotherhood that we express this desire.

In Italy, a very comprehensive strategy plan for the fight against AIDS has been elaborated. These choices were incorporated in the act approved in June 1990 by Parliament, 'Program of Urgent Intervention for the Fight against AIDS' with a budget of US$ 1.7 billion.

The total strategy of this law, together with the law on drug addiction, favors prevention through information campaigns aimed at the general public and groups at risk.

Other initiatives aim to favor ‘solidarity’ against discrimination and ignorance. This commitment has proven that the groups at risk have indeed acquired a better knowledge of AIDS and its prevention. AIDS is no longer and must not be a taboo. The production of self-blocking syringes has been started and the production of condoms is now subject to
quality control. This last objective has to also overcome cultural, psychological and political difficulties and resistance.
In addition, updated training has been organized for health care workers in order to make their activity more efficient and gratifying. Since 1988, research programs have contributed to the growth of international scientific knowledge and to detailed studies of the specific features affecting particularly the Italian population.
In this context, the Italian strategy of intervention is also based on international collaboration. Thus, we are already involved in European experiments on vaccines and clinical trials for the in vivo testing of new drugs. Now we intend to expand our collaboration with developing countries.
In the field of care services for people with HIV/AIDS, we want to provide treatment in hospitals as in-patient services during periods of acute crises and follow-up care mainly in day hospitals or out-patient clinics. In addition, an extensive program of home care treatment has been started under the supervision of the hospital units. In this way, we shall ensure to all citizens the free public health care they so rightfully deserve, including the distribution of necessary drugs, such as AZT.
The act against AIDS of June 1990 includes a whole chapter concerning the ethical problems relating to AIDS: from confidentiality to the request of informed consent to the elimination of discrimination toward the patient.

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We are aware that laws and financial measures are not enough to rapidly change the course of events. At times we witness episodes and events that demonstrate how difficult it is to create a climate of collaboration and solidarity which encourage the prevention of the spread of HIV infection, and to provide the necessary help - both moral and economic. For this reason our commitment will be steadfast and constantly growing. It would be unfair to underestimate how much has been done and how much we are doing, in particular the efforts of health care workers who, with much diligence and responsibility, work to improve the conditions of the AIDS patients. In the same way, we are grateful to the NGOs, those groups of people who freely, silently and lovingly give of themselves, dedicating time and efforts to those suffering and sometimes outcast from society. They help to transform good intentions into concrete, and efficient interventions.
In conclusion, my hope is in presenting this book that all these important scientific contributions, which gave such prestige to the Florence Conference, will be useful for increasing the knowledge and interest of all those
involved around the world in the fight against AIDS. This demonstrates the irreplaceable role of these conferences as a forum and focal point for the cultural, but also humanistic, exchange that contributes so much to the development of a global strategy for the fight against AIDS.

Foreword

AIDS and Its Impact on the Health, Social and Economic Infrastructure in Developing Countries

His Excellency Yoweri Kaguta Museveni

President of the Republic of Uganda

The AIDS/HIV epidemic has reached catastrophic proportions. Globally, WHO estimates that 8-10 million people are infected by HIV. Over 1.2 million men, women and children have already developed AIDS and, by the year 2000, there may be 25-30 million people infected by the virus. There are millions of people around the world whose lives have been affected by the consequences of this epidemic in one way or another. AIDS has not only become the most important public health challenge of our time, but it has sweeping global consequences, social, economic, cultural and even political.

At the same time, social, economic and cultural conditions have encouraged and are fueling the epidemic especially in the developing world. According to WHO estimates, the global balance of HIV is rapidly tipping towards the developing world. In 1985, about 50% of the world total infections estimated were in developing countries. But now, it is estimated that by the year 2000, 75-80% will be in developing countries and be the year 2010 as much as 90%. Some think that this is but one of the first of many developmentally linked infectious diseases. If that is true, then, unless there is a concerted effort to redress the economic imbalance between the rich and poor nations, we may see untold millions of people die.

While AIDS is the pre-eminent public health threat of our time, socio-economic factors, crucial in the transmission of AIDS and other sexually transmitted diseases, have deep historical roots. In Africa, sexually transmitted diseases, such as gonorrhoea and syphilis, were a big health
hazard before the advent of modern Western medicine. To discourage the spread of these in society, Africans had evolved cultural taboos against premarital sex and strict sanctions had been established against premarital sex or sex out of wedlock. With the advent of sulfas and penicillin, ‘The Magic Bullet’, in the early 1940s, the fear of sexually transmitted diseases subsided, ushering in the era of permissive sexuality. This was later encouraged by the era of the 'Sexual Revolution' of the 1960s, mainly inherited from events in Western Europe which in turn had been set in motion by the universal availability of the contraceptive pill. Traditional checks based on morality and self-control were thrown aside. This was accompanied by complete neglect of our traditional herbal and other medicines. Their further development was aborted. In the developing world, though, the promise of the wonder drugs in controlling sexually transmitted diseases was not to be fulfilled, because of the prevailing socio-economic circumstances.

One can appreciate why this was not to be if one considers the following. For sub-Saharan Africa, in particular, we find that, between 1960 and 1986, the average share of public health expenditure of gross national product (GNP) increased only from 0.7 to 0.8%. This average does not, however, tell us that in a number of African countries the share allotted to health actually declined. In some countries, for example, it fell from 1 % in 1960 to 0.7% in 1986.

If we look at the per capita public health expenditure in real dollar terms, we note a clear downward trend. In 1987, the average per capita public health expenditure in the sub-Saharan countries was a mere US$ 3.50 per year as compared to more than US$ 1000.00 in the USA and Scandinavian countries. This trend is explained by the marked slow-down of economic growth in the 1980s. In 12 sub-Saharan countries, the per capita growth rate of the period 1965-1988 was negative. Starting in 1970, the average income per head of population fell to the level of the 1960s. It is easy to understand that, in such a depressed economic environment, expenditure on public health was severely constrained.

In Uganda, now, we have the following distorted ratios: (1) 1 doctor for every 23,000 people compared to 1 doctor for about 1,000 people in industrial countries; (2) 1 hospital for every 200,000 people; (3) 1 health unit for every 150,000 people; (4) 1 nurse for every 2,332 people, and (5) 1 health bed facility for every 800 people.

It is, therefore, not surprising that by the early 1970s, sexually transmitted diseases had reached epidemic proportions. Studies done at the
time showed an incidence of up to 14% among mothers attending antenatal clinic in some of our cities. Where modern medical facilities are inadequate, sexually transmitted diseases are usually not diagnosed at all, or when they are diagnosed, proper or adequate treatment is not given. We are told by scientists that heterosexual transmission appears to be much more important in the epidemiology of HIV infection in Africa than in Europe and North America, and sexually transmitted diseases which are hyperendemic in tropical Africa have been considered possible co-factors in heterosexual transmission of HIV in this region. Some studies have shown that in uncircumcized men who acquired genital ulcer disease, such as syphilis or chancre, the cumulative transmission rate for HIV after a single sexual exposure was 43%. I understand that in developed countries the heterosexual transmission is less than 0.1% per single sexual exposure. In view of the socio-economic factors enumerated above, it is, therefore, not surprising that when HIV arrived in East and Central Africa in the early 1980s it landed on fertile ground. The AIDS epidemic has demonstrated the historical continuity of social, political and medical reaction of epidemics among socially deprived populations. AIDS was heralded by epidemics of sexually transmitted diseases. A historical appreciation of the resilience of social conditions that promote diseases like AIDS may help society in rationally responding to protect the public's health. Epidemiological studies have traditionally focused on the biological dynamics of disease such as incubation period, infectiousness of the disease organism and its ability to cause death. AIDS has, more than any other disease, brought about the recognition that the spread of disease may be driven more by sociological and economic dynamics. AIDS cannot be understood in biological terms alone. Sex is not a simple manifestation of a biological drive, it is socially dictated. Sexual opportunities available to an individual and the type of partners deemed appropriate will vary from one social group to another. It is in view of this background that I have been emphasizing a return to our time-tested cultural practices which emphasized fidelity and condemnation of premarital or extramarital sex. I believe that the best response to the threat posed by AIDS and other sexually transmitted diseases is to reaffirm publicly and forthrightly the reverence, respect and responsibility every person owes to his or her neighbour. Young people must be taught the virtues of abstinence, self-control and postponement of pleasure and sometimes sacrifice. Just as we were offered the magic bullet of penicillin from the early 1940s, our public health figures
are now offering us the condom and 'safe sex'. In countries like ours, where a mother often has to walk 20 miles to get an aspirin for her sick child or 5 miles to get any water at all, the practical questions of getting a constant supply of condoms or using them properly may never be resolved.

Meantime, we are being told that only a thin piece of rubber stands between us and the death of our continent. I feel condoms have a role to play as a means of contraception especially in couples who are HIV-positive, but condoms cannot be the main means of stemming the tide of AIDS. The initial response of AIDS in Africa, similar to that in the rest of the world, was denial followed by accusation of an 'us' being victimized by a foreign 'them'.

Early reports on AIDS in Africa were clouded by sensationalism, panic, politics and narrowly focused academic research that ignored socio-cultural issues.

AIDS was first recognized in Uganda in 1981, but the negative feelings mentioned above prevailed and the government of the time decided to bury its head in the sand like the proverbial ostrich. A lot of time was, therefore, lost from 1981 up to 1986, when we got into government. Our government has not had any qualms about being frank to our people on issues of a national catastrophe such as the AIDS epidemic. When we got into power in 1986, the problem had already spread to most parts of the country. We opened gates to national and international efforts to the control of the epidemic. Unfortunately, despite my government's effort, the AIDS situation in Uganda is becoming more and more serious, despite the high level of awareness among the population. However, this awareness has over the last few years started paying off. There has been a singular decline in the incidence of other sexually transmitted diseases. The disease has hit hardest those who are not only in their most sexually active years, but also in their most productive years. Loss of labour force is already being experienced both at the national and household levels. A number of professionals working in government and other institutions have died. In our countries, where education and technical expertise are at a premium, this will offset our economic and social gains.

For many rural households, current levels of agricultural production may be threatened, especially as the agricultural activities are labour-intensive. This will affect coffee production by small holders, which account for over 90% of the country's export earnings. This reduction will cause more economic strain, especially when the coffee are not favourable.

Foreword XV
With regard to the social services, AIDS is already affecting our overstretched medical services. Apart from looking after AIDS patients, secondary infections such as tuberculosis (TB) have increased because of AIDS. We understand that already a 2- to 3-fold increase has been observed in our region where dormant TB is common, yet treatment for a single case of TB is US$ 126.00. In Uganda, over the last 6 years, with the help of UNICEF, we have managed to achieve over 90% immunization coverage for the 6 immunizable diseases including TB, thus dramatically bringing down the infant mortality rate. AIDS might reverse these achievements. UNICEF predicts that, by the year 2000, there will be 590,000 maternal AIDS deaths in Africa leaving behind 5.5 million AIDS orphans. Traditionally, in an African society, when parents die, the children go to live with another member of the extended family. These families' resources, already overstretched by their own children's needs and the orphaned children, are going to wind up at the end of the family line. If the orphaned children survive, they will find it increasingly difficult to occupy a niche in society as they will have missed education opportunities and, later, have no hereditary rights in their adopted families. Government and other bodies have, therefore, to come in and fill the gap. Apocalyptic visions of the virtual decimation of much of Africa may be unwarranted, but the growing devastation of a range of national aspirations is very real unless something is done quickly.

In Uganda we have realized that the AIDS problem goes beyond the mere health of the people. We have, therefore, adopted a multisectoral strategy for the control of the epidemic. Where control measures were centered in the health sector, we are now establishing full-fledged control programmes in other key sectors of communication, rehabilitation, education, community services, defence and economic planning. An independent body, the Uganda AIDS Commission, has been established to guide, direct, co-ordinate and monitor the strategy. The Commission, which I am chairing myself, so as to give the necessary political support, will establish policies and guidelines on HIV and AIDS-related matters. The Commission will monitor the control measures of the various sectors by listening to the voices of the people through the Commission's field officers and the grass-root leaders. This strategy, we hope, will be able to harness our efforts in combating AIDS.

I understand that in Romania and the Soviet Union hundreds of children got infected through use of unsterile injections in medical facilities. If
this is true, then, I wonder what is happening in our countries where sterility is worse. I am surprised that our scientists have not looked at this exhaustively with a view to eliminating this possibility and protecting our people.

Is it not possible that people with sexually transmitted diseases are more likely to get unsterilized injections in unlicensed clinics, in addition to their genital ulcers being a good port of entry of the HIV virus?

Uganda and Africa's forests and savannahs still conserve the largest variety of plant and animal life. These are a potential source of natural chemotherapeutics for AIDS and other diseases.

In my country, we have embarked on research on these. We welcome international collaboration.

Our emphasis, though, has been in health education and change of sexual behaviour, having realized that HIV infection is mostly dependent on voluntary behaviour unlike most other transmittable diseases. Even so, we shall ultimately depend on the concerted efforts of you scientists in your various disciplines to lead us out of this dark abyss.

It is in view of this that I salute you for the achievements of the last 10 years in the pursuit of an affordable drug and/or vaccine.

Introduction

The volume is based on the VIIth International Conference on AIDS, held in Florence, June 16-21, 1991, and sponsored by the Istituto Superiore di Sanita', Rome, Italy with the co-sponsorship of the Italian Ministry of Health, the World Health Organization, International AIDS Society, European Economic Community and the Regione Toscana, Italy as well as also sponsored in association with: Associazione Nazionale per la Lotta contro l'AIDS (ANLAIDS), Associazione per la Salute della Donna, Comune di Firenze, Comitato Firenze '91 and Fondazione Italiana per la Ricerca sul Cancro (FIRC).

These proceedings contain the Master- and State-of-the-Art Lectures, followed by the four best papers selected from an impressive total of 3,500 accepted abstracts, and finally five Conference Summary papers concerning basic science, clinical science and trials, epidemiology and prevention, social and behavioral science, and communities challenging AIDS.

The book opens with three main topics: (a) the Impact of Biomedical Research on the AIDS Epidemic identifying also the gaps in knowledge and some of the goals for the coming years; (b) Progress and Challenges in Therapy: progress is possible if continuous attention is paid to the basic causes of the disease; and (c) the Implications of AIDS in Developing Countries; WHO estimates a total of 40 million HIV-infected persons worldwide.
by the end of this decade with more than 90% of infections taking place in developing countries.

The following state-of-the-art overviews deal with present and future dimensions of the HIV/AIDS pandemic: the virology of AIDS - biological aspects including co-factors; the molecular biology of HIV, looking backwards to 10 years of discovery and hope for the future; as well as the cellular pathogenesis of both viruses, HIV-1 and HIV-2; as well as the etio-pathogenesis of AIDS-related malignancies.

A critical outlook for clinical trials urges that if progress is to be made in 1991-1992, science must continue to be questioned and challenged in order to move faster. Advances in AIDS vaccine research are reviewed thereafter. Significant progress has been made and the prospects for efficacious vaccines by the year 2000 are not outside the realm of possibility.

The psychosocial aspects and impact of AIDS on social, economic, health and welfare systems in developed and developing countries is the subject of the following two contributions which demand that if mankind is to withstand the impact of AIDS and eliminate it from our midst, then a family perspective which heightens global solidarity and global learning is needed with an imperative global ethic.

The following four papers selected from the best abstracts of the four major areas of this International Conference report novel results on (a) genes or domains within genes that control cellular tropism, cytopathology and repliative properties of HIV-1; (b) the development of opportunistic non-Hodgkin's lymphomas in AIDS patients receiving long-term antiretroviral therapy; (c) risk reduction and stabilization of HIV seroprevalence among drug injectors in New York City and Bangkok; and (d) change in AIDS risk behaviors from adolescence to adulthood.

The book ending with the Conference commentaries on: (a) Basic Science Challenging AIDS; (b) Clinical Science and Trials; (c) Epidemiology and Prevention; (d) Social and Behavioral Science, and (e) Communities Challenging AIDS is highlighting the most pertinent new data, overviews and reflections on AIDS mechanisms, novel designs and strategies, enhanced international cooperations, and call for global solidarity.

Lastly, the editors wish to thank Francesco A. Manzoli, Director General, Istituto Superiore di Sanità, Rome, Italy, the Members of the International Steering Committee, and of the Program, Communications, Developing Countries Sponsored Delegates and Communities Committees.

Furthermore, we thank Cristina D'Addazio, Secretary General, and all other Conference Personnel as well as Daniela Rosselli, Rita Pestellini and
their staff for their contributions to this International Conference.

Editors
Giovanni Battista Rossi, Rome
Ferdinando Dianzani, Rome
Elke Beth-Giraldo, Naples
Gaetano Giraldo, Naples
Luigi Chieco-Bianchi, Padua
Paola Verani, Rome

Acknowledgments

The Executive Committee for the VIIth International Conference on AIDS was constituted of Giovanni B. Rossi, Conference Chair; Luigi Chieco-Bianchi, Conference Co-Chair; Gaetano Giraldo; Paola Verani; Elke Beth-Giraldo, Chair, Developing Countries Delegates Committee. The Steering Committee included the Members of the Executive Committee and Michael Merson, Lars Olof Kallings, Manuel Carballo, World Health Organization; Paul A. Volberding, Meinrad Koch, Friedrich Deinhardt, International AIDS Society; Alexandre Berlin, European Economic Community (EEC); Ferdinando Dianzani, Chair, Program Committee; Elio Guzzanti, Chair, Communities Committee, and Antonio Siccardi, Chair, Communication Committee. The Program Committee included Luigi Chieco-Bianchi, Coordinator, Basic Science; Carlo Zanussi, Coordinator, Clinical Science and Trials; Gaetano M. Fava, Coordinator, Epidemiology and Prevention, and Elio Guzzanti, Coordinator, Social and Behavioral Science.

Communities Challenging AIDS Sessions were organized by: Manuel Carballo, World Health Organization; Giovanni Rezza and Laura Thomas in collaboration with the World Federation of Hemophilia and the World Health Organization.

The core staff for the conference included Cristina D'Addazio, Secretary General; Lucy Felicissimo, Coordinator and Ulla Johansson, Assistant Coordinator, Scientific Program; Catherina Ramel, Co-coordinator, Registration; Benjamin Junge, Coordinator, Developing Countries Sponsored Delegates Program; Laura Thomas, Coordinator, Community Relations.

International Conferences on AIDS

Ist International Conference on AIDS,
Atlanta, Ga., April 14-17, 1985
Chairman: Gary Noble

Und International Conference on AIDS,
Paris, June 23-25, 1986
Chairman: Jean-Claude Gluckman

IIIrd International Conference on AIDS,
Washington, D.C., June 1-5, 1987
Chairman: George J. Galasso

IVth International Conference on AIDS,
Stockholm, June 12-16, 1988
Chairman: Lars Olof Kallings

Vth International Conference on AIDS,
Montreal, June 4-9, 1989
Chairman: Ivan L. Head
Leitmotiv/Slogan of the Conference:
The Scientific and Social Challenge

VIth International Conference on AIDS,
San Francisco, Calif., June 20-24, 1990
Chairman: John L. Ziegler
Co-Chairman: Paul A. Volberding
Leitmotiv/Slogan of the Conference:
AIDS in the Nineties: From Science to Policy

VIIth International Conference on AIDS,
Florence, June 16-21, 1991
Chairman: Giovanni B. Rossi
Co-Chairman: Luigi Chieco-Bianchi
Leitmotiv/Slogan of the Conference:
Science Challenging AIDS

The International Conference on AIDS
is the most prestigious, mondial forum for
the life-threatening pandemic of HIV infection
which is taking its heaviest tolls
now and will continue to do so in the years
to come, particularly in all the developing
countries. The conference is hosted each
year by local/national organizers and co-sponsored
by the International AIDS Society
and the World Health Organization in
recognition of the global scientific and social challenge of HIV infection/AIDS. The conference promotes mondial cooperation, participation, solidarity, and respect for the human rights and dignity of HIV-infected people and people with AIDS. The uniqueness of this conference series resides in the blueprint of program which is built around four balanced themes:

1. Basis research.
2. Clinical research and trials.
3. Epidemiology and prevention.
4. Social and behavioral science.

Thus ensuring joint participation by scientists, clinicians, public health workers and volunteers - any and everyone working in AIDS research or involved in the care of AIDS patients - in solidarity to enrich knowledge and understanding, i.e. the impact of new research data and scientific observations on treatment, preventive strategies, public health policy, and all other fields affected by the AIDS epidemic.