

REPORT
OF

THE STUDY GROUP
ON HIV INFECTION OF HAEMOPHILIACS
THROUGH BLOOD PRODUCTS
IN HONG KONG

May 1993

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INTRODUCTION

The Ad-hoc Study Group on HIV infection of Haemophiliacs was appointed by the Secretary for Health and Welfare on 6 January 1993 to carry out an independent investigation on the cause and extent of HIV infection of haemophiliacs in Hong Kong, to ascertain if the hazards of such infection had been contained and to recommend appropriate assistance which the Hong Kong Government may extend to the infected individuals. The Terms of Reference for the Study Group and its membership are as detailed in Appendix I. The Study Group met twice on 15 January and 15 March 1993. Working papers submitted by individual members on various aspects of the infections were studied. The Study Group has now completed its investigation. The following details its findings and recommendations.

SUMMARY OF PRINCIPAL FINDINGS AND RECOMMENDATIONS

2. Having completed its investigation, the Study Group is of the opinion that the infection was most probably acquired through HIV contaminated factor VIII used in Hong Kong before July 1985 for the treatment of bleeding disorders. Sixty-four individuals were known to be thus infected, sixty-one of whom being haemophiliacs, and the total number of affected individuals was estimated to be between seventy and eighty. The Study Group, however, considers that for all the practical purposes, the infection could not have been avoided because the test for HIV was not available at the time, and that it was the general consensus of medical experts that the medical benefits of treating severe bleeding disorders as of haemophiliacs with factor VIII would outweigh the risk of infection associating with it.

3. The factor VIII used in Hong Kong since July 1985 is produced from donor blood which had been individually tested beforehand and had been subjected to heat or solvent/detergent treatment to ascertain that they are free of HIV. Close monitoring of haemophiliacs carried out at several centres in Hong Kong since 1985 confirmed that these measures combined had essentially eliminated the hazards of HIV infection from the new factor VIII used in Hong Kong since July 1985. The Study Group has also noted that because of timely actions taken by the then Medical and Health department, Hong Kong was among the first countries to receive supplies

of the safer factor VIII.

3. The Study Group, however, considers that the circumstances of those who had been inadvertently infected with HIV through blood and blood products in Hong Kong deserve sympathetic considerations and recommends the Hong Kong Government to extend to them special assistance for their medical, socio-psychological and financial needs.

DIMENSION OF THE PROBLEM

5. HIV infection of sixty-four individuals was confirmed by a positive blood test conducted over a period of time since 1985 when the test became generally available. Sixty-one of them were haemophiliacs and the remaining three were not. There were nine, who had since developed full blown symptoms of AIDS, or which six, had deceased. A blood specimen taken in June 1985 from one of these individuals was tested negative for HIV, and another taken four months later in September of the same year was tested positive. The sero-conversion is evidenced that this individual had contracted HIV infection several weeks to months before October 1985. The remaining individuals were found to be positive when they were first tested for HIV at various time after 1985. This was evidenced that these individuals had contracted HIV infection sometimes in the past, but without a pre-infection blood specimen, it was not possible to determine the time when the infection occurred.

6. Apart from the above documented cases, there could well be a few more cases, which have not been traced as of to-dated, emerging later. The Study Group estimated the total number of individuals infected through medical treatment they received in Hong Kong between seventy and eighty.

SAFETY OF BLOOD AND BLOOD PRODUCTS

7. As the blood and the blood products used by these individuals at the time are no longer available for testing, it is not possible to ascertain whether these

blood and blood products were indeed contaminated with HIV. Nevertheless, HIV contaminated blood products were believed to be the most probable cause of the infection on the basis of the following considerations:

8. Before 1985, HIV infection was quite common among haemophiliacs in Hong Kong whose condition required frequent treatment with factor VIII. The infection rates reported from other countries over the same period were as high as 78%.

9. The factor VIII used before 1985 were prepared in batches from large pools of blood from several thousands to tens of thousand blood donors. Blood from individual donors could not be tested for HIV, because such a test was not generally available at the time. Given these circumstances, the chances of contamination of an entire batch of factor VIII by few donors unknowingly infected with HIV would be quite significant.

10. Routine HIV testing of all donor blood implemented since 1985 has markedly reduced, but will not entirely eliminate, the hazard of HIV contamination. Improved method of production of factor VIII by the introduction of heat treatment or treatment with solvent and detergent will further reduce such infection hazard.

11. Concomitant with the use of the safer factor VIII, there had not been a single case of HIV infection in Hong Kong, which can be unequivocally shown to have been contracted through the new factor VIII. On the contrary, extensive follow-up study for various periods of one to seven years showed that of a total of eighty haemophiliacs in Hong Kong, who had escaped the infection initially, none had contracted the infection since 1985. The only possible exception came to the notice of the Study Group after an exhaustive search. In this instance, the infection was confirmed in October 1985, two months earlier in June 1985, the same individual gave a negative result for HIV. However, given the usual delay in antibody response to infection with HIV or other microbial agent, the Study Group considered that this individual most probably had contracted the infection before the new factor VIII was introduced to Hong Kong

12. In sum, the above described showed that

- (1) it was highly likely that factor VIII used in Hong Kong before 1985

had been contaminated with HIV, and because their medical conditions required frequent treatment with the blood product, haemophiliacs also became infected with HIV much more commonly than healthy individuals; and

- (2) the improvements instituted in the production of factor VIII used since 1985 has markedly reduced the hazard of HIV contamination, and concomitant with use of the safer products, HIV infection of haemophiliacs also became markedly less frequent, despite their medical conditions.

13. Combined with similar overseas experiences which also strongly associate prevalence of HIV infection of haemophiliacs with factor VIII used before and after 1985, the Study Group concluded

- (1) that the infection of the haemophiliacs and the other three individuals in Hong Kong was most probably acquired through medical treatment from HIV contaminated blood and factor VIII used before 1985; and
- (2) that for all the practical purposes, the blood and blood products used in Hong Kong since 1985 had been rendered safe from the hazard of HIV infection.

MEASURES TAKEN TO CONTAIN THE INFECTION

14. Without being able to ascertain the time of HIV infection or the exact source of the infection, the Study Group did not consider it a fruitful course to review each of the sixty-four cases of HIV infection individually in order to determine if the infection could have been avoided. Instead, it drew on overseas experiences and examined the events leading up to 1985 and beyond as they occurred in Hong Kong. In particular, it reviewed the measures taken by the government medical authority to contain the spread of HIV infection among haemophiliacs as knowledge of the association of the infection with AIDS and the implications of which on haemophiliacs came to light.

15. The Study Group noted that AIDS refers to a complex of symptoms characterized by unusually severe and progressive infections and/or cancer associated with depletion of certain immunological functions in an otherwise healthy individual.

The disease was first described in homosexuals in 1981, and it was found to also occur in haemophiliacs in the following year. The latter finding alerted the medical community to the possibility that the medical treatment haemophiliacs received might be associated with a risk of the disease; and this was reinforced by the discovery in the subsequent two years in 1983 and 84 that HIV might be a cause of the disease. Subsequently, a blood test for HIV antibody was developed and received approval by FDA in 1985. This paved the way for implementing specific measures to contain HIV infection through contaminated blood and blood products, by routinely testing all donor blood for the presence of HIV antibody. The introduction of heat treatment and, later, solvent/detergent treatment in the manufacturing processes were proved to be efficacious and this further reduces the hazards of HIV infection associating with factor VIII.

16. The risk of infection due to blood-borne microbial agents is inherent in the treatment with blood and especially blood products, but the medical conditions of haemophiliacs are such that the benefits of the treatment would outweigh the associated risk of infection. This was and remains to be the general consensus opinion of medical experts in the world even after the discovery of HIV and as the extent of the risk of HIV infection associating with factor VIII treatment was being recognized. Indeed national organizations such as the National haemophilia Foundation of the U.S.A., for example, urged as late as 1984 that treatment of haemophilia with factor VII should not be withheld, despite the associated risk of HIV infection, because there was no viable alternative treatment especially for the more severe forms of haemophilia.

17. Pre-testing of donor blood and the heat or the solvent/detergent treatment had markedly reduced, but do not eliminate, the risk of HIV infection associating with blood and blood product. The residual risk was evidenced by a report by the Centre for Disease Control, U.S.A., of six cases of HIV infection apparently related to treatment with the safer factor VIII produced after 1985. Recombinant factor VIII and other blood products are expected to be available in the near future and this development will help, in the foreseeable future, to eliminate the risk of HIV infection associated with natural products derived from blood.

18. In the light of the above described global development, the Study Group examined the events pertaining to HIV infection of haemophiliacs in Hong Kong as they transpired since 1982 when the first case of HIV infection of haemophiliacs was reported. The issue was discussed by the Expert Committee on AIDS in its first

meeting in November 1984. The committee was set up by the then Medical and Health Department to keep in review the global development in AIDS, monitor the disease as it occurred in Hong Kong and co-ordinate effort in containing the spread of the disease.

19. Several measures were taken by the health authority in Hong Kong in an attempt to contain the spread of HIV infection through blood and blood product. In 1983, before the blood test for HIV was developed, the Hong Kong Red Cross instituted screening of blood donors, and those who have a history associated with known risk of having AIDS were asked to defer from donating blood. Evaluation of prototype blood test for HIV commenced in the beginning of 1985 in the Virus Unit of Pathology Institute and the Hong Kong Red Cross, and by August of the same year, five months following approval of the test by the Food and Drug Administration, U.S.A., all donor blood used in Hong Kong was routinely tested for HIV. Meanwhile, as a result of a continue procurement effort on the part of the medical authority, the safer heat treated factor VIII was made available to replace all old stock held by government hospitals in July 1985 --- at a time when there was still a global short supply of the new product.

20. As seen in the light of global development, the Study Group is of the opinion that

- (1) the medical authority in Hong Kong had acted promptly and prudently to contain the spread of HIV infection through blood and blood products; and
- (2) it further noted that it was because of the actions taken, Hong Kong was among the first countries to receive the supply of the new factor VIII, ahead of, for example, Singapore and Japan.

COMPREHENSIVE ASSISTANCE PACKAGE

21. HIV infected haemophiliacs suffer from a potentially lethal underlying hereditary bleeding disorder compounded by an incurable infectious disease contracted inadvertently through medical treatment for their bleeding disorder. The dual tragedy mainly affects children and young adults. It compromises the

psychological well-being of these patients and carries with it social stigmatization that affects their schooling and career. All these combined place an undue burden, financially and otherwise, on the family of these patients. The Study Group believes that

these circumstances are deserving of special assistance from the Government to provide for the medical, psycho-social and financial needs of these patients.

22. Having examined the current medical and support services available and after consultation with the patients and their families, the Study Group wishes to propose a comprehensive programme of support services outlined as follows for the HIV infected haemophiliacs. The Study Group further recommends that

this special assistance to be extended also to those, who are not haemophiliacs, but were inadvertently infected with HIV through transfusion of blood/blood product they received in Hong Kong.

(A) Medical Support Services

23. The Government should remain committed to ensure that appropriate medical services are affordable and available to the haemophiliacs. A good HIV/haemophiliac care system requires from the outset an efficient clinical network including at least the primary care physician and the hematologist plus a quality laboratory support service. Other specialist care including in-patient service, and blood transfusion service should also be co-ordinated to form a comprehensive framework for optimum delivery.

24. Effective management can be achieved by a specialist physician or by the hematologist who has, in many cases, assumed the role of the primary care physician of the HIV-infected haemophiliacs, through the provision of

- (a) regular physical and immunological assessment,
- (b) antiviral treatment,
- (c) antibiotic prophylaxis,

- (d) treatment of complications, and
- (e) referral for specialized services as indicated including psycho-social counselling, schooling etc.

25. An appropriate professional body should be identified to bring about networking of health care providers who managed haemophiliacs in the private and public sectors to achieve general consensus on some important issues like standards of management, treatment protocols, organization of health care providers, procedural guide to streamline referrals and hospital admissions, infection control policy, staff training and education.

(B) Psycho-social Support Service

26. Psycho-social supports are often necessary in view of the complexity of issues faced by HIV-infected haemophiliacs. Services provided by clinical psychologists, specialty nurses, counsellors, social workers are inseparable components of the comprehensive care system for the haemophiliacs. Support for their family is also important, especially when the infected persons develop late-stage complications.

27. The social and psychological support services offered in public hospitals and clinics are generally insufficient. There is a case to bring together such resources from the non-governmental organizations, voluntary agencies and concerned groups to provide the much needed psycho-social support services to the haemophiliacs and their family.

28. The Study Group felt that it would be desirable to establish a centralized referral system to co-ordinate available support services and to avoid inappropriate utilization and duplication. Existing support services included public assistance and social services, patient support groups, AIDS counselling service, nursing service and genetic counselling. Other support services like home help, community nursing service and hospice care should also be extended or developed to cater for the new and emerging needs of the haemophiliacs and their families.

(C) Schooling and Employment

29. haemophiliac patients quite often have problems in schooling because of

frequent absence from classes for treatment. The situation is even worse for HIV-infected ones which therefore deserves understanding of the schools and education authority.

30. Patients are confronted with the same difficulty when they come to employment. Without good educational background, it is hard to settle down on an indoor job which would be advantageous in view of their joint problems. Positive attitudes of employers towards haemophilia and HIV infection are essential.

31. On a macro-level, responsible Government departments should strengthen and sustain their efforts in educating school teachers and principals, parents, employers and the community at large to dispel misconception prejudice against HIV-infected persons and to promote a more sympathetic attitude towards these people in school and at work.

32. AIDS and its related issues are growing and will stay with us for many years to come. On the educational front, the Education Department may wish to consider having a high level committee to establish AIDS policy, supervise development of education programme on AIDS, and resolve education problems faced by schools in the context of haemophilia/HIV infection. Haemophiliac parents interviewed by us felt that flexibility should be allowed for the upper age limit for the 9-year free education for their children. In view of their need for frequent hospitalization, the 9-year free education should be extended to haemophiliac students above the age of sixteen.

33. There should be no pre-employment HIV testing. Haemophiliacs should be employed on the basis of their capabilities. The Labour Department should promote non-discriminatory policies in this respect. Vocational training should be offered to haemophiliac patients to enhance employment opportunities.

(D) Financial Assistance

34. It was apparent to the Study Group as it examined the events transpired that the medical authority of the government of Hong Kong has kept pace with global development and acted promptly and prudently on information as they arose. It has taken several pro-active steps to contain the spread of HIV infection through medical treatment, and because of its effort it was able to control the spread of the infection in Hong Kong earlier than many other countries, including Japan, Singapore and

Australia. The Study Group was not aware of any evidence suggesting negligence on the part of the government throughout the course of the events. Nevertheless, in line with practice in other countries, the Study Group recommends that

financial assistance should be extended on compassionate ground to individuals who had contracted HIV infection through medical treatment.

35. The Study Group reviewed several financial assistance schemes provided for HIV infected haemophiliacs in different countries. In some countries, for example, Germany, the cost of the assistance scheme is born by the pharmaceutical industries, which would not be appropriate for Hong Kong. In other countries, for example, Australia, Japan and the U.K., the cost of assistance scheme is born by the respective governments. Of these, the scheme operating in Japan is considered to be especially in light of the small number of potential beneficiary of the scheme.

36. The Study Group considers the U.K. assistance scheme, which is similar as the Australian scheme, as being the most appropriate for Hong Kong. Reasons are as follows:

- (1) It recommends the government to formulate its financial assistance scheme along this line. As the U.K. scheme, the amount to be awarded should be determined according to the circumstances of its intended beneficiaries and, in addition, to take into account of the medical and other support services which will be extended to these individuals under the comprehensive assistance package as outlined above.
- (2) The Study Group expressed concern that money awarded minors might be misused and urged the government to take necessary precaution against such possible abuse of the scheme.

- END -

TERMS OF REFERENCE

In the light of reports on HIV infection of haemophiliacs through transfusion of blood products, particularly factor VIII,

- (a) to establish the facts regarding treatment of blood products in Hong Kong for preventing HIV transmission.
- (b) to examine the adequacy of such treatment, having regard to internationally accepted standards at the time;
- (c) to assess the extent to which haemophiliacs in Hong Kong have been infected by HIV through transfusion of such products and identify the source of such infection; and
- (d) in the light of the above, to recommend to Secretary for Health & Welfare any special course of action appropriate to Hong Kong for the assistance of haemophiliacs who have contracted HIV through transfusion of blood products in Hong Kong.

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