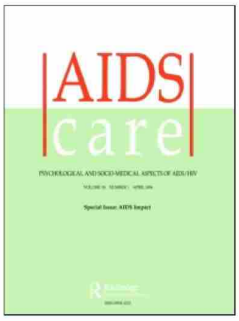

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Treatment Dilemmas for HIV Infected Haemophiliacs

C. A. LEE, R. MILLER & E. GOLDMAN
Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London, United Kingdom

Abstract *A description of a structured group, held for anti-HIV positive haemophiliacs and their relatives, to discuss the implications of participating in the MRC/INSERM double-blind control trial of zidovudine is given. The group discussion is used to define, evaluate and rank the many treatment dilemmas inherent in participating in this drug trial.*

Introduction

Haemophiliacs have a high prevalence of antibody to human immunodeficiency virus (anti-HIV) as a result of treatment with unheated clotting factor concentrates (U.K. Haemophiliac Centre, 1988). Of 525 haemophiliacs registered at the Royal Free Haemophilia Centre, 111 and one wife of a haemophiliac have been found to be anti-HIV positive (Lee *et al.*, 1989). These patients have largely been infected by imported commercial concentrates manufactured from blood donated in the United States of America. A few patients have also been infected with National Health Service concentrate. The first seroconversion occurred in December 1979 and the last occurred in July 1985. By late 1984 heated concentrate became available for treatment, and as a consequence there have been no new seroconversions since July 1985.

Zidovudine is now the treatment of choice for patients with symptomatic HIV disease in group IV of the Center for Diseases Control (CDC) classification (CDC, 1987; Barry, 1989). Although it is probable that all patients would benefit from such therapy, the uncontrolled use of zidovudine in asymptomatic patients has caused side-effects (Lancet, 1989). Thus, the joint MRC/INSERM trial has been designed to provide information about asymptomatic patients, who face the near certainty of disease progression, in the context of a double-blind placebo controlled trial of zidovudine.

Group meetings for different combinations of patients and their relatives or close friends have been held regularly in our Haemophilia Centre since 1979. These meetings are co-ordinated and led by the social worker, and they have a structured format established by careful planning involving all members of the staff.

This is a report of a group held to discuss the implications of participating in the MRC/INSERM trial.

Correspondence address: Dr Christine A. Lee, Consultant Haematologist, Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, Pond Street, Hampstead, NW3 2QG, U.K.

Methods

The following letter was sent to haemophiliacs who were anti-HIV positive:

> "We are planning to hold another evening group for people who are antibody positive. We hope to discuss antiviral treatment for HIV disease, in particular AZT treatment. At the previous meeting we found that wives, girlfriends and other family members had many interesting and helpful comments to make. We will be very pleased to see them at this meeting."

The people who attended the group are shown in Table 1. The group was held from 8 to 10 pm on a weekday evening. At the beginning of the meeting, introductions were made—participants sat in a circle and in turn said who they were. The salient features of the proposed trial were then described. It was explained that 1,000 patients would be enrolled in the United Kingdom and 1,000 would be enrolled in France. The aims of the trial: to delay the progression to clinical HIV disease and AIDS; to be an acceptable form of therapy in asymptomatic patients; and to prolong life were listed. The details of the planned follow-up during the 3 years of the trial were also explained: fortnightly for the first 3 months; monthly for the first year; and thereafter 3-monthly. The end-point of the trial would be symptoms of HIV disease or side-effects of the drug.

Table 1. *People who attended the group*

Anti-HIV positive haemophiliacs:	
AIDS or HIV related disease on prescription AZT	7
Asymptomatic	12
Relatives of anti-HIV positive haemophiliacs:	
Fathers	7
Mothers	7
Wives	3
Staff:	
Senior Medical Social Worker	1
Haemophilia Nursing Sisters	3
Regional co-ordinating Sister, NE Thames	1
Charge Nurse, NW Thames	1
AIDS Consultant, Royal Free Hospital	1
Consultant Haematologist, Haemophilia Centre	1
Associate Specialist, Haemophilia Centre	1
Occupational Therapist	1
Clinical Psychologist	1
Director, Hammersmith Hospital Haemophilia Centre	1

Participants were then divided into groups to complete a task. The groups were as follows: haemophiliacs who were HIV anti-positive and asymptomatic; haemophiliacs who were being treated with zidovudine; parents; wives; and staff. Each group were given the same task and discussed together in separate areas.

The task was to consider the advantages and disadvantages of entering the trial for the patient, his family, the work situation, and the staff of the Centre. Each group were asked to list a number of questions they would like addressed. A spokesman was to be appointed for each group who was to report back anonymously what had been discussed in the group.

Everyone rejoined the main group after 20 minutes to report back. Finally, an

intervention or summing-up of what was seen or heard during the discussion was given (Miller & Bor, 1988).

After the meeting, a questionnaire was sent to non-staff participants to be returned anonymously. This asked whether the participant had found the meeting helpful, and whether he or she would attend again.

Results

The advantages and disadvantages for anti-HIV positive and asymptomatic patients are shown in Table 2. The anti-HIV positive patients, who were taking zidovudine because they were classified CDC IV—listed the advantages and disadvantages in Table 3.

Table 2. *The advantages and disadvantages of entering the trial listed by anti-HIV positive but asymptomatic patients*

Advantages
1. Zidovudine might work.
2. Doing something would help mentally.
3. They would be cared for more.
4. Their family and friends would be more confident.
5. It would provide something for other people.
6. There would be regular information about HIV.
7. They were inquisitive to know if zidovudine worked.
8. They thought it would ensure one doctor for follow-up.
Disadvantages
1. That the body would get used to zidovudine resulting in tolerance.
2. There would be side-effects particularly on the liver.
3. There was concern that zidovudine might make them more susceptible to AIDS.
4. They thought there would be a waste of taxpayers money.
5. Participation in the trial might lead to disclosure of HIV status in the family and at work.

Table 3. *The advantages and disadvantages of entering the trial listed by anti-HIV positive patients receiving zidovudine therapeutically*

Advantages
1. There would be long-term benefit for others.
2. There would be hope for families.
Disadvantages
1. The patient would have to attend the hospital regularly.
2. The family might worry, especially if the trial was kept secret from them.
3. The patient might be seen to take tablets at work, and therefore confidentiality would be broken.
4. The staff would be involved in more work, especially more paperwork.

The respective advantages and disadvantages for patients and wives, and staff are shown, respectively, in Tables 4 and 5. Questions which were asked are reported vertabim in Table 6, and these covered a wide spectrum of topics.

The intervention was given through discussion between the social worker and a doctor practised and trained in this counselling approach. It was that haemophiliacs were used to making difficult decisions throughout their lives: decisions about whether to treat bleeds,

what treatment to use, and decisions about work. The decision about whether to enter this trial was yet another decision to be made. Issues of great personal concern had been raised during the meeting, and it was hoped that if patients had problems they wished discussed, they should make appointments following the meeting. Participants would be contacted about a future meeting for anti-HIV positive patients. Finally, it was stated that much had been learnt at this meeting, and appreciation was expressed to those who had attended.

Twenty-four of 33 (73%) returned replies to the questionnaire, 23/24 (96%) found the meeting helpful. The main reason given was that it was valuable to share experiences with similarly affected people (20/24 (83%). The main criticism was that the participants would have preferred to hold discussions in smaller groups for longer.

Table 4. *The advantages and disadvantages of entering the trial as listed by parents and wives*

Advantages
1. There would be hope where previously there had been none.
2. It would give the staff something to look forward to, particularly if successful.
3. There would be preferential treatment for trial patients.
Disadvantages
1. Regular follow-up at hospital would result in time off work, and therefore questions would be asked—a breach of confidentiality.

Table 5. *Advantages and disadvantages of entering the trial as listed by staff*

Advantages (for staff)
1. It would be established if zidovudine was beneficial for asymptomatic patients.
2. The patients would be seen regularly.
3. There would be something to offer.
4. There would be a chance to talk about concerns.
5. Psychosexual problems could be addressed.
Advantages (for families)
1. Families of staff members would be glad that treatment was available should staff be infected.
Advantages (for work)
1. There would be resulting scientific publications.
2. There would be more funding.
Disadvantages
1. All that could be offered therapeutically would be offered early.
2. There would be an increased workload.
3. There would be side-effects of zidovudine.

Discussion

Although zidovudine is now widely used in the treatment of patients with symptomatic HIV disease (CDC, 1987), it has only been proved to be beneficial in patients with pneumocystis carinii pneumonia or with ARC (Fisch *et al.*, 1987). A number of major side-effects have now been reported following use of zidovudine (Lancet, 1989), in addition to the common side-effects of macrocytic anaemia and granulocytopenia. Thus, the early use of zidovudine

Table 6. *The questions that were asked*

1.	What is the new drug for pneumonia?
2.	How does zidovudine work?
3.	Which is the best brand of AZT?
4.	If ill, could a patient drop out of the trial?
5.	How would progress be measured during the trial?
6.	What would be the interaction of zidovudine with other drugs or alcohol?
7.	If the dose is changed, are there side-effects?
8.	If there are side-effects, is the code broken?
9.	What are the legal implications of consent?
10.	What happens if the patient gets AIDS?
11.	What are the other side-effects?
12.	What about the 17 strains of AIDS?
13.	What would be the effect after 2 years?
14.	What is involved in the monthly visits?
15.	What are the alternatives?
16.	Might AZT do harm?

presents dilemmas for both patient and physician: the balance between potential benefit from early treatment, and unnecessary toxicity or even zidovudine resistance.

The advantages and disadvantages listed by our groups reflected this dilemma. The fact that a trial could establish a long-term beneficial effect in asymptomatic patients was a clear advantage appreciated by all groups. There was an emergent altruism, in that the information obtained might be of benefit to others. The disadvantage of side-effects of the drug were of lesser significance and listed only by asymptomatic patients and staff. The patients who were already taking zidovudine did not consider this a disadvantage. The lesser concern about side-effects may be due to the fact that haemophiliacs are long used to trials of new treatments: indeed the field of haemophilia provides one of the best examples in medicine of how advances in basic science and clinical research can in a very short space of time, lead to advances in clinical practice (Lee, 1986).

There are over 30 clinical trials of antiretroviral or immunomodulatory agents in HIV-infected patients under the auspices of the National Institute of Health AIDS Clinical Trial Group in America (Hirsch, 1989). As experimental drug trials for asymptomatic seropositive individuals are initiated, there is concern of the exacerbation of psychological stress resulting from knowledge of anti-HIV seropositivity (Pindyck *et al.*, 1986). This may result from the frequent out-patient visits entailed in drug trials. Participation in this trial emphasises that the patient is infected with HIV: taking drugs and follow-up visits are constant reminders of infectivity. This emerged as a particular concern in our group, and was closely related to concerns about breaches of confidentiality both in the family and work situation as a result of frequently visiting the hospital or taking tablets.

Asymptomatic homosexual and bisexual males have been psychologically assessed during an experimental trial of ribavirin (Jacobsen *et al.*, 1987). During the study period, participants reported more emotional distress than non-participating seropositive males, and this was related to the patients' perception of how HIV test results were communicated prior to the study. However, the high level of stress did not impede adherence. Haemophiliacs might be expected to be compliant because of their life-long experience of attending hospital—however, there is clearly a role for counselling in relieving the related distress, and addressing the most 'dreaded issues' ahead of time (Bor & Miller, 1988). The observation that the majority of participants found the group helpful, particularly because of sharing

experiences with others in a similar situation, suggests that a group may provide a useful forum for such counselling.

This description has shown how a group can be used to define, evaluate and rank the many treatment dilemmas in treating asymptomatic, anti-HIV positive haemophiliacs with zidovudine in the context of a double-blind control trial.

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