THE SCOTTISH OFFICE

Department of Health

NHS
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NHS Management Executive
St. Andrew's House
Edinburgh EH1 3DG

21st May 1999

Dear Colleague

TREATMENT OF HIV INFECTION AND AIDS IN SCOTLAND

Summary

1. This letter draws attention to the attached report by an expert working group which is intended to assist Health Boards in the planning and provision of HIV treatment and care services.

Action

2. **Health Board General Managers and Trust Chief Executives** are asked to ensure that the recommended treatment protocols are brought to the attention of appropriate managers, Directors of Public Health, hospital clinicians and general practitioners and to take account of the conclusions of the report in providing services for HIV and AIDS patients currently and in assessing future services.

3. The report describes the treatment protocol for HIV antiretroviral therapy recommended by the working group; it also includes information on the pattern of treatment of HIV patients across Scotland in 1997; and seeks to estimate the numbers of patients likely to be eligible for antiretroviral treatment in the foreseeable future.

4. The report also recommends that in order to ensure optimum use of available resources, treatment should be provided at a limited number of centres of expertise and allowance should be made for cross-boundary flow.

5. Health Boards are advised that any additional costs incurred in consequence of implementing the recommended treatment protocol should be met from existing allocations.

Yours sincerely

DAVID R STEEL
Head of Health Gain

Addressees

For action:
General Managers, Health Boards
Chief Executives, NHS Trusts

For information:
Directors of Public Health
Medical Directors, NHS Trusts
HB AIDS Co-ordinators
General Manager, State Hospitals Board for Scotland
General Manager, CSA
Chief Executive, HEBS
Director, SCIEH
Executive Director, SCPMDE

Enquiries to:
Dr Barbara Davis
Department of Health
Room 326
St Andrew's House
EDINBURGH EH1 3DG

Tel: 0131-244-2158
Fax: 0131-244-2030

Further copies:
Mrs M Aitken
PHPU 1/1
Room 335
St Andrew's House
Edinburgh EH1 3DG

Tel: 0131-244-2241
Fax: 0131-244-2157

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TREATMENT OF HIV INFECTION AND AIDS IN SCOTLAND: REPORT OF AN EXPERT WORKING GROUP

INTRODUCTION

Since 1996 there has been increasing evidence of the effectiveness of combinations of antiviral agents in increasing survival time, and delaying the onset of symptomatic disease, in HIV-infected patients. The importance of viral load testing as a means of monitoring disease progression and guiding therapeutic decisions has been increasingly recognised.

At an early stage, however, it was acknowledged that effective antiretroviral therapy could have unpleasant, and on occasions serious, side-effects; that compliance with the complicated treatment regimens required motivation and self-discipline; that development of viral resistance could limit the duration of effect of treatment, both in individual cases and in population terms; and that widespread use of expensive combinations of drugs would impose a heavy burden on health care resources. Despite early optimism, it became increasingly apparent that combination therapy was unlikely to prove curative.

Against a background of growing concern among clinicians, patients and voluntary groups regarding the availability of combination therapy and the equity of its provision, an announcement was made by Mr Sam Galbraith, the Scottish Office Health Minister, on 30 October 1997 that a small group of experts would be set up to consider the implications of combination therapies for HIV infection and AIDS in Scotland. In particular, the group would consider the number of patients likely to benefit from such treatment, currently and in the foreseeable future; appropriate treatment protocols; and the impact on resources for treatment of in-patients and out-patients. It was anticipated that the group's findings would be of value to health boards in forward planning in relation to this patient group.

The group first met on 12 January 1998, under the Chairmanship of Dr Andrew Fraser, Deputy Chief Medical Officer. The group's membership (Annex A) included representatives of clinicians caring for HIV/AIDS patients throughout Scotland, experts in the epidemiology of HIV infection, a health board AIDS Co-ordinator and representatives from The Scottish Office Department of Health. This report from the group sets out:

- The current epidemiology of HIV infection in Scotland, with reference to data from immunological monitoring
- Information on patterns of treatment for HIV-infected patients across Scotland in 1997
- A recommended treatment protocol for HIV-infected patients in Scotland
- An estimate of treatment needs in terms of numbers of patients eligible for antiretroviral therapy in the foreseeable future
- The group's conclusions.

CURRENT EPIDEMIOLOGY OF HIV INFECTION IN SCOTLAND

The Scottish Centre for Infection and Environmental Health (SCIEH) has responsibility for surveillance of HIV infection and AIDS in Scotland. The SCIEH HIV-positive Register contains confidential information on all HIV-infected individuals, including AIDS cases, reported in Scotland by clinicians and by HIV-testing laboratories.

During 1997 there were:

- 153 new HIV-positive diagnoses, while a further 37 infections diagnosed in earlier years were first reported to SCIEH in 1997
- 54 new AIDS cases registered, the lowest annual total since 1988
- 39 deaths from AIDS

Even when allowance is made for delayed reporting of recent deaths, there has been a considerable decline in AIDS mortality since 1995 (Figure 1). This recent decrease in numbers of AIDS cases and of AIDS deaths is almost certainly the result of increased prescribing of combination antiretroviral therapy in Scotland since late 1996.

By the end of December 1997, a cumulative total of 2725 HIV-infected individuals had been reported in Scotland. Just under half of these cases were injecting drug users, one-third were homosexual/bisexual men, and one-sixth were men and women in whom infection was attributed to heterosexual intercourse; 76% of all infected cases were male. Forty-five per cent (1235) of all known infections had been reported from Lothian Health, 19% (528) from Greater Glasgow Health Board and 15% (419) from Tayside Health Board. In total, 1011 (37%) HIV-infected individuals were known to have died.

Immunological monitoring

Since 1991 SCIEH HIV surveillance data have included counts of CD4 cells; this type of white blood cell contributes to the body's defence against infection. CD4 counts, provided by immunology laboratories, give an indication of stage of disease and rate of disease progression and are useful in therapeutic decision-making. A CD4 count of less than 200 cells per cubic ml is generally associated with severe HIV disease, while a count between 200 and 400 cells per cubic ml indicates a moderate impact on the immune system. Of the 37 persons included in SCIEH CD4 monitoring known to have died during 1997, 24 (65%) had a last CD4 count less than 200 and 9 (24%) had a last CD4 count of 200-349.

Approximately 5% of patients in Scotland currently undergoing immunological monitoring are not in the SCIEH CD4 database; these include children acquiring HIV infection from their mothers ante-natally or perinatally.

It is acknowledged that quantitative measurement of serum HIV-RNA (viral load) gives a more accurate indication of disease progression and prognosis in individual patients but viral load data are not currently available on a population basis.

TREATMENT FOR HIV INFECTION IN SCOTLAND IN 1997

Evidence from various sources indicates that there was some degree of geographical variation in treatment provided for HIV-infected patients in Scotland in 1997.

CD4 monitoring data

Of the 1714 patients in Scotland reported to be HIV positive and not known to have died by the end of 1997, 1028 were included in SCIEH CD4 monitoring during 1997. In the course of the year, 523 (51%) of these patients had two consecutive CD4 counts of less than 350 cells per cubic ml while 505 (49%) had counts greater than 350; these results are relevant to the recommended treatment protocol. As described below, a low or falling CD4 count is an indication for treatment while successful treatment will lead to an increase in numbers of CD4 cells. The numbers of patients in these two CD4 ranges reported as receiving various types of treatment during 1997 are shown in Table 1. The treatment classification in Tables 1 to 3 reflects the highest number of drugs received by each patient at any time during 1997. It will thus tend to overestimate the total treatment received by patients in 1997.

Table 1: Type of treatment received by HIV-infected patients undergoing CD4 monitoring in Scotland in 1997, according to CD4 status (n = 1028)

Type of treatment	Did patient have two consecutive CD4 counts below 350?	
	Yes (n = 523)	No (n = 505)
Monotherapy	16 (3%)	17 (3%)
Dual therapy	167 (32%)	101 (20%)
Triple therapy	230 (44%)	67 (13%)
Not recorded/none	100 (21%)	320 (63%)

Regardless of the patient's area of residence, treatment for HIV infection tends to be based in the main centres of population. In 1997 more than half of the monitored patients (56%) were reported from Edinburgh, 26% from Glasgow, 12% from Dundee and 5% from Aberdeen. Type of treatment recorded in Edinburgh, Glasgow and Dundee varied, as shown in Table 2.

Table 2: CD4 status of HIV-infected patients undergoing CD4 monitoring in Scotland, and treatment received, in 1997, according to centre of treatment (n = 1028)

	Edinburgh	Glasgow	Dundee	Aberdeen
Proportion of patients with two consecutive CD4 counts < 350	54%	52%	41%	40%
Proportion of all patients receiving any antiretroviral therapy (mono, dual or triple)	59%	71%	51%	*
Proportion of all patients receiving triple therapy	26%	43%	29%	*

* Only limited information was available from Aberdeen.

A total of 151 'new' patients entered CD4 monitoring in 1997; 44% of these reports were from Edinburgh, 30% from Glasgow, 14% from Dundee and 13% from Aberdeen. Types of treatment received by these new patients are shown in Table 3.

Table 3: CD4 status of patients entering CD4 monitoring in 1997, and treatment received, by centre of treatment (n = 151)

	Edinburgh	Glasgow	Dundee	Aberdeen
Proportion of patients with two consecutive CD4 counts <350	38%	49%	48%	16%
Proportion of all new patients receiving any antiretroviral therapy (mono, dual or triple)	50%	56%	43%	*
Proportion of all new patients receiving triple therapy	26%	44%	29%	*

* only limited information was available from Aberdeen.

Information from clinical units

Lothian

During 1997, 524 HIV-infected patients were recorded as having clinical follow-up in Edinburgh. Of these, 279 (53%) received antiretroviral therapy, mainly dual therapy, while a further 92 (18%) fulfilled the agreed criteria (see protocol below) but were not on treatment.

In the Regional Infectious Disease Unit (RIDU), by mid 1997, antiretroviral therapy had, in relation to AIDS cases, led to a 50% fall in admissions, a 51% fall in bed-days, a 56% fall in disease progression and a 73% fall in death rate. In HIV-infected patients without AIDS, however, admissions, bed-days and disease progression rate all increased in the first half of 1997 compared with 1995 levels. This is probably related to the fact that a much higher proportion of AIDS cases were receiving combination therapy.

Glasgow

Between January 1997 and January 1998, 39 new HIV-infected patients attended Ruchill Hospital. During 1997, compared with 1995, in relation to HIV positive patients, there was a 73% fall in number of deaths, a 42% fall in admissions and a 48% fall in bed-days. The number of newly registered AIDS cases fell by 63%. In early 1998, 215 patients were attending, of whom 140 were on anti-retroviral therapy.

Scottish hospital discharge data

The SMR-1 database records all discharges (including deaths) from Scottish hospitals. As shown in Figure 2, the half-yearly total of discharges, and of bed-days where HIV infection or AIDS was quoted as a principal or subsidiary diagnosis increased until mid-1995 and then fell as the availability of antiretroviral therapy increased. A degree of under-reporting in all years is likely.

SMR-1 data also enable comparison between health board of residence and health board of treatment of discharged patients. In 1997, as shown in Table 4, in only three health board areas was the number of discharges from hospitals in the health board area greater than the

number of discharges throughout Scotland of patients resident in the health board area. These data suggest that 14.7% of in-patients treated in Lothian were residents of other health board areas, with corresponding figures of 19.4% for Greater Glasgow and 25.3% for Grampian. Such conclusions must be regarded with caution as the data refer to discharges rather than to patients, and in-patient episodes account for an increasingly small proportion of HIV/AIDS treatment. However, independent clinical data from Glasgow show that 20% of patients treated are from other health board areas.

Table 4: HIV/AIDS related hospital discharges, Scotland, 1997, by health board of residence and health board of treatment

Health Board	AC	AA	BR	DG	FF	FV	GR	GG	HG	LN	LO	OR	SH	TY	WI
Discharges: (resident)	27	31	17	10	26	49	56	203	22	16	636	-	9	168	-
Discharges: (treatment)	-	30	17	1	8	20	75	252	12	11	746	-	-	117	-

HIV TREATMENT PROTOCOL

Clinical members of the Working Group, in consultation with clinical colleagues, agreed a protocol for treatment of HIV-infected adult patients in Scotland. This protocol was adapted from current US and UK (BHIVA) guidelines. It is recommended that antiretroviral therapy, which is becoming increasingly complex, should be prescribed and supervised by consultants with specialist training and experience in HIV medicine. General practitioners should be kept fully informed of their patients' treatment.

Indications for treatment

Antiretroviral treatment (ART) should be offered to all patients with any of the following:

- symptomatic HIV disease *or* CD4 < 350 (or falling CD4) *or* viral load > 50,000 copies/ml
- acute seroconversion illness
- HIV infection in pregnancy
- needlestick injury requiring post-exposure prophylaxis

ART may also be considered for asymptomatic patients with CD4 counts between 350 and 500, and viral loads between 10,000 and 50,000 copies/ml.

Decisions to treat based on CD4 count and viral load criteria require two sets of results (at least a month apart) within the above parameters. Increasingly, viral load monitoring will guide treatment decisions and the importance of access to ultrasensitive viral load testing is acknowledged. In virological terms, the aim of therapy should be to lower viral load to undetectable levels (ie <50 copies/ml) and to maintain these levels. The viral load nadir (ie the lowest level achieved after initiation of therapy) predicts the durability of the virological response.

Reasons for change of ART

- intolerance/side effects
- new clinical event
- inadequate fall in viral load† (or return towards baseline) or falling CD4 count
- new results from clinical trials demonstrating a need for change

† Some clinicians believe that persistently detectable HIV-RNA (viral load) above 500 copies/ml at 16 weeks and 50 copies/ml at 24 weeks represent treatment failure, and that ART should be changed accordingly.

Changing ART

Ideally the entire regimen should be changed, although this may be difficult in heavily pre-treated patients; a single drug change or addition should not normally be made to a failing regimen. However if the change is made because of intolerance or side-effects, ie there has been no loss of antiviral effect, a single drug switch may be adequate. Specific points are:

- AZT may be substituted for d4T and vice versa.
- 3TC may be used following ddI, but ddI may have reduced effect in 3TC-experienced patients.
- A non-nucleoside analogue reverse transcriptase inhibitor (NNRTI) can seldom be replaced with another NNRTI because of cross-resistance.
- For treatment-experienced patients with limited options, due to drug intolerance or suspected resistance, there is some evidence in favour of the use of two protease inhibitors, or the use of protease inhibitors in conjunction with NNRTIs.

It is likely that viral resistance testing will become routinely available and will influence choice of initial therapy and subsequent changes to therapy.

Other considerations

The choice and use of prophylactic antimicrobial drugs to prevent opportunistic infections is determined by the nadir of the CD4 count prior to starting ART. However, if prophylaxis against *Pnemocystis carinii* pneumonia was commenced because the CD4 count was less than 200, there is evidence that if the count rises to greater than 200, and remains so far more than three months, then such prophylaxis may be discontinued. Each case should be considered individually.

Pregnant women should be offered ART with a view to reducing the risk of transmission of HIV to the foetus. Such treatment decisions should be made only in consultation with an obstetrician with specialist knowledge of HIV infection in pregnancy.

PREDICTIONS OF FUTURE TREATMENT NEEDS

SCIEH immunological monitoring data were used to estimate the future treatment needs of HIV-positive patients in Scotland. Table 6 shows the estimated numbers of patients expected

Drug regimens

Treatment should be with a minimum of three drugs (unless the patient requests fewer drugs or concomitant disease, such as cirrhosis, makes it difficult to find a safe three-drug regimen). Care should be taken not to reduce future therapeutic options by using drugs generating significant cross-resistance. Before starting ART, all patients should receive education about the important of adherence to therapy, and literature relating to the specific drugs they will be taking.

Drugs used in the treatment of HIV infection include:

- nucleoside reverse transcriptase inhibitors such as zidovudine (AZT), didanosine (ddI), lamivudine (3TC), stavudine (d4T), zalcitabine (ddC), abacavir*
- protease inhibitors such as indinavir, ritonavir, saquinavir, nelfinavir
- non-nucleoside reverse transcriptase inhibitors such as nevirapine, delavirdine*, efavirenz*

The initial regimen should consist of one choice from column A and one from column B of Table 5. Drugs are listed in random, not priority, order. It is not yet clear whether abacavir should be included in column A or column B.

Table 5: Anti-retroviral drugs currently recommended for treatment of HIV infection

Column A	Column B
indinavir	AZT + ddI
nelfinavir	D4T + ddI
ritonavir	AZT + 3TC
saquinavir (soft gel) *	D4T + 3TC
nevirapine	AZT + ddC
efavirenz*	
ritonavir/saquinavir*	
ritonavir/indinavir	

* not yet licensed, but available on a named-patient basis.

Follow-up of patients on ART

CD4 count and viral load measurement should be carried out 4-8 weeks after commencing treatment and then monthly until viral load is below the detectable limit. Thereafter, measurements should be carried out every 3-4 months. Ideally viral load should be below 400 copies/ml by week 8-12 and below 50 copies by week 16-20.

to be in need of antiretroviral treatment at the mid-years from 1997 to 2000, given the treatment protocol outlined above.

The total number of patients in medical care in 1997 was calculated from patients currently under immunological monitoring, with some allowance for patients under monitoring in previous years and possibly still under medical care, but without current immunological measurements. The proportion of these patients meeting the criteria for treatment in mid 1997 is derived by applying the treatment protocol to the patients' stage of disease progression; disease progression was estimated from predicted values of what CD4 counts would be in the absence of any effect of treatment. Using data from the Regional Infectious Diseases Unit in Edinburgh on viral load and associated CD4 counts, it was estimated that all patients with CD4 count <200 should be offered antiretroviral treatment, as should 80% of those with CD4 count 200-300, 60% of those with CD4 count 300-500 and 10% with CD4 count >500. All paediatric and blood/blood product recipient cases alive at June 1997 were assumed to meet the criteria for antiretroviral therapy as were a proportion of patients who had not received monitoring since the end of 1995. Upper and lower limits for the numbers allow for uncertainty in the proportions meeting clinical criteria, with a further assumption that 75% (low estimate) and 85% (high estimate) of all patients who are offered therapy will accept it.

Table 6: Antiretroviral therapy for HIV infection in Scotland: predictions of patient numbers, 1997-2000

Date	Total HIV positive patients under medical care		Total patients meeting the criteria for antiretroviral therapy		Total patients accepting therapy	
	Low estimate	High estimate	Low estimate	High estimate	Low estimate	High estimate
mid 1997	1110	1110	680	750	510	640
mid 1998	1120	1220	720	870	540	740
mid 1999	1130	1330	760	1000	570	850
mid 2000	1140	1450	800	1120	600	950

The predictions for future years were made under the following assumptions:

- The disease stage of patients not yet meeting the criteria for treatment would progress at the same rate as disease progressed before combination therapy was available.
- New entrants for treatment would have a profile of disease stage similar to patients entering monitoring in 1996/7.
- The numbers of new entrants to treatment would be as in Table 7. The lower range corresponds to a return to the trend of fewer new entrants per year seen prior to 1996/97. The upper range corresponds to a continuation of the higher numbers of patients per year entering treatment observed since mid 1996.
- Assumptions about deaths of patients according to treatment category are based on a number of sources of information including statistical modelling of data on deaths and information about changes in mortality in England and Wales. The lower death rate corresponds to the decreased numbers of deaths seen in recent years, whereas the higher death rate corresponds to a return towards the numbers of deaths seen in previous years.

Even the low prediction assumes that treatment will continue to have some efficacy to the end of the time considered.

Table 7: Assumptions made in low and high predictions of the number of patients in Scotland receiving antiretroviral therapy

	Low predictions	High predictions
Proportions accepting treatment	0.75	0.85
New patients entering monitoring per year: June 1997-June 1998	100	150
June 1998-June 1999	90	150
June 1999-June 2000	80	150
Annual death rate in those on treatment	10%	2.5%
Annual death rate in those not accepting treatment	20%	20%
Annual death rate in those not meeting the criteria for treatment	2.5%	2.5%

Calculations have been made for each of the major health boards, using the same assumptions, but with numbers of new entrants obtained by extrapolating the trends over the last few years in each health board. (Table 8).

Table 8: Predicted numbers of new patients entering immunological monitoring by health board

Health Board	Lothian		Glasgow		Tayside		Grampian		Other	
Estimate	Low	High	Low	High	Low	High	Low	High	Low	High
Year										
June 1997-June 1998	35	50	20	30	15	20	6	10	29	40
June 1998-June 1999	31	50	17	30	12	20	5	10	26	40
June 1999-June 2000	27	50	15	30	11	20	4	10	23	40

Table 9 gives the predicted numbers of patients on antiretroviral treatment by health board. Note that, due to independent rounding of the predictions to the nearest 10 cases, the totals do not necessarily agree exactly with Table 6 for all Scotland. Given the degree of uncertainty in the underlying assumptions, it was not possible to make predictions beyond 2000.

Table 9: Predicted numbers of patients receiving antiretroviral treatment, by health board, 1997-2000

Date	Total HIV positive patients under medical care		Total patients meeting the criteria for antiretroviral therapy		Total patients accepting therapy	
	Patients resident in Lothian					
	Low estimate	High estimate	Low estimate	High estimate	Low estimate	High estimate
mid 1997	490	490	300	330	230	280
mid 1998	490	520	310	370	240	320
mid 1999	480	560	320	410	240	350
mid 2000	480	590	330	450	250	380
	Patients resident in Greater Glasgow					
mid 1997	210	210	130	140	100	120
mid 1998	210	230	140	170	100	140
mid 1999	220	260	150	190	110	160
mid 2000	220	280	150	220	110	190
	Patients resident in Tayside					
mid 1997	140	140	80	90	60	80
mid 1998	140	150	90	110	70	90
mid 1999	150	170	90	120	70	100
mid 2000	150	190	100	140	70	120
	Patients resident in Grampian					
mid 1997	50	50	30	30	20	30
mid 1998	50	50	30	40	20	30
mid 1999	50	60	30	50	30	40
mid 2000	50	70	40	60	30	50
	Patients resident in other health boards					
mid 1997	220	220	140	150	100	130
mid 1998	230	250	150	180	110	150
mid 1999	240	290	170	220	130	190
mid 2000	250	320	190	260	140	220

Further details of all patients currently estimated to be under monitoring

The predictions given above have been calculated using data accrued at SCIEH up to June 1997. In order to have the most up-to-date data on patients under monitoring for regional breakdowns a more recent set of data has been used. These data are in good agreement with the predicted total numbers under medical care presented in the earlier tables. Table 10 shows the total (1206) of HIV positive patients who presented for immunological monitoring between January 1996 and September 1998, and who are not known to have died or to have left the country by September 1998.

Table 10: Number of HIV-infected patients under immunological monitoring in Scotland between January 1996 and September 1998

Transmission category	Number of patients
Main risk groups ie IDU, homosexual, heterosexual	1130
Vertical transmission (mother-to-child)	15
Haemophiliacs	48
Blood/tissue transmission	13
Total	1206

This number of HIV positive patients registered as under medical care at September 1998, comes within the range of such patients predicted at mid 1998. Table 11 cross-classifies the 1130 patients in the main risk groups by health board of clinician requesting the CD4 test and by health board of residence.

Table 11: Patients in main risk groups under immunological monitoring between January 1996 and September 1998 by health board of residence and health board of treatment (n = 1130)

Health board of residence	Health board of treatment							
	Fife	Forth Valley	Grampian	Greater Glasgow	Lothian	Tayside	Other	Total
Argyll & Clyde	0	0	0	31	1	0	0	32
Ayrshire & Arran	0	0	0	6	0	0	2	8
Borders	0	0	0	0	10	0	1	11
Dumfries & Galloway	0	0	0	0	3	0	1	4
Fife	25	0	0	2	17	2	0	44
Forth Valley	0	6	1	9	7	0	0	23
Grampian	1	0	61	0	1	0	0	63
Greater Glasgow	1	0	0	205	1	2	0	209
Highland	0	0	0	5	1	0	0	6
Lanarkshire	0	0	0	14	0	0	12	26
Lothian	0	1	0	1	511	0	0	513
Shetland	0	0	3	0	0	0	0	3
Tayside	1	0	2	1	0	150	0	154
Other	1	0	1	4	27	0	1	34
Total	29	7	68	276	579	154	16	1130

5. The total cost of providing antiretroviral therapy, largely on an out-patient basis, has doubled in the space of a year; this increase is likely to continue, but at a more gradual rate. In-patient costs have fallen but, in the absence of curative treatment, this may prove to be a temporary effect with future increased requirements for terminal and palliative care.

6. The changing scene in relation to treatment for HIV infection and AIDS, and associated patient monitoring, has implications for resource allocation. Treatment should be provided at a limited number of centres of expertise and allowance must be made for cross-boundary flow.

7. Treatment outcomes must be subject to ongoing audit.

8. It is not possible to make accurate medium or long- term predictions in an area of such rapid change. The Working Group will continue to monitor the situation as additional data become available.

9. There continues to be no curative treatment and no effective vaccine in relation to HIV infection and AIDS. The importance of prevention and health promotion thus remains paramount.

COST IMPLICATIONS

The overall cost of triple therapy is currently of the order of £8,500 per patient per year. In Glasgow the total cost of antiretroviral drugs increased from £441,708 in 1996-97 to £703,432 for the first ten months of 1997-98. In the Regional Infectious Diseases Unit in Edinburgh, between 1995-96 and 1996-97, reduction in in-patient activity produced a saving of £197,859 while pharmacy costs increased by £175,020 (ie by 34%). Most antiretroviral drugs were prescribed in outpatient clinics: annual outpatient pharmacy costs increased by 84% while in-patient pharmacy costs fell by 51%.

Using the predicted patient numbers shown in Table 6, the total annual cost of ART in Scotland could be between £5m and £8m by mid 2000. This is total cost rather than additional cost; many of these patients are currently on treatment and many patients currently stabilised on dual therapy would not have a change of regimen. In Lothian, HIV/AIDS drug expenditure was £1,983K in 1997/98, based on criteria of a CD4 count <200 or viral load >60,000. Since April 1998, the Lothian protocol has been revised to include patients with CD4 count <350 and viral load >50,000 and current annual expenditure is projected to be £2,600K. The current annual cost of ART is of the order of £1,350K in Glasgow and £587K in Dundee. Thus, currently, approximately £4.5M is spent on ART in the three major Scottish HIV treatment centres.

Increased drug costs have been accompanied by a significant decrease in in-patient costs, at least in the short term, and there is evidence that antiretroviral therapy is not only effective, but also cost-effective in the developed world. In the absence of any curative treatment, however, there may well be an increased requirement for palliative and terminal care in the future.

CONCLUSIONS

1. Recent major therapeutic advances have been followed by a reduction in numbers of new AIDS cases and of AIDS-related deaths in Scotland.

2. The number of patients receiving antiretroviral therapy in Scotland is likely to increase in the foreseeable future because of increased survival, increased compliance with treatment and lowering of thresholds for initiating treatment. It is possible that viral resistance may increase to the extent that the current favourable therapeutic situation is short-lived but new drugs and classes of drugs will become available and immune reconstitution may become possible.

3. Combination antiretroviral therapy has costs in terms of side-effects and restrictions on patients' lifestyles, as well as in relation to health service resources.

4. It is estimated that antiretroviral therapy is appropriate for approximately 60% of current Scottish HIV-positive patients; during 1997 approximately 75-80% of patients were on treatment, but this may have been dual rather than triple therapy. There has been considerable geographical variation in the proportion of patients receiving dual rather than triple therapy in Scotland.

Figure 1: AIDS cases and deaths, Scotland, 1982-1997

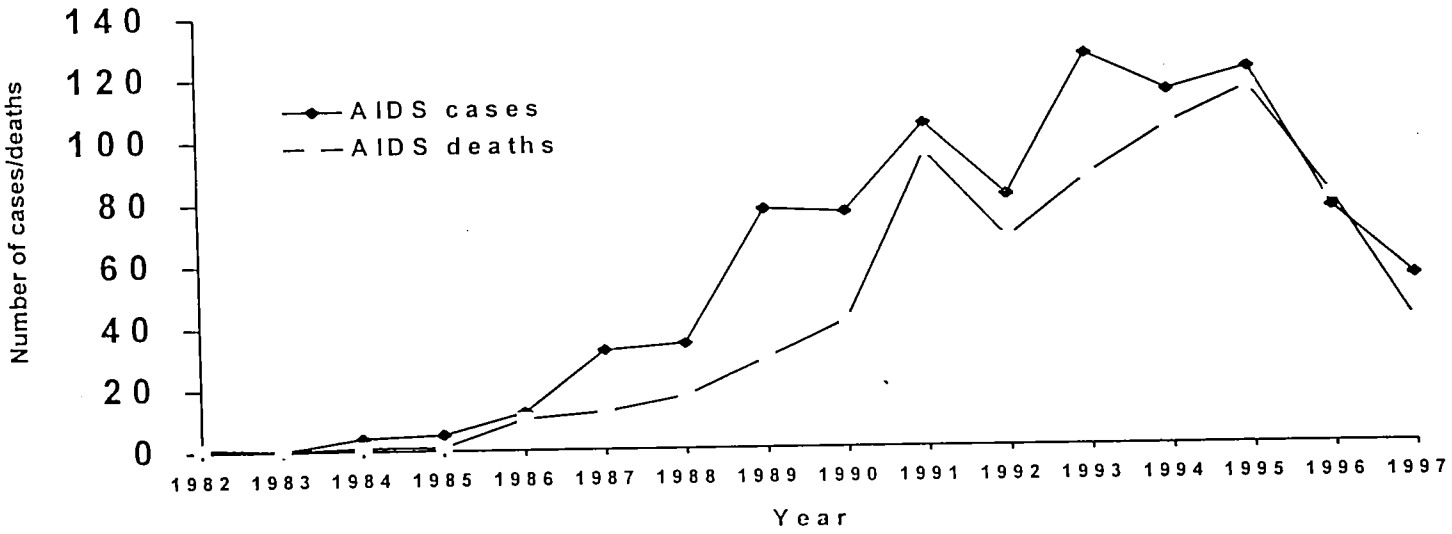
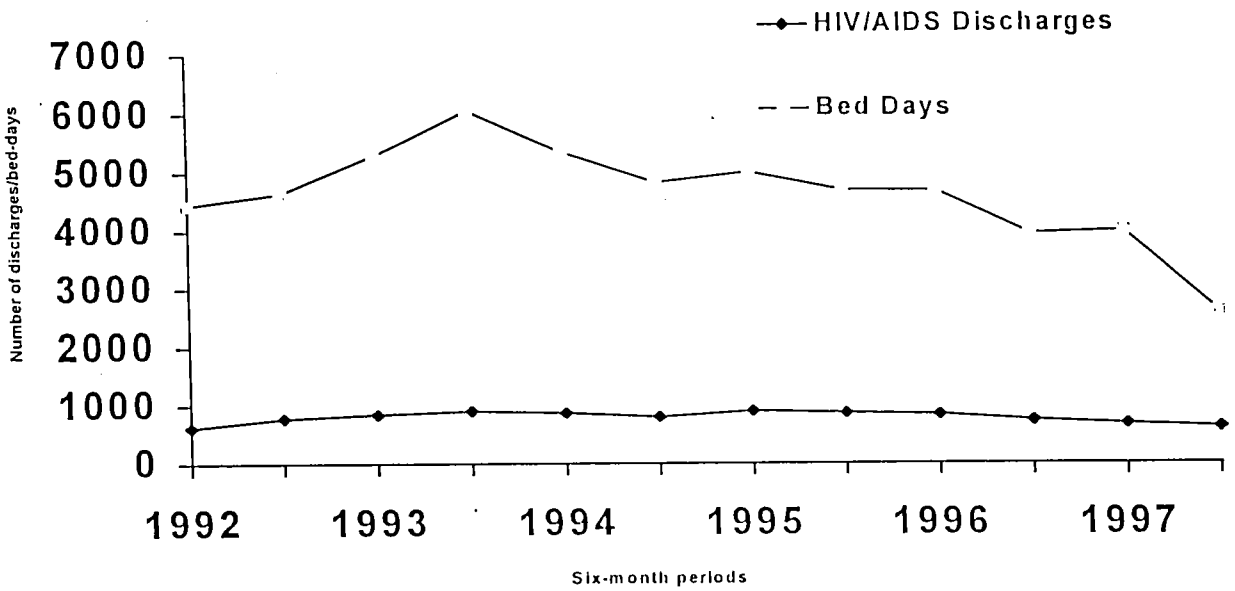


Figure 2: Hospital discharges and bed-days attributed to HIV infection or AIDS, Scotland, by six-month periods 1992-1997



ANNEX A: MEMBERSHIP OF EXPERT WORKING GROUP

Dr Andrew Fraser, DCMO (Chairperson)
Dr Tony France, Consultant in Infectious Diseases, Dundee
Dr David Goldberg, Consultant Epidemiologist, SCIEH
Mr Alan Oliver, PHPU, SODoH
Mr David Palmer, Deputy Director of Finance, SODoH
Dr Alan Pithie, Consultant in Infectious Diseases, Glasgow
Professor Gillian Raab, Department of Mathematics, Napier University
Dr Gordon Scott, Consultant in Genito-Urinary Medicine, Edinburgh
Dr Hester Ward, AIDS Co-ordinator, Lothian Health
Dr Barbara Davis, SODoH (Secretary)

THE SCOTTISH OFFICE
Department of Health

Public Health Policy Unit
St. Andrew's House
Edinburgh EH1 3DG

Telephone 0131-244 2241
Fax 0131-244 2157

Addressees:

General Managers, Health Boards
Chief Executives, NHS Trusts
Directors of Public Health
Medical Directors, NHS Trusts
HB AIDS Co-ordinators
General Manager, State Hospitals
Board for Scotland
General Manager, CSA
Chief Executive, HEBS
Director, SCIEH
Executive Director, SCPMDE

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8 June 1999

Dear Colleague

TREATMENT OF HIV INFECTION AND AIDS IN SCOTLAND, MEL (1999)47

I refer to the above MEL which was issued on 21 May 1999. Unfortunately Annex A to the report of the expert working group was not attached to the MEL and I now enclose a copy for your information.

I apologise for this omission and for any inconvenience caused.

Yours sincerely

Michele Aitken

Michele Aitken
Public Health Policy Unit