

## Dietary pattern and 20 year mortality in elderly men in Finland, Italy, and the Netherlands: longitudinal cohort study

Patricia Huijbregts, Edith Feskens, Leena Räsänen, Flaminio Fidanza, Aulikki Nissinen, Alessandro Menotti, Daan Kromhout

### Abstract

**Objective:** To investigate the association of dietary pattern and mortality in international data.

**Design:** Cohort study with 20 years' follow up of mortality.

**Setting:** Five cohorts in Finland, the Netherlands, and Italy.

**Subjects:** Population based random sample of 3045 men aged 50-70 years in 1970.

**Main outcome measures:** Food intake was estimated using a cross check dietary history. In this dietary survey method, the usual food consumption pattern in the 6-12 months is estimated. A healthy diet indicator was calculated for the dietary pattern, using the World Health Organisation's guidelines for the prevention of chronic diseases. Vital status was verified after 20 years of follow up, and death rates were calculated.

**Results:** Dietary intake varied greatly in 1970 between the three countries. In Finland and the Netherlands the intake of saturated fatty acids and cholesterol was high and the intake of alcohol was low; in Italy the opposite was observed. In total 1796 men (59%) died during 20 years of follow up. The healthy diet indicator was inversely associated with mortality ( $P$  for trend  $< 0.05$ ). After adjustment for age, smoking, and alcohol consumption, the relative risk in the group with the healthiest diet indicator compared with the group with the least healthy was 0.87 (95% confidence interval 0.77 to 0.98). Estimated relative risks were essentially similar within each country.

**Conclusions:** Dietary intake of men aged 50-70 is associated with a 20 year, all cause mortality in different cultures. The healthy diet indicator is useful in evaluating the relation of mortality to dietary patterns.

### Introduction

Selected nutrients or food groups have often been studied in relation to mortality,<sup>1-5</sup> but studying dietary patterns in relation to mortality has several advantages. Using dietary patterns takes into account the high intercorrelation of nutrients within the diet, which is due to the choice of foods in which these nutrients

occur or to the consumption of a particular food at the expense of another one.<sup>6</sup> Also, studying dietary patterns in relation to mortality provides a practical way to evaluate the health effects of adherence to dietary guidelines by individuals.<sup>7</sup> It can help to identify groups with an unhealthy dietary pattern and disclose possibilities for prevention of chronic diseases or disability.

To our knowledge, dietary pattern has been used to study the association with mortality only within individual countries.<sup>7-10</sup> We developed a healthy diet indicator, based on the World Health Organisation's dietary recommendations for the prevention of chronic diseases,<sup>11</sup> and investigated its association with all cause mortality during 20 years of follow up in population based samples from three different countries (Finland, Italy, and the Netherlands).

### Methods

#### Population

From 1958 to 1964, 16 population samples of men aged 40-59 years from seven countries were enrolled and examined at baseline for the seven countries study.<sup>12</sup> Since 1984, Finland, Italy, and the Netherlands have continued the examination of their cohorts, focusing on health and its determinants in elderly people. The population has been described in detail.<sup>13</sup> The participating cohorts were eastern and western Finland; Crevalcore and Montegiorgio, Italy; and Zutphen, the Netherlands.

The study was started in 1959 in Finland and in 1960 in Italy and the Netherlands. Baseline dietary information used in this study was gathered in 1969 in the Finnish cohorts and in 1970 in the Dutch cohort and one Italian cohort (Crevalcore). As the 1970 data from Montegiorgio were available only on a non-random subset of men, the dietary data gathered in 1965 from the men who were still alive in 1970 were used as an approximation for dietary intake in 1970. This is justifiable because dietary intake in Finland, Italy, and the Netherlands was relatively stable within the cohorts during the first 10 years of the seven countries study.<sup>12</sup>

Department of Chronic Diseases and Environmental Epidemiology, National Institute of Public Health and the Environment, PO Box 1, NL-3720 BA Bilthoven, Netherlands

Patricia Huijbregts, *research fellow*  
Edith Feskens, *senior epidemiologist*  
Daan Kromhout, *professor of public health research*

Division of Nutrition, Department of Applied Chemistry and Microbiology, University of Helsinki, 00014 Helsinki, Finland  
Leena Räsänen, *assistant professor of nutrition*

Institute of Food Sciences and Nutrition, University of Perugia, Perugia, 00610 Italy  
Flaminio Fidanza, *professor of nutrition*

Department of Community Health and General Practice, University of Kuopio, 70211 Kuopio, Finland  
Aulikki Nissinen, *professor of community health and general practice*

*BMJ* 1997;315:13-7  
continued over

Division of  
Epidemiology,  
School of Public  
Health, University  
of Minnesota,  
Minneapolis, MN  
55454-1015, USA  
Alessandro Menotti,  
*professor of  
epidemiology*

Correspondence to:  
Ms Huijbrechts.

Information on diet around 1970 was available for 612 men in eastern Finland, 694 men in western Finland, 615 men in Zutphen, and 592 men in Crevalcore. We had dietary information in 1965 for 662 men in Montegiorgio. The analyses in this study are based on subjects for whom complete information on diet and confounding variables was available at baseline (1969-70): 606 men from eastern Finland (89%), 683 men in western Finland (91%), 608 men in Zutphen (79%), 591 men in Crevalcore (69%), and 557 men in Montegiorgio (85%)

### Collection of information

Food intake around 1970 was estimated with the cross check dietary history method, adapted to the local situation and carried out by experienced dietitians and nutritionists. This method provides information about the usual food consumption pattern in the 6-12 months preceding the interview.<sup>14-18</sup> The usual food consumption pattern of the subject during weekdays and weekends was assessed by recording foods eaten at breakfast, lunch, and dinner, and between meals. This information was checked by registering from a comprehensive food list the frequency and amount of foods consumed and, in the case of discrepancies, discussing the recorded food consumption pattern with the participant. This method has satisfactory reproducibility.<sup>19-20</sup> In Finland the interviews were carried out in autumn and in the Netherlands and Italy in spring. Nutrient intakes were assessed by using computerised versions of food tables for each country.<sup>16-18-21</sup>

Information about cigarette smoking was collected by a standardised questionnaire. Subjects were classified as men who had never smoked, men who had stopped smoking, and current smokers. Men who never drank alcohol were classified as abstainers. On the basis of mortality in Italian men, moderate drinkers were categorised as men who consumed up to six glasses of alcohol a day. Those who drank more than six glasses a day were categorised as heavy drinkers.<sup>22</sup>

The men were followed for mortality for 20 years. None of the men was lost to follow up. The underlying cause of death was coded in a standardised way by one reviewer (AM), using the eighth revision of the international classification of diseases (ICD-8). The cause of death was based on information from the official death certificate, in combination with information from medical and hospital records. In Finland, after the fifth year of follow up only death certificates were available for assigning the cause of death. The coder of the causes of death was blind to the risk factor status of the subject. In the case of multiple causes of death, priority was given to accidents, followed by cancer in advanced stages, coronary heart disease, and stroke. For the present analyses cardiovascular disease was defined as ICD-8 codes 390-450 and A795 (code A795 was a special choice of the study group, identifying sudden death of probable coronary origin, occurring within two hours of the onset of symptoms). Cancer was defined as ICD-8 codes 140-239. Other causes included all other deaths not covered in these rubrics.

### Dietary measures

The healthy diet indicator was calculated by using the dietary guidelines for the prevention of chronic

**Table 1** Criteria used for healthy diet indicator (dichotomous values), based on the dietary guidelines for the prevention of chronic diseases.<sup>11</sup> Values are percentage of energy intake unless indicated otherwise

Nutrient or food group (daily intake)	Dichotomous value	
	1	0
Saturated fatty acids	0-10	>10
Polyunsaturated fatty acids	3-7	<3 or >7
Protein	10-15	<10 or >15
Complex carbohydrates	50-70	<50 or >70
Dietary fibre (g)	27-40	<27 or >40
Fruits and vegetables (g)	>400	<400
Pulses, nuts, seeds (g)	>30	<30
Monosaccharides and disaccharides	0-10	>10
Cholesterol (mg)	0-300	>300

diseases, defined by the WHO.<sup>11</sup> A dichotomous variable was generated for each food group or nutrient that was included in these guidelines (table 1). If a person's intake was within the recommended range this variable was coded as 1; otherwise it was coded as 0. The healthy diet indicator was the sum of all these dichotomous variables.

To avoid overlap, total fat and total carbohydrates were omitted in the calculation of the healthy diet indicator. Salt was not included because only information about the sodium content in foods was available and it was not known how much salt was added during preparation of meals and at the table. We used the variable "monosaccharides and disaccharides" instead of free sugars because the free sugars variable was not comparable between the countries. The use of monosaccharides and disaccharides has overestimated the actual intake of free sugars, especially in Finland, where the intake of milk products and therefore of lactose is high. Alcohol consumption in Italy was higher than in the two other countries, so for all three countries, before the intake of macronutrients was entered in the healthy diet indicator it was calculated as a percentage of energy intake without the energy provided by alcohol.

Both in the pooled populations and in each country separately, participants were divided into thirds (low, medium, and high) according to their healthy diet indicator. In Finland and the Netherlands, and also in the pooled populations, cut off values were <2, 2, and >2. In Italy the cut off values were <3, 3-4, and >4.

### Statistics

Differences in baseline characteristics between cohorts were tested with analysis of variance, using Scheffé's test for multiple comparisons. Frequencies of categorical variables in the different cohorts were compared by the  $\chi^2$  test. Cox's proportional hazards survival analysis was used to investigate the relation between healthy diet indicator groups and mortality in the total study population after a model including the interaction between healthy diet indicator and country had been tested. Adjustments were made for age at baseline, cigarette smoking, and alcohol consumption. All confounders except age at baseline were entered in the model as dummy variables. Analyses were repeated for each country separately. All P values were based on two sided tests, and a P value of 0.05 was considered to be

**Table 2** Characteristics of cohorts in 1969 (Finland) and 1970 (Italy and Netherlands) followed for 20 years

	Finland		Netherlands (n=608)	Italy	
	Eastern (n=606)	Western (n=683)		Crevalcore (n=591)	Montegiorgio (n=557)
No who died (from all causes)	395	412	346	346	297
Person years	8408	9942	9239	8588	8527
Mortality (No died/1000 person years)	47	41	37	40	35
Mean (SD) age in 1970	58.3 (5.4)	59.6 (5.5)*	59.5 (5.3)*	59.5 (5.0)*	59.1 (4.8)
No (%) smoking in 1970†:					
Never smokers	78 (12.9)	171 (25.0)	46 (7.6)	160 (27.1)	177 (31.8)
Former smokers	180 (29.7)	223 (32.7)	241 (39.6)	127 (21.5)	98 (17.6)
Present smokers	348 (57.4)	289 (42.3)	321 (52.8)	304 (51.4)	282 (50.6)
No (%) consuming alcohol†:					
Abstainers	226 (37.3)	248 (36.3)	172 (28.3)	27 (4.6)	8 (1.4)
Moderate ( $\leq 60$ g/day)	372 (61.4)	422 (61.8)	432 (71.1)	266 (45.0)	2317 (39.0)
Heavy ( $>60$ g/day)	8 (1.3)	13 (1.9)	4 (0.6)	298 (50.4)	332 (59.6)

\*P&lt;0.05 (Scheffé test, multiple comparisons) for difference from eastern Finland.

†P<0.05 ( $\chi^2$  test) for difference between cohorts.**Table 3** Median (range) of daily intake in 1970 of dietary components on which healthy diet indicator was based. Values are percentage of energy intake unless indicated otherwise

	Finland		Netherlands	Italy	
	East	West		Crevalcore	Montegiorgio
Energy (MJ)	14.8 (5.2-33.6)	15.4 (5.1-45.7)	10.7 (4.1-20.8)	12.2 (3.3-26.0)	11.7 (4.1-28.0)
Saturated fatty acids	21.7 (9.7-40.6)	21.6 (8.0-36.7)	17.5 (5.8-28.1)	14.1 (2.5-28.6)	9.2 (3.1-23.1)
Polyunsaturated fatty acids	2.8 (1.8-7.2)	2.9 (1.4-5.4)	6.7 (1.3-18.6)	4.6 (1.3-13.6)	3.5 (1.6-20.4)
Protein	12.7 (7.2-20.2)	12.7 (5.4-19.4)	12.7 (6.3-23.1)	14.9 (7.9-24.0)	11.6 (7.1-21.4)
Complex carbohydrates	23.5 (6.5-42.9)	25.0 (8.9-41.5)	22.4 (8.7-35.8)	36.3 (9.3-65.6)	49.3 (20.3-69.6)
Dietary fibre (g)	37.9 (6.2-108.9)	35.1 (6.9-111.2)	23.7 (6.4-51.1)	28.9 (4.1-87.7)	35.9 (8.0-98.3)
Fruits and vegetables (g)	200.1 (4.7-1479.6)	209.8 (0.9-3067.9)	333.5 (0-1433)	250.0 (0-1717)	137.0 (6.0-844.0)
Pulses, nuts, seeds (g)	4.1 (0-53.8)	6.0 (0-59.3)	3 (0-71)	0 (0-50)	2.0 (0-117.0)
Monosaccharides and disaccharides	25.2 (10.6-52.0)	23.5 (12.2-64.0)	21.6 (6.2-45.4)	11.4 (1.5-34.3)	4.8 (1.5-24.9)
Cholesterol (mg)	627 (136-2209)	649 (215-1907)	374 (76-1305)	349 (36-1043)	202 (22-909)

significant. The SAS statistical analysis computer package (version 6.10) was used.

## Results

Out of the total study population of 3045 men, 1796 men (59%) died during 20 years of follow up (table 2). Mortality was highest in eastern Finland and lowest in Montegiorgio. Mean age at baseline varied between 58 and 60 years and was significantly lower in eastern Finland than in western Finland, Zutphen, and Crevalcore. The percentage of smokers varied from 42% to 57%, and alcohol intake varied greatly among the cohorts.

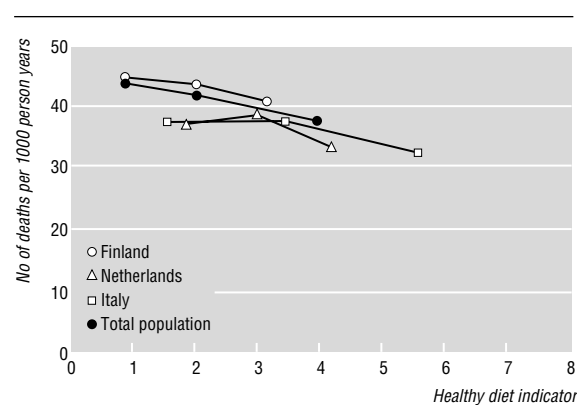
Dietary intake around 1970 varied greatly between the cohorts (table 3). Median energy intake ranged from 11 MJ to 15 MJ, and nutrient intake varied greatly: for example, median saturated fatty acid intake was 22% in Finland and 9% in Montegiorgio, Italy. The minimum healthy diet indicator was 0; the maximum healthy diet indicator varied from 5 in Finland to 8 in Italy. The healthy diet indicator was positively associated with alcohol intake ( $r=0.42$ ,  $P=0.0001$ ). A significant but small inverse association ( $r=-0.05$ ,  $P=0.005$ ) with cigarette smoking was found.

The healthy diet indicator was inversely related to all cause mortality in the pooled population analyses (table 4). The crude analysis showed a 15% lower risk of deaths from all causes in the group with the highest healthy diet indicator. After adjustment for age, cigarette smoking, and alcohol consumption the all cause mortality risk was 13% lower. In an additional

analysis the interaction between healthy diet indicator and country was not significant ( $P>0.20$ ); we therefore considered it appropriate to do a pooled analysis. In separate analyses, the healthy diet indicator and all cause mortality were inversely associated in each country; the association was similar to that in the pooled populations but was not significant.

Although the relative risks for all cause mortality were within the same order of magnitude for the three countries, the absolute mortality was highest in Finland and lowest in Italy (fig 1). Men with the healthiest diet in Finland had higher mortality than the men with an unhealthy diet in Italy, but absolute risks in the Netherlands and Italy were similar.

Overall, after adjustment for confounders, the group with the highest healthy diet indicator had an

**Fig 1** Mortality 1970-90 in Finland, Italy, and the Netherlands

**Table 4** Risk of death from all causes in 3045 men aged 50-70 years at baseline

	Relative risk (95% CI)			P value for trend
	Low*	Medium*	High*	
<b>Pooled populations</b>				
No of subjects	785	969	1291	
Mean healthy diet indicator	0.9	2.0	4.0	
Mortality†:	42	42	37	
Crude	1.00	1.00 (0.88 to 1.13)	0.85 (0.76 to 0.96)	0.004
Adjusted for age	1.00	0.95 (0.84 to 1.07)	0.82 (0.73 to 0.92)	0.0006
Adjusted for confounders‡	1.00	0.99 (0.87 to 1.11)	0.87 (0.77 to 0.98)	0.03
<b>Finland</b>				
No of subjects	529	552	208	
Mean healthy diet indicator	0.9	2.0	3.1	
Mortality†:	46	44	41	
Crude	1.00	0.96 (0.83 to 1.11)	0.89 (0.72 to 1.09)	0.25
Adjusted for age	1.00	0.93 (0.80 to 1.08)	0.86 (0.70 to 1.06)	0.14
Adjusted for confounders‡	1.00	0.97 (0.83 to 1.12)	0.90 (0.73 to 1.10)	0.31
<b>Netherlands</b>				
No of subjects	139	214	255	
Mean healthy diet indicator	0.9	2.0	3.4	
Mortality†:	37	40	35	
Crude	1.00	0.95 (0.74 to 1.20)	0.79 (0.57 to 1.11)	0.20
Adjusted for age	1.00	0.93 (0.73 to 1.19)	0.73 (0.52 to 1.02)	0.08
Adjusted for confounders‡	1.00	0.91 (0.72 to 1.16)	0.75 (0.53 to 1.05)	0.09
<b>Italy</b>				
No of subjects	320	459	369	
Mean healthy diet indicator	1.6	3.4	5.5	
Mortality†:	38	39	33	
Crude	1.00	1.01 (0.83 to 1.22)	0.85 (0.69 to 1.04)	0.11
Adjusted for age	1.00	1.04 (0.86 to 1.26)	0.86 (0.70 to 1.06)	0.13
Adjusted for confounders‡	1.00	1.04 (0.86 to 1.26)	0.89 (0.72 to 1.09)	0.23

\*In the pooled population, in Finland, and in the Netherlands, cut off values for the thirds were: low <2, medium 2, high >2; in Italy the cut off values were: low <3, medium 3 or 4, high >4.

†No of deaths per 1000 person years.

‡Adjusted for age, cigarette smoking, and alcohol consumption.

18% lower risk of death from cardiovascular disease than the group with the lowest healthy diet indicator (P for trend <0.05). Risk of death from cancer was 15% lower in the highest group than in the lowest group (P for trend = 0.13).

## Discussion

This study shows that 20 year mortality is lowest in men with the healthiest diet according to WHO recommendations. After adjustment for age, cigarette smoking, and alcohol consumption, the group with the highest healthy diet indicator had a 13% lower risk of death than the group with the lowest. The healthy diet indicator had an even stronger inverse association with mortality from cardiovascular diseases.

### Dietary patterns

Several other studies have examined dietary patterns or a combination of nutrients instead of single nutrients or dietary components, but these were all done within single countries.<sup>7-10 23 24</sup> Trichopoulou and coworkers recently used an approach similar to ours. They assessed the influence of a specific dietary pattern on overall survival among 182 elderly residents of three rural Greek villages. A diet score was calculated on the basis of eight component characteristics of the traditional Mediterranean region; an increase of one unit was associated with a 17% reduction in overall mortality.<sup>8</sup> Nube and coworkers investigated the effect of a dietary score on longevity among 2820 middle aged Dutch civil servants. Using the recall of the

frequency of intake of particular foods instead of an extensive dietary history, they found a significant linear trend for 25 year survival from highest (healthiest) to lowest scores.<sup>7</sup> Our results confirm these national results.

Since dietary patterns are highly determined by cultural influences (for example, the Mediterranean dietary pattern<sup>25-27</sup>), we did not adjust for country in the pooled population analyses. Country has a strong cultural component which is responsible for (part of) the variation in dietary patterns. Adjustment for this variable would result in an overcorrection and hence an underestimation of the true association between the quality of the diet and mortality. When the countries were analysed separately, the associations between the healthy diet indicator and all cause mortality were essentially the same, although they no longer reached significance. This was due to a low statistical power resulting from the smaller numbers of subjects within a country.

In our analyses we assumed that the diet around 1970 is indicative of diet between 1970 and 1990. The general dietary patterns in the different cultures can still be recognised after 20 years, but the differences between them have become smaller.<sup>13</sup> This may have resulted in attenuation of the association.

### Healthy diet indicator

To assess whether one of the components of the healthy diet indicator could be responsible for the observed association with mortality, we analysed the same models for each of the components of the healthy diet indicator separately. For most of the components the association was not significant (data not shown), and different components were responsible for the association in different countries. Trichopoulou and coworkers, too, found significant results for only one of the individual components.<sup>8</sup> We therefore concluded that the dietary pattern as a whole, as reflected in the healthy diet indicator, was responsible for the observed association.

Though some of the criteria of the healthy diet indicator overlap and some of the variables may be U shaped, we found a significant inverse association with 20 year mortality. The healthy diet indicator will be refined in future studies.

### Alcohol intake and energy intake

Alcohol intake varied greatly among the cohorts. In Italy mean alcohol intake was on average 10 times higher than in Finland. Giving macronutrient intakes within total energy intake would be misleading, since the high alcohol intake in the Italian cohorts would dilute macronutrient intake in comparison to that in Finland and the Netherlands. To separate the effect of alcohol from that of the healthy diet indicator, in each of the countries we calculated macronutrient intake relative to energy intake excluding energy from alcohol. We regarded alcohol intake as a possible confounder in the association of the healthy diet indicator with mortality. The high cut off for moderate alcohol consumption was chosen for practical reasons. Although these categories were rather crude, residual confounding would not have resulted in large artefacts since inverse associations between alcohol intake and

## Key messages

- Studying dietary patterns instead of single nutrients in relation to mortality takes into account the intercorrelation of nutrients in the diet
- A healthy diet, as measured by an indicator based on WHO recommendations, is associated with a reduction of 13% after 20 years in all cause mortality for men aged 50-70
- The dietary pattern as a whole is more important than specific dietary components with respect to survival among older people
- The WHO dietary recommendations for the prevention of chronic diseases seem to be effective
- The healthy diet indicator is useful for evaluating the relation of dietary patterns and mortality in a cross cultural setting

mortality have been observed for up to six glasses per day.<sup>22</sup>

To adjust for physical activity in the survival analyses, we calculated energy intake per kilogram of body weight as an approximation.<sup>28</sup> The results were essentially the same as without the adjustment (data not shown). Since no other reliable measure of physical activity was available we could not adjust for it in the present study.

### Mortality

Besides all cause mortality, we were also able to investigate mortality from cardiovascular diseases and cancer, the most important causes of premature death in developed industrialised countries.<sup>11</sup> There is abundant evidence that diet affects these diseases, and this was recognised in the WHO recommendations for the prevention of chronic diseases. Our results show that these recommendations may be effective. The healthy diet indicator, which was based on the WHO recommendations, was associated not only with reduced all cause mortality but with an even stronger reduced mortality from cardiovascular diseases.

We are indebted to the many people who were involved in this longitudinal study: the men who took part in the surveys; Dr S Giampaoli, who organised the late part of the field work in Italy; Professor M Pekkarinen, who was responsible for the data collection in Finland in 1969; and the fieldwork team in Zutphen, especially Drs EB Bosschieter and B Bloemberg, who helped prepare a common dataset.

Funding: National Institute of Aging, Bethesda, USA; Netherlands Prevention Foundation (Praeventiefonds), The Hague, Netherlands; NATO Research grant (A Menotti).

Conflict of interest: None.

- 1 Kushi LH, Lew RA, Stare FJ, Ellison CR, Lozy M el, Bourke G, et al. Diet and 20-year mortality from coronary heart disease. The Ireland-Boston Diet-Heart Study. *N Engl J Med* 1985;312:811-8.
- 2 Dolecek TA, Grandits G. Dietary polyunsaturated fatty acids and mortality in the multiple risk factor intervention trial (MRFIT). *World Rev Nutr Diet* 1991;66:205-16.
- 3 Kim I, Williamson DF, Byers T, Koplan JP. Vitamin and mineral supplement use and mortality in a US cohort. *Am J Public Health* 1993;83:546-50.
- 4 Kromhout D, Bosschieter EB, De Lezenne Coulander C. Dietary fibre and 10-year mortality from coronary heart disease, cancer and all causes. The Zutphen study. *Lancet* 1982;ii:519-22.

- 5 Kromhout D, Bosschieter EB, De Lezenne Coulander C. The inverse relation between fish consumption and 20-year mortality from coronary heart disease. *N Engl J Med* 1985;312:1205-9.
- 6 Gordon T, Fisher M, Rifkind BM. Some difficulties inherent in the interpretation of dietary data from free-living populations. *Am J Clin Nutr* 1984;39:152-6.
- 7 Nube M, Kok FJ, Vandenbroucke JP, van der Heide-Wessel C, van der Heide RM. Scoring of prudent dietary habits and its relation to 25-year survival. *J Am Diet Assoc* 1987;87:171-5.
- 8 Trichopoulou A, Kouris-Blazos A, Wahlqvist ML, Gnardellis C, Lagiou P, Polychronopoulos E, et al. Diet and overall survival in elderly people. *BMJ* 1995;311:1457-60.
- 9 Kant AK, Schatzkin A, Harris TB, Ziegler RG, Block G. Dietary diversity and subsequent mortality in the first national health and nutrition examination survey epidemiologic follow-up study. *Am J Clin Nutr* 1993;57:434-40.
- 10 Farchi G, Mariotti S, Menotti A, Seccareccia F, Torsello S, Fidanza F. Diet and 20-year mortality in two rural population groups of middle-aged men in Italy. *Am J Clin Nutr* 1989;50:1095-103.
- 11 World Health Organisation. *Diet, nutrition, and the prevention of chronic diseases*. Report of a WHO Study Group. Geneva: World Health Organisation, 1990. (WHO Technical Report Series No 797.)
- 12 Keys A. *Seven countries. A multivariate analysis of death and coronary heart disease*. Cambridge, MA: Harvard University Press, 1980.
- 13 Huijbregts PPCW, Feskens EJM, Räsänen L, Alberti-Fidanza A, Mutanen M, Fidanza F, et al. Dietary intake in five ageing cohorts of men in Finland, Italy and the Netherlands. *Eur J Clin Nutr* 1995;49:852-60.
- 14 Burke BS. The dietary history as a tool in research. *J Am Diet Assoc* 1947;23:1041-6.
- 15 Hartog C, Van Schaik ThFSM, Dalderup LM, et al. The diet of volunteers participating in a long term epidemiological field survey on coronary heart disease at Zutphen, the Netherlands. *Voeding* 1965;26:184-208.
- 16 Pekkarinen M. Dietary surveys in connection with coronary heart disease studies in Finland. In: Bazan NG, Paoletti R, Iacono JM, eds. *New trends in nutrition, lipid research, and cardiovascular diseases*. New York: Liss, 1981:243-61. (Current topics in nutrition and disease, Vol 5.)
- 17 Kromhout D. Changes in energy and macronutrients in 871 middle-aged men during 10 years of follow-up (the Zutphen study). *Am J Clin Nutr* 1983;37:287-94.
- 18 Alberti-Fidanza A, Seccareccia F, Torsello S, et al. Diet of two rural population groups of middle-aged men in Italy. *Int J Vitamin Nutr Res* 1988;58:442-51.
- 19 Bloemberg BPM, Kromhout D, Obermann-de Boer GL, van Kampen-Donker M. The reproducibility of dietary intake data assessed with the cross-check dietary history method. *Am J Epidemiol* 1989;130:1047-56.
- 20 Alberti-Fidanza A, Alunni Paolacci C, Chiuchiu MP, Colli R, Fruttini D, Cereducci G, et al. Dietary studies on two rural Italian population groups of the seven countries study. I. Food and nutrient intake at the first year of follow-up in 1991. *Eur J Clin Nutr* 1994;48:85-91.
- 21 Hautvast JGAJ. Commissie uniforme codering voedingsenquetes; ontwikkeling van een systeem om gegevens van voedingsenquetes met behulp van de computer te verwerken. *Voeding* 1975;36:356-61.
- 22 Farchi G, Fidanza F, Mariotti S, Menotti A. Alcohol and mortality in the Italian rural cohorts of the seven countries study. *Int J Epidemiol* 1992;21:74-81.
- 23 Farchi G, Fidanza F, Grossi P, Lancia A, Mariotti S, Menotti A. Relationship between eating patterns meeting recommendations and subsequent mortality in 20 years. *Eur J Clin Nutr* 1995;49:408-19.
- 24 Huijbregts PPCW, Feskens EJM, Kromhout D. Dietary patterns and cardiovascular risk factors in elderly men: the Zutphen elderly study. *Int J Epidemiol* 1995;24:313-30.
- 25 Fidanza F. The Mediterranean Italian diet: keys to contemporary thinking. *Proc Nutr Soc* 1991;50:519-26.
- 26 Willett WC, Sacks F, Trichopoulou A, Drescher G, Ferro-Luzzi A, Helsing E, et al. Mediterranean diet pyramid: a cultural model for healthy eating. *Am J Clin Nutr* 1995;61(suppl 6):1402-6S.
- 27 Willett WC. Diet and health: what should we eat? *Science* 1994;264:532-7.
- 28 Kromhout D, Saris WH, Horst CH. Energy intake, energy expenditure, and smoking in relation to body fatness: the Zutphen study. *Am J Clin Nutr* 1988;47:668-74.

(Accepted 15 April 1977)

### Endpiece

#### A very short report admired by Dr Johnson

Johnson said he could repeat a complete chapter of *The Natural History of Iceland*, from the Danish of Horrebow, the whole of which was exactly thus:-  
"CHAP. LXXII. Concerning snakes. There are no snakes to be met with throughout the whole island."

James Boswell, *The Life of Samuel Johnson*

# Substance use in remand prisoners: a consecutive case study

Debbie Mason, Luke Birmingham, Don Grubin

See pp 21, 30, 61, 65

Department of Forensic Psychiatry, University of Newcastle upon Tyne, St Nicholas Hospital, Gosforth, Newcastle upon Tyne NE3 3XT  
Debbie Mason, research associate  
Luke Birmingham, research associate  
Don Grubin, senior lecturer in forensic psychiatry

Correspondence to: Dr Debbie Mason, Parkhead Hospital, Glasgow G31 5ES.

BMJ 1997;315:18-21

## Abstract

**Objectives:** To determine the prevalence of drug and alcohol use among newly remanded prisoners, assess the effectiveness of prison reception screening, and examine the clinical management of substance misusers among remand prisoners.

**Design:** A consecutive case study of remand prisoners screened at reception for substance misuse and treatment needs and comparison of findings with those of prison reception screening and treatment provision.

**Setting:** A large adult male remand prison (Durham).

**Subjects:** 548 men aged 21 and over awaiting trial.

**Main outcome measures:** Prevalence of substance misuse; treatment needs of substance misusers; effectiveness of prison reception screening for substance misuse; provision of detoxification programmes.

**Results:** Before remand 312 (57%) men were using illicit drugs and 181 (33%) met DSM-IV drug misuse or dependence criteria; 177 (32%) men met misuse or dependence criteria for alcohol. 391 (71%) men were judged to require help directed at their drug or alcohol use and 197 (36%) were judged to require a detoxification programme. The prison reception screen identified recent illicit drug use in 131 (24%) of 536 men and problem drinking in 103 (19%). Drug use was more likely to be identified by prison screening if an inmate was using multiple substances, using opiates, or had a diagnosis of abuse or dependence. 47 (9%) of 536 inmates were prescribed treatment to ease the symptoms of substance withdrawal.

**Conclusions:** The prevalence of substance misuse in newly remanded prisoners is high. Prison reception health screening consistently underestimates drug and alcohol use. In many cases in which substance use is identified the quantities and numbers of different substances being used are underestimated. Initial management of inmates identified by prison screening as having problems with dependence producing substances is poor. Few receive a detoxification programme, so that many are left with the option of continuing to use drugs in prison or facing untreated withdrawal.

## Introduction

There has been a dramatic increase in the use of illicit drugs in England and Wales in recent years. This is reflected in the increase in numbers of notifiable drug addicts from around 17 000 in 1990-1 to around 33 000 in 1995-6. An even steeper rise has been noted in prisoners, who accounted for 12% of notifications in 1990 and 23% in 1995.<sup>1</sup> In addition to the general social problems and adverse effects on health associated with illicit drug use, there are particular problems secondary to drug use in prison, such as the

fostering of gangs, debt to other prisoners, and violence.

We recently reported that 26% of men newly remanded to a large prison in north east England had some form of mental disorder (excluding drug and alcohol misuse diagnoses) at the point of reception.<sup>2</sup> By using data on substance use from the same subjects this paper reports on the prevalence of drug and alcohol use, the extent to which prison reception screening detects this, and the initial management of subjects whose substance misuse is identified.

## Subjects and methods

The study was conducted at Durham prison, a typical male remand and short sentence prison. All new prisoners are screened at reception by a healthcare officer for physical and mental health problems as well as substance use. A standard prison questionnaire (F2169) is used which contains several specific questions about recent drug and alcohol use. This provides useful information for the prison doctor, who assesses each inmate the next working day and decides about detoxification regimens and any other treatment needs. All unconvicted men remanded into custody over seven months from 1 October 1995 to 30 April 1996 were eligible for the study. The research was explained to each man and assurances given that any information he offered was confidential and would not be passed on to prison staff. Each man gave written consent. Subjects were interviewed by one of two researchers trained in psychiatry.

## Screening

A semistructured interview designed specifically for the study was used. A comprehensive drug and alcohol history was taken, levels of use recorded, and DSM-IV (*Diagnostic and Statistical Manual of Mental Disorders*, fourth edition) diagnoses of abuse and dependence made when appropriate. The CAGE questionnaire<sup>3</sup> was incorporated to help detect problem drinking and the severity of dependence scale<sup>1</sup> was used to quantify severity of drug dependence.

Virtually all interviews were conducted on the working day after reception into prison, shortly after the medical officer had seen the inmate. Interviews lasted between 20 minutes and one hour depending on the complexity of an inmate's presentation. On the basis of our findings a decision was made about suitability for a detoxification programme. After each inmate had been interviewed his medical record was examined. The findings of the healthcare officer's screen and the prison doctor's assessment were recorded and any treatment prescribed was noted.

A pilot study was undertaken. During the pilot study and throughout the main study, interrater reliability was monitored. A total of 116 prisoners were interviewed by one researcher in the presence of the

other. Both researchers recorded lifetime diagnoses independently. From this information the agreement between raters was measured by means of a  $\kappa$  coefficient.<sup>5</sup> Agreement in this setting is likely to be higher than with separate interviews; given the practicalities of research in prison, separate interviews were not feasible.

## Results

During the study 606 unconvicted men were newly remanded to Durham prison. Of those available for interview, 548 were comprehensively screened for substance use. In the 116 interviews that were jointly rated to assess interrater reliability, 184 separate diagnoses of substance misuse were recorded by either one or both raters. There was diagnostic agreement in 175 cases ( $\kappa = 0.930$ ).

### Prevalence and patterns of substance use

A total of 382 men (70%; 95% confidence interval 66% to 74%) gave a history of illicit drug use at some point in their lives. Of these men, 312 (57%; 53% to 61%) said they had used illicit drugs in the past year and 181 (33%; 29% to 37%) currently met abuse or dependence criteria for one or more drugs. Table 1 gives the numbers of men currently using each class of drug according to level of use. Many inmates using drugs complained of withdrawal symptoms, but only 12 diagnoses of drug withdrawal syndrome were made.

Intravenous drug use was reported by 101 men (26%; 22% to 30%), 29 of whom said they had shared needles. Table 2 shows the extent of multiple drug use. Of the 181 subjects with drug abuse or dependence diagnoses, 60 had two such diagnoses and 20 had three or more.

### Treatment needs and expectations of substance users

Of 391 men (71%; 67% to 76%) who admitted using illicit drugs regularly or abuse of or dependence on alcohol, or both, and who were judged to require treatment directed at their substance use, 244 (62%; 58% to 66%) said they wanted help. A total of 197 (36%; 32% to 40%) of the study population who were physiologically dependent on benzodiazepines, alcohol, opiates, or a combination of these substances at the time of reception into prison were judged to be potential candidates for a detoxification programme. Of these, 64 requested treatment including detoxification, 22 wanted methadone maintenance, 45 wanted other treatments such as group work, and 66 did not want help.

### Alcohol use

Table 3 shows the levels of reported alcohol use in the previous year. Four diagnoses of acute alcohol withdrawal syndrome were made.

### Detection of substance use by reception screening

The inmate medical records of 536 of the 548 subjects were inspected. In general the healthcare officers' screens were more comprehensive than the doctors' assessments. In particular, they contained information about which substances were being used whereas the doctors' assessments usually just recorded "drugs"

**Table 1** Numbers of subjects currently using each class of illicit drug at recreational (non-abusive or non-dependent use), DSM-IV abuse and DSM-IV dependence levels (n=312 subjects\*)

Drug	Recreational use	Abuse	Dependence	Total
Amphetamine	67	25	44	136
Benzodiazepines	32	12	75	119
Cannabis	244	13	1	258
Cocaine	35	8	4	47
Hallucinogens	32	4	0	36
Opiates	13	3	84	100
Solvents	4	0	5	9
Other substances	2	5	1	8

\*Many subjects were using more than one illicit substance.

when their use was detected and "alcohol abuse" when alcohol consumption was thought to be excessive. To some extent prison screens are designed to be complementary and doctors may have thought it unnecessary to duplicate information recorded by the healthcare worker. However, in cases in which the healthcare worker had not detected substance use but this had been identified subsequently by the doctor, information was still minimal. In most cases when it would have been appropriate to do so, neither screen sought further information on quantities of substances used or problems associated with substance use.

### Drugs

The healthcare officers' questionnaire identified 131 of 536 subjects (24%; 20% to 28%) using illicit drugs recently. Table 4 shows the detection rates for each of the four drugs that we identified as being used most commonly. The healthcare officers' screen detected 56 of the 81 subjects we had identified as currently dependent on opiates (difference = 0.046; 0.028 to 0.063), 22 of the 70 subjects we identified as currently dependent on illicit benzodiazepines (difference = 0.088; 0.076 to 0.100), and 15 of the 43 we identified as currently dependent on amphetamines (difference = 0.051; 0.032 to 0.069).

Subsequent interviews with the prison medical officer identified a further 42 subjects as "using drugs" (without identifying the class of drug), increasing the number detected to 172 (32%; 28% to 36%). Six subjects who when asked by us denied ever using illicit drugs were identified by prison screening as using cannabis.

**Table 2** Numbers of illicit drugs used by 312 subjects

No of drugs used currently	No (%) of subjects
1	108 (34.6)
2	96 (30.7)
3	55 (17.6)
4	27 (8.7)
5	17 (5.4)
6	8 (2.6)
7	1 (0.3)

**Table 3** Current levels of alcohol use in 548 subjects

Level of use	No (%) of subjects
None	122 (22)
< 21 U/week	193 (35)
≥ 21 U/week (with no DSM-IV alcohol diagnosis)	56 (10)
DSM-IV abuse	61 (11)
DSM-IV dependence	116 (21)

**Table 4** Numbers identified by hospital officers' screening according to level of use of four most frequently encountered illicit drugs

Drug	Level of use according to research screening	Use identified by hospital officer	
		No	Yes
Cannabis	Not used	118	6
	Recreational	191	45
	Abuse or dependence	10	4
Amphetamines	Not used	234	4*
	Recreational	58	7
	Abuse or dependence	45	23
Benzodiazepines	Not used	256	2*
	Recreational	33	3
	Abuse or dependence	61	22
Opiates	Not used	274	4*
	Recreational	11	0
	Abuse or dependence	25	57

\*All subjects identified by study as currently using illicit drugs other than cannabis.

Drug users were increasingly likely to be detected by the prison reception screen as the number of drugs they were using increased ( $P < 0.0001$ ,  $\chi^2 = 60.14$ ;  $df = 6$ ) and if they had one or more current drug abuse or dependency diagnoses ( $P < 0.0001$ ,  $\chi^2 = 56.90$ ;  $df = 1$ ).

#### Alcohol

Problem drinking was identified by one or both prison screens in 88 of the 172 subjects identified by us as having a current alcohol abuse or dependency diagnosis. A further 15 men were said to have alcohol problems when no alcohol diagnosis was made by us (difference = 0.133; 0.099 to 0.168).

#### Provision of detoxification programmes

Of 197 subjects potentially requiring a detoxification regimen, 113 needed a reducing course of benzodiazepines to ease withdrawal from benzodiazepines or alcohol or both. Only six men (5%) received this, though a further five men were prescribed benzodiazepines for other reasons. Forty two subjects were judged by us to require methadone detoxification, of whom 15 (36%) received it; three men were given benzodiazepines instead. A further 42 subjects potentially required detoxification with both benzodiazepines and methadone, of whom 10 received this, nine were given methadone alone, and four were given benzodiazepines alone.

#### Discussion

Before their reception into Durham prison over 70% of unconvicted remand prisoners reported the use of illicit drugs, regular consumption of excessive amounts of alcohol, or both. Amounts of drugs and alcohol consumed were often substantial, reflected by 56% of the population having one or more current diagnoses of substance abuse or dependency. Multiple substance use was also common.

Our results show that whereas over one third of all newly remanded prisoners provisionally needed to be considered for detoxification, only about one in four actually received treatment to help manage withdrawal from drugs and alcohol. Clinical assessment of substance use at reception relies to a large extent on self reporting. We found that when questioned by prison staff many inmates played down the extent of

their substance use, disclosing only what they thought was necessary, as they were not confident of receiving treatment but risked being labelled as drug users. When interviewed by researchers, who were not perceived to be part of the system, inmates seemed more willing to disclose substance misuse. The fact remains, however, that substantial numbers of drug users were missed by prison reception screening.

Though considerable emphasis has so far been placed on the role of the inmate, this is not the only factor that determines the effectiveness of screening for substance use. We found that information recorded by prison staff at the time of reception was often inadequate or ambiguous. Such standards have led to criticism of prison medical staff in the past.<sup>6,7</sup> Concern has also been expressed about treatment programmes for drug misusers in prisons based on Home Office guidelines, which are said to breach normal standards of professional ethical care.<sup>8</sup>

The prison service has other means than clinical assessment of identifying drug use which do not rely so heavily on a prisoner's cooperation. Compulsory urine testing of prisoners for drugs, with penalties for positive results or refusal, was piloted in early 1995. Despite a lack of evidence for its effectiveness in reducing drug use, testing was extended to all prisons in England and Wales by March 1996. The cost of this programme is estimated at around half the total healthcare expenditure for a prison of 500.<sup>9</sup> This is primarily a deterrent measure, however, as tests give little information about substance related problems or health needs and are not a substitute for thorough clinical assessment. We believe that if drug use in prison is to be tackled effectively greater emphasis needs to be placed on more rigorous clinical screening and provision of drug treatment programmes comparable to those in the community.

There are no other published studies of substance misuse at the time of reception into prison in the

#### Key messages

- In screening for substance use in remand prisoners a positive finding must be considered the norm rather than the exception
- Present prison reception procedures fail to identify the extent to which substances are used and misused by people newly remanded to prison
- Provision of detoxification programmes for prisoners identified by reception screening as having serious drug and alcohol related problems is inadequate
- Prisoners who need help but think that asking for this is more likely to result in punishment than treatment are not likely to be truthful about their substance use
- More consideration needs to be given to reducing substance misuse in prisons by improving assessment at reception and providing better treatment for misusers rather than using random urine screening to detect and punish offenders



United Kingdom, but there is no reason to suspect that the scale of the problem differs in other remand prisons. A recent national study of mental disorder in remand prisoners by Brooke et al reported harmful or dependent misuse of alcohol or other drugs in 38% of subjects<sup>10</sup> (compared with a similar finding in 56% of our population). There are, however, important differences between their study and our own. Many of the inmates screened by Brooke et al had already spent a considerable period on remand before being interviewed (median time 64 days), and therefore the results of their study cannot be interpreted as accurately reflecting the scale of substance misuse at the point of reception. In addition, Brooke et al reported a much higher refusal rate (18% compared with 3% in this study), which may have biased their results.

Without adequate detoxification programmes many inmates will continue to use drugs in prison. In some cases this will be accompanied by the risk of needle sharing. Others who attempt to stop or who do not establish a supply quickly enough are exposed to the effects of acute withdrawal. Ultimately the picture that emerges is one of a self perpetuating and rapidly growing problem of substance use in prisons, which,

because most prisoners are released after comparatively short periods (the mean length of remand was under two months in our sample), will inevitably spill over into the community.

Funding: Northern Regional Health Authority and the prison service.

Conflict of interest: None.

- 1 Joyce L. Drug use in prison: the current picture. *Prison Ser J* 1996;107:16-23.
- 2 Birmingham L, Mason D, Grubin D. Prevalence of mental disorder in remand prisoners: consecutive case study. *BMJ* 1996;313:1521-4.
- 3 Mayfield D, McLeod G, Hall MSW. The CAGE questionnaire: validation of a new alcoholism screening instrument. *Am J Psychiatry* 1974;131:121-3.
- 4 Phillips GT, Gossop MR, Edwards G, Sutherland G, Taylor C, Strang G. The application of the SODQ to the severity of opiate dependence in a British sample. *Br J Addict* 1987;82:691-9.
- 5 Maxwell AE. Coefficients of agreement between observers and their interpretation. *Br J Psychiatry* 1977;130:79-83.
- 6 Smith R. Prison medicine: beginning again. *BMJ* 1992;304:134-5.
- 7 Bluglass R. Recruitment and training of prison doctors. *BMJ* 1990;301:249-50.
- 8 Ross M, Grossman AB, Murdoch S, Bunday R, Golding J, Purchase S, et al. Prison: shield from threat, or threat to survival? *BMJ* 1994;308:1092-5.
- 9 Gore SM, Bird G. Cost implications of random mandatory drugs tests in prisons. *Lancet* 1996;348:1124-7.
- 10 Brooke D, Taylor C, Gunn J, Maden A. Point prevalence of mental disorder in unconvicted male prisoners. *BMJ* 1996;313:1524-7.

(Accepted 15 April 1997)

## Harm reduction measures and injecting inside prison versus mandatory drugs testing: results of a cross sectional anonymous questionnaire survey

A Graham Bird, Sheila M Gore, Sharon J Hutchinson, Stephanie C Lewis, Sheila Cameron, Sheila Burns on behalf of the European Commission Network on HIV infection and hepatitis in prison

### Abstract

**Objectives:** (a) To determine both the frequency of injecting inside prison and use of sterilising tablets to clean needles in the previous four weeks; (b) to assess the efficiency of random mandatory drugs testing at detecting prisoners who inject heroin inside prison; (c) to determine the percentage of prisoners who had been offered vaccination against hepatitis B.

**Design:** Cross sectional willing anonymous salivary HIV surveillance linked to a self completion risk factor questionnaire.

**Setting:** Lowmoss prison, Glasgow, and Aberdeen prison on 11 and 30 October 1996.

**Subjects:** 293 (94%) of all 312 inmates at Lowmoss and 146 (93%) of all 157 at Aberdeen, resulting in 286 and 143 valid questionnaires.

**Main outcome measures:** Frequency of injecting inside prison in the previous four weeks by injector inmates who had been in prison for at least four weeks.

**Results:** 116 (41%) Lowmoss and 53 (37%) Aberdeen prisoners had a history of injecting drug use but only 4% of inmates (17/395; 95% confidence interval 2% to 6%) had ever been offered vaccination against hepatitis B. 42 Lowmoss prisoners (estimated 207

injections and 258 uses of sterilising tablets) and 31 Aberdeen prisoners (229 injections, 221 uses) had injected inside prison in the previous four weeks. The prisons together held 112 injector inmates who had been in prison for more than four weeks, of whom 57 (51%; 42% to 60%) had injected in prison in the past four weeks; their estimated mean number of injections was 6.0 (SD 5.7). Prisoners injecting heroin six times in four weeks will test positive in random mandatory drugs testing on at most 18 days out of 28. **Conclusions:** Sterilising tablets and hepatitis B vaccination should be offered to all prisoners. Random mandatory drugs testing seriously underestimates injector inmates' harm reduction needs.

### Introduction

Willing anonymous salivary HIV (WASH) surveillance in Scottish prisons provided consistent estimates in 1991-5 of the prevalence of risk behaviours inside and outside prisons, of their geographic and sentencing correlates, and of the prevalence of HIV among injector inmates.<sup>1-4</sup> Two studies in 1996 were important for different reasons<sup>5</sup>: the study in Lowmoss prison, Glasgow, monitored changes since willing anonymous

See pp 18, 30, 61, 65

Churchill Hospital,  
Oxford OX3 7LJ  
A Graham Bird,  
consultant  
immunologist

MRC Biostatistics  
Unit, Cambridge  
CB2 2SR  
Sheila M Gore,  
senior statistician

MRC-BIAS,  
Edinburgh  
EH9 3JN

Sharon J  
Hutchinson,  
statistician

Stephanie C Lewis,  
statistician

Regional Virus  
Laboratory,  
Glasgow G20 9NB  
Sheila Cameron,  
clinical virologist

*BMJ* 1997;315:21-4  
continued over

Regional Virus  
Laboratory,  
Edinburgh  
EH10 5SB

Sheila Burns,  
*clinical virologist*

Correspondence to:  
Dr Gore  
(sheila.gore@mrc-bsu.  
cam.ac.uk)

**Table 1** Composition of study groups in HM prisons Lowmoss and Aberdeen

	Lowmoss	Aberdeen
Total No of prisoners	312	157
Total No of respondents	293	146
Response rate (%)	(94)	(93)
No (%) excluded for failing logical checks	7 (2)	3 (2)
No completing valid questionnaire	286	143

salivary HIV surveillance in 1994 at Barlinnie prison, also in Glasgow; the study in Aberdeen prison gave the first insight to injector and HIV prevalence in north east Scotland at a time of concern about the availability of cheap heroin.<sup>6</sup>

Questions were added in 1996 to evaluate prisoners' access to harm reduction measures, including hepatitis B vaccination. Sterilising tablets have been available to all Scottish prisoners since December 1993 for purposes including the cleaning of needles and

works. But are they being used for the intended harm reduction purpose? Random mandatory drugs testing has been challenged as "a means of gathering information."<sup>7,8</sup> We used volunteered information on the frequency of injecting inside prison in the previous four weeks to estimate the likely efficiency of random mandatory drugs testing at detecting inmates who inject class A drugs such as heroin inside prison. So far as we know this is the first such study.

## Methods

Willing anonymous salivary HIV surveillance was conducted with ethical approval and as described<sup>1-3,9</sup> by external teams of volunteers at Lowmoss prison on 11 October and at Aberdeen prison on 30 October 1996. Saliva samples were tested for HIV antibodies at the regional virus laboratories in Glasgow and Edinburgh respectively. On the surveillance days AGB briefed prisoners about why the survey was being performed,

**Table 2** Results of questionnaire survey at Lowmoss and Aberdeen. Figures are numbers (percentages) of prisoners

	Lowmoss		Aberdeen	
	All participants (n=286)	Injector inmates (n=116)	All participants (n=143)	Injector inmates (n=53)
<b>Q9 In which year did you first inject drugs (excluding insulin)?</b>				
No of non-respondents	4	0	1	0
Never injected	166 (59)	0	89 (63)	0
1982 or earlier	20 (7)	20 (17)	6 (4)	6 (11)
1983-5	27 (10)	27 (23)	2 (1)	2 (4)
1986-8	17 (6)	17 (15)	4 (3)	4 (8)
1989-91	17 (6)	17 (15)	9 (6)	9 (17)
1992-4	19 (7)	19 (16)	13 (9)	13 (25)
1995 or later	16 (6)	16 (14)	19 (13)	19 (36)
<b>Q10 When did you last inject drugs before coming into prison this time (including remand prison)?</b>				
No of non-respondents	7	3	2	1
Never injected	166 (59)	0	92 (65)	3 (6)
On day came into prison	21 (8)	21 (19)	15 (11)	15 (29)
On day before coming into prison	40 (14)	40 (35)	12 (9)	12 (23)
In week before coming into prison	12 (4)	12 (11)	6 (4)	6 (12)
Between one and four weeks before coming into prison	7 (3)	7 (6)	6 (4)	6 (12)
More than four weeks before coming into prison	33 (12)	33 (29)	10 (7)	10 (19)
<b>Q11 Have you ever injected while inside?</b>				
No of non-respondents	10	0	1	0
Yes	66 (24)	66 (57)	39 (27)	39 (74)
No	210 (76)	50 (43)	103 (73)	14 (26)
<b>Q12 Did you start injecting while inside?</b>				
No of non-respondents	19	1	6	1
Yes	5 (2)	5 (4)	10 (7)	10 (19)
No	262 (98)	110 (96)	127 (93)	42 (81)
<b>Q14 How many times have you injected drugs in prison in last four weeks?</b>				
No of non-respondents	12	2	1	0
Never	232 (85)	72 (63)	111 (78)	22 (42)
One or more times	42 (15)	42 (37)	31 (22)	31 (58)
<b>Q15 How many times have you used sterilising tablets to clean needles or works in prison in last four weeks?</b>				
No of non-respondents	15	3	3	0
Never	229 (85)	71 (63)	112 (80)	26 (49)
One or more times	42 (15)	42 (37)	28 (20)	27 (51)
<b>Q18 Have you ever had an acute attack of hepatitis or yellow jaundice?</b>				
No of non-respondents	3	2	4	0
Yes	31 (11)	27 (24)	7 (5)	7 (13)
No	252 (89)	87 (76)	132 (95)	46 (87)
<b>Q19 Have you ever been offered vaccination against hepatitis B?</b>				
No of non-respondents	24	11	10	1
Yes, and completed full course of three injections	6 (2)	4 (4)	2 (2)	1 (2)
Yes, but received only one or two injections	3 (1)	1 (1)	2 (2)	2 (4)
Yes, but declined offer	2 (1)	1 (1)	2 (2)	1 (2)
No, never offered	251 (96)	99 (94)	127 (95)	48 (92)

and explained the linkage of questionnaire and saliva sample by sealed number pair (chosen at random by the prisoners)<sup>2</sup> and that the survey and research team were unconnected with random mandatory drugs testing (due to be introduced to both prisons in 1997).

## Results

The participation rate was 94% (293 of 312 prisoners) at Lowmoss and 93% (146/157) at Aberdeen (table 1). Two Lowmoss prisoners (both injectors) tested positive for HIV antibody. HIV prevalence was 0.7% overall and 1.7% (2/116) for injector inmates. At Aberdeen one saliva sample was insufficient and two prisoners (both non-injectors and heterosexual, one known to the prison's medical service) were HIV positive; HIV prevalence was 1.4% (2/145) overall but nil for injector inmates.

Table 2 gives prisoners' answers to questions about injecting, use of sterilising tablets, and uptake of hepatitis B vaccination for all 286 Lowmoss and 143 Aberdeen participants whose questionnaires passed logical checks and, separately, for the 116 and 53 injecting drug users (that is, people with a history of injecting drug use).

### Injecting drug users and injecting inside prison

Forty five per cent (52/116) of Lowmoss's injecting drug users began their injecting career in 1989 or later compared with 77% (41/53) of Aberdeen prison's injector inmates, 19 of whom had started injecting very recently (in 1995 or later). Fifty four per cent (61/113) of Lowmoss's injecting drug users had injected on the day of entering prison or the day before, as had 52% (27/52) of injecting drug users at Aberdeen. Fifty seven per cent (66/116) of Lowmoss's injecting drug users had ever injected inside prison but only five (4%) had started to inject inside; at Aberdeen these figures were 74% (39/53;  $P < 0.03$ ) and 19% (10/52;  $P < 0.01$ ).

Forty two Lowmoss prisoners (15% of all inmates; 37% of injector inmates) and 31 Aberdeen prisoners (22% of all inmates; 58% of injector inmates) had injected in prison in the previous four weeks. The prisons together held 112 injector inmates who had been in prison for more than four weeks, of whom 57 (51%) had injected in prison in the previous four weeks as follows: once (10 inmates), two to five times (24), 6-10 times (17), 11-20 times (5), 21-50 times (1); their estimated mean number of injections in the four weeks was 6.0 (SD 5.7).

### Sterilising tablets and hepatitis B vaccination

Injector inmates' answers to questions about both injecting in prison and the use of sterilising tablets to clean injecting equipment in the past four weeks were broadly concordant (Lowmoss: estimated 207 injections and 258 uses of sterilising tablets to clean needles or works; Aberdeen: estimated 229 injections and 221 uses of sterilising tablets) (table 3). In both prisons local arrangements satisfactorily allowed prisoners to access sterilising tablets for the harm reduction purpose intended.

Only 4% of Lowmoss's inmates (11/262) and 5% of inmates of Aberdeen prison (6/133) had ever been offered vaccination against hepatitis B. The low reported offer rate is the more surprising because 43%

**Table 3** Frequencies of injecting and of using sterilising tablets among injector inmates at Lowmoss and Aberdeen

No of times injected in past four weeks	No of times used sterilising tablets to clean needles or works in prison in past four weeks					
	Never	Once	2-5	6-10	11-20	21-50
Never	85	3	6	0	1	1
Once	2	5	5	2	1	0
2-5	3	0	20	2	0	0
6-10	1	2	5	13	1	1
11-20	0	0	0	1	2	1
21-50	0	0	0	0	1	0
>50	1	0	0	0	0	0

Data on these questions were missing for four Lowmoss prisoners.

of convicted prisoners in Lowmoss and Aberdeen prisons (169/392) had been sentenced for more than six months and is disappointing in view of the high rates of clinical hepatitis reported by injector inmates (20%; 34/167; table 2).

## Discussion

Results at Aberdeen prison indicated that local injecting drug use was as prevalent but more recent than in Glasgow. Injecting behaviour in Aberdeen prison mirrored that in nearby Perth prison<sup>10</sup>: 74% of Aberdeen's injector inmates had ever injected inside prison (Perth 85%) and 19% had started to inject inside prison (Perth 31%). Three fifths of injecting drug users in Aberdeen prison first injected in 1992 or later and 43% were under 26 years of age.

### Use of sterilising tablets

In contrast with England and Wales,<sup>11 12</sup> the Scottish Prison Service has provided sterilising tablets in accordance with the World Health Organisation's recommendations<sup>13</sup> since December 1993.<sup>14</sup> Prisoners regularly used these tablets to clean injecting equipment.

### Hepatitis B immunisation

In contrast with almost universal acceptance by prison officers, at most 5% of the inmates studied had ever been offered immunisation against hepatitis B. Similarly low rates were discovered in audit studies in Oxford and Anglia prisons (J Cassidy, personal communication) and in over 3500 prisoners in Victoria, Australia,<sup>15</sup> where only 5% of non-immune prisoners had been immunised. Other studies suggest that low awareness<sup>16</sup> and unwillingness (M Rotliy, personal communication) contribute to low immunisation uptake by injecting drug users. Specific resources need to be allocated to prison medical services, general practitioners, and drug treatment centres for universal offering of hepatitis B immunisation to prisoners and former prisoners as routine.<sup>17 18</sup>

### Frequency of injecting inside prison: implications for random drugs testing

The combined data showed that 51% (57/112) of injectors who had been in prison for more than four weeks had injected in the past four weeks while inside. Their mean number of injections was 6.0 (SD 5.7). If we assume that the substance injected remained in the urine for three days (as occurs with heroin), then these prisoners would be liable to have a positive result in

## Key messages

- Half of injector inmates of two Scottish prisons who had been in prison for more than four weeks had injected in the previous four weeks—an average of six times
- Injector inmates used sterilising tablets to clean injecting equipment as often as they injected
- Only 4% of inmates had ever been offered vaccination against hepatitis B
- Vaccination against hepatitis B and sterilising tablets are prisoners' rights
- Random mandatory drugs testing is likely to detect only one third to two thirds of heroin injectors in prison and so seriously underestimates injector inmates' drug reduction needs

random mandatory drugs tests on a maximum of 18 days out of 28. If, however, random mandatory drugs testing did not operate at weekends, as in England and Wales, and prisoners could organise their injecting accordingly (for Friday evenings and one Tuesday and one Wednesday evening, say), then they may test positive on many fewer days—for example, on (4 Mondays + (Wednesday + Thursday + Friday) + (Thursday + Friday))=9 days out of 28. On these assumptions we would expect only two thirds to one third of prisoners who are injecting heroin inside prison to test positive in random mandatory drugs tests.

Random mandatory drugs testing is therefore likely seriously to underestimate prisoners' injection related drug use problems. Underestimation will entail underresourcing of these and other prisons in respect of the healthcare and drug reduction needs of their injector inmates.

### Obligations to injector inmates

The current extent of injecting among inmates of our prisons demands that we think again about society's obligation to these addicted people. As they continue to take class A drugs by injection inside prison, we must enable them to do so more safely. This requires that ready access to sterilising tablets should be extended to all prisoners in Britain, not just to those in Scotland. It also requires that all prisoners who could benefit from substitute prescribing should receive it, the primary goal being to help them stop injecting; drug reduction is a secondary objective. If sterilising tablets are used suboptimally they may not protect absolutely against bloodborne virus transmission; hence prisoners, like other citizens in Britain, need access to various harm reduction measures. Some are denied methadone, all are denied needle exchange. Prison needle exchange has been pioneered in Switzerland,<sup>19</sup> is being evaluated in Germany, and is under consideration in Canada.<sup>20</sup>

If the current limited access to harm reduction measures is perpetuated it represents a serious gulf between the standards of health care and public health available to the same individuals in prison and outside. Prison medical service policy promotes equality but is short on delivery.<sup>21</sup>

We thank HM prison governors Mr Bill Middleton (Lowmoss) and Mr John Bywalec (Aberdeen) and their officers for welcom-

ing WASH surveillance, for the efficiency of the escort, and for domestic arrangements for the volunteer team; Mrs Linda McDonald and Mrs Karen Wilson, and Mr Tom Shaw, for over-seeing saliva samples at the regional virus laboratories in Glasgow and Edinburgh; and the prisoners at Lowmoss and Aberdeen for their participation. We also thank our volunteer teams, both local and from the European Commission Network for HIV Studies in Prisons: Dr Gwen Allardice, Ms Margaret Beveridge, Dr Graham Bird, Mrs Pat Bolam, Mr Donald Cameron, Ms Amanda Cardy, Ms Jan Cassidy, Ms Leonie Craig, Mrs Shona Donald, Ms Laura Ewen, Dr Sheila Gore, Ms Anne Greenhill, Mr Harry van Haastrecht, Mrs Vivien Herring, Dr Richard Herriot, Ms Sharon Hutchinson, Ms Jillian Ireland, Dr Emma Jandolo, Dr Kerstin Kall, Ms Stephanie Lewis, Ms Helena Liddell, Mr George Macdonald, Mrs Joy Macdonald, Mr Bryce MacGregor, Dr Pam Molyneux, Ms Sarah Morrison, Mr Dougal Quin, Mr Tony O'Reilly, Dr Michel Rotily, Ms Sarah Sutherland, Ms Jenny Wallin, Dr Karen Weilandt, Mr Andrew Weild.

Neither the European Commission nor any person acting on behalf of the European Commission is responsible for the use which might be made of the data presented.

Funding: Medical Research Council (grant G9102632) and the European Commission (grant DGV, SOC-95-202181-05F02). Conflict of interest: None.

- 1 Gore SM, Bird AG. Cross-sectional willing anonymous salivary HIV (WASH) surveillance studies and self-completion risk-factor questionnaire in establishments of the Scottish Prison Service. *AIDS News Supplement to the Weekly Report (ANSWER)* 1995;39:1-4.
- 2 Bird AG, Gore SM, Jolliffe DW, Burns SM. Anonymous HIV surveillance in Saughton prison, Edinburgh. *AIDS* 1992;6:725-33.
- 3 Bird AG, Gore SM, Cameron S, Ross AJ, Goldberg DJ. Anonymous HIV surveillance with risk factor elicitation at Scotland's largest prison, Barlinnie. *AIDS* 1995;9:801-8.
- 4 Gore SM, Bird AG, Burns SM, Goldberg DJ, Ross AJ, Macgregor J. Drug injection and HIV prevalence in inmates of Glenochil prison. *BMJ* 1995;310:293-6.
- 5 Freeman J. Health experts praise Scots AIDS-testing scheme. *The Herald* 1996 Oct 12:4.
- 6 Woods J. If your image of a heroin user is a spaced-out jobless smackhead, think again. Think young and affluent—and think Aberdeen. *Scotsman* 1997 Jan 14:13.
- 7 Gore SM, Bird AG. Mandatory drug tests in prisons. *BMJ* 1995;310:595.
- 8 Bird AG, Gore SM. Drug testing in prisons. *The Herald* 1996 Jan 22:12.
- 9 Bird AG, Gore SM. Inside methodology: HIV surveillance in prisons. *AIDS* 1994;8:1345-6.
- 10 Gore SM, Bird AG, Burns SM, Ross AJ, Goldberg DJ. Anonymous HIV and risk-factor surveillance at Perth (for men) and Cornton Vale (for women) prisons in Scotland. *Int J STD AIDS* (in press).
- 11 HM Prison Service. *Drug misuse in prison: policy and strategy*. London: HMPS, 1995:7, 23.
- 12 Acheson D. Prison service for England and Wales has been designated a WHO collaborating centre. *BMJ* 1997;314:302.
- 13 World Health Organisation. *Global programme on AIDS: WHO guidelines on HIV infection and AIDS in prisons*. Geneva: WHO Global Programme on AIDS, 1993.
- 14 Taylor A, Goldberg D, Emslie J, Wrench J, Gruer L, Cameron S, et al. Outbreak of HIV infection in a Scottish prison. *BMJ* 1995;310:289-92.
- 15 Crofts N, Stewart T, Hearne P, Ping XY, Breshkin AM, Locarnini SA. Spread of bloodborne viruses among Australian prison entrants. *BMJ* 1995;310:285-8.
- 16 Payne-James JJ, Dean PJ, Keys DW. Drug misusers in police custody: a prospective survey. *J R Soc Med* 1994;87:13-4.
- 17 Task Force to Review Services for Drug Misusers. *Report of an independent review of drug treatment services in England*. London: Department of Health, 1996. (Task force chairman: Reverend Dr John Polkinghorne.)
- 18 Mangtani P, Kovats S, Hall A. Hepatitis B vaccination policy in drug treatment services. *BMJ* 1995;311:1500.
- 19 Nelles J, Fuhrer A. *Drug and HIV prevention at Hindelbank penitentiary. Abridged report of the evaluation results*. Berne: Swiss Federal Office of Public Health, 1995.
- 20 Jurgens R. *HIV/AIDS in prisons: final report*. Montreal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996.
- 21 Her Majesty's Inspectorate of Prisons for England and Wales. *Patient or prisoner? A new strategy for health care in prisons*. London: Home Office, 1996.

(Accepted 25 April 1997)

### Endpiece

#### Cyril Connolly on obesity

Imprisoned in every fat man a thin one is wildly signalling to be let out.

Cyril Connolly, *The Unquiet Grave* (1944)

# Physiotherapy for patients with soft tissue shoulder disorders: a systematic review of randomised clinical trials

Geert J M G van der Heijden, Daniëlle A W M van der Windt, Andrea F de Winter

## Abstract

**Objective:** To assess the effectiveness of physiotherapy for patients with soft tissue shoulder disorders.

**Design:** A systematic computerised literature search of Medline and Embase, supplemented with citation tracking, for relevant trials with random allocation published before 1996.

**Subjects:** Patients treated with physiotherapy for disorders of soft tissue of the shoulder.

**Main outcome measures:** Success rates, mobility, pain, functional status.

**Results:** Six of the 20 assessed trials satisfied at least five of eight validity criteria. Assessment of methods was often hampered by insufficient information on various validity criteria, and trials were often flawed by lack of blinding, high proportions of withdrawals from treatment, and high proportions of missing values. Trial sizes were small: only six trials included intervention groups of more than 25 patients. Ultrasound therapy, evaluated in six trials, was not shown to be effective. Four other trials favoured physiotherapy (laser therapy or manipulation), but the validity of their methods was unsatisfactory.

**Conclusions:** There is evidence that ultrasound therapy is ineffective in the treatment of soft tissue shoulder disorders. Due to small trial sizes and unsatisfactory methods, evidence for the effectiveness of other methods of physiotherapy is inconclusive. For all methods of treatment, trials were too heterogeneous with respect to included patients, index and reference treatments, and follow up to merit valid statistical pooling. Future studies should show whether physiotherapy is superior to treatment with drugs, steroid injections, or a wait and see policy.

## Introduction

Pain is the primary symptom in most patients with shoulder disorders affecting the soft tissue. In many patients, painful restriction of the range of shoulder movement limits the ability to perform daily activities. Estimates of the cumulative annual incidence of shoulder disorders vary from 7 to 25 per 1000 general practice consultations.<sup>1-3</sup> Five per cent of all general practice consultations are reported to be related to shoulder disorders.<sup>4,5</sup> Half of all presented episodes resolve within six months, but some last a year or more. Most patients with such disorders are treated in primary care. Their management includes advice, analgesics, non-steroidal anti-inflammatory drugs, steroid injections, and physiotherapy. Evidence from randomised clinical trials on shoulder disorders shows small effects favouring the effectiveness of non-steroidal drugs<sup>6</sup> and steroid injections.<sup>7</sup> A wide array of physiotherapy methods is used to treat shoulder disorders.<sup>8,9</sup>

Patients are often referred for physiotherapy<sup>10,11</sup>; in the Netherlands as many as a third of all patients with

shoulder disorders are referred.<sup>2,3,12</sup> So far, little effort has been invested in establishing the effectiveness of management with physiotherapy. We examined whether certain methods in physiotherapy are effective for patients with soft tissue shoulder disorders by reviewing reports of 20 randomised clinical trials.

## Methods

### Selection of studies

Relevant trial reports were harvested from Medline (*Index Medicus* January 1966 to December 1995) and Embase (*Excerpta Medica* January 1984 to December 1995) according to the computerised search strategy of Dickersin et al.<sup>13</sup> This strategy was supplemented with citation tracking of relevant publications. GH identified trial reports that met the following five conditions: firstly, patients had shoulder pain at inclusion; secondly, treatments were allocated by a random procedure; thirdly, at least one of the treatments included physiotherapy; fourthly, success rate, pain, mobility, or functional status were included as outcome measures; and, finally, results were published as a full report before January 1996. From this selection DW and AW independently selected the trials that included patients with soft tissue shoulder disorders.

### Assessment of methods

To assess trial methods, eight criteria for internal validity were used (box). These criteria are based on generally accepted requirements of methods for design and conduct of intervention research.<sup>14-17</sup> In addition, five data display and extraction criteria (box) were used to provide information on the feasibility of statistical pooling.<sup>18</sup>

We independently analysed the completeness of information from the selected trial reports. For each criterion we logged whether incomplete information had hampered the assessment of methods. If sufficient information was given we judged and logged whether bias was likely or not. For criteria for which consensus could not be reached, the presented results are based on agreement of two reviewers. Subsequently, the trials were ranked according to the number of validity criteria for which bias was considered to be unlikely.

Success rates were determined for each intervention group by dividing the number of documented successes at the end of the intervention period by the number of patients randomly allocated to the intervention (that is, intention to treat analysis). When success rates could not be calculated, we determined change in scores for pain and mobility ratings. Missing values for outcome measures were assumed to represent failures (that is, worst case assumption). Next, to judge the effectiveness of treatments we calculated the differences between groups for outcome measures, with 95% confidence intervals. Finally, to draw conclusions we related these confidence intervals to the number of satisfied validity criteria.

Institute for Rehabilitation Research, PO Box 192, 6430 AD Hoensbroek, Netherlands  
Geert J M G van der Heijden,  
*senior researcher*

Institute for Research in Extramural Medicine, Vrije Universiteit, Amsterdam, Netherlands  
Daniëlle A W M van der Windt,  
*research fellow*  
Andrea F de Winter,  
*research fellow*

Correspondence to:  
Dr van der Heijden.

BMJ 1997;315:25-30

### Validity criteria for assessment of methods of trials

- 1 Enrolment—Restriction to a homogeneous population with respect to prognosis and susceptibility to allocated interventions by explicit selection criteria. Used as prognostic indicators: age, duration of complaint, painful arc, pain at night, number of relapses, radiating pain, previous treatment
- 2 Randomisation—Adequate procedure for generation of random numbers list and concealed allocation of interventions
- 3 Similarity at baseline—Similarity of intervention groups at baseline with respect to prognosis and susceptibility to allocated interventions. Used as prognostic indicators: baseline scores for outcome measures, age, duration of complaint, painful arc, pain at night, number of relapses, radiating pain, previous treatment
- 4 Withdrawals from treatment—No patients withdrew from treatment or number of patients was < 10% in each group, with comparable reasons for withdrawal
- 5 Missing values (for example, loss to follow up)—Number of randomised patients minus number of reported patients at main moment of effect measurement for main outcome measure—if not stated according to reviewers—divided by all randomised patients  $\times 100$  was < 10% in each group
- 6 Cointerventions—Either standardised or excluded in trial design
- 7 Blinded application of interventions—Therapists: blinding by credible placebo. Patients: blinding by credible placebo or by enrolment of patients who were naive to allocated interventions
- 8 Blinded assessment of outcome—Assessor of effect of variables (for example, patient, therapist, physician, or research staff) blinded for allocated interventions

## Results

### Study selection

GH identified 47 trial reports that met the five conditions for further selection. DW and AW excluded 24 trials: seven in which the results of patients who

### Data display and extraction criteria

- 1 Sample size of groups
- 2 Standardisation of allocated interventions—Adequate description of type, method, application of technique, intensity, duration, number, and frequency of sessions for all allocated interventions
- 3 Reported outcome variables—Success rate (for example, proportion of patients cured or improved); pain; functional state (activities of daily living); mobility (range of movement); non-trial cointerventions (for example, drugs or surgery)
- 4 Outcome assessments—Identical timing of assessment for all intervention groups: immediately after last treatment or over three months
- 5 Actual data for outcome variables—An adequate point estimate is presented for each intervention group (with corresponding distribution measure) for success rate or improvement for pain or most important outcome measure on most important moment of effect measurement

received physiotherapy for shoulder disorders were not presented separately, one in which similar physiotherapy was given as a cointervention to all patients, four on exercise therapy after mastectomy, four on physiotherapy for shoulder pain after fracture, seven on physiotherapy for shoulder pain in hemiplegic subjects, and one trial on rheumatoid arthritis. The methods of the remaining 23 trial reports were assessed.<sup>19-41</sup> Information was combined for three trials that were reported twice.<sup>23 33 40</sup> Hence, the systematic review included 20 trials on the effectiveness of physiotherapy for patients with soft tissue shoulder disorders.

### Assessment of methods

Table 1 lists for each trial the validity criteria for which bias was considered likely. This table also presents the validity and data display and extraction criteria for which incomplete information had hampered the assessment of methods. The trials are ranked according to the number of validity criteria that were satisfied. Equally ranked trials are ordered alphabetically.

*Validity criteria*—Eleven of the 20 trials satisfied at least four of the eight validity criteria. One trial satisfied all eight<sup>19</sup>; three other trials satisfied six.<sup>20-22</sup> Three trials seemed to be flawed by a large proportion of withdrawals from treatment<sup>28 31 37</sup>; two trials by a large proportion of missing values<sup>26 37</sup>; nine trials by insufficient blinding of intervention<sup>25 27 28 31 35-39</sup>; and three trials by a insufficient blinding of outcome assessment.<sup>25 30 39</sup> Many reports lacked adequate information on several validity criteria. The randomisation procedure was adequately reported for one trial<sup>19</sup> and prognostic status at baseline for four trials<sup>19 25 28 30</sup>; information on cointerventions was often insufficient.

*Data display and extraction criteria*—In general the sample sizes of the studies were small: six trials compared groups of 25 or more patients<sup>25 26 29 33 35 39</sup> and six trials compared groups of 15 to 25 patients.<sup>21 27 28 30 36 40</sup> All other trials included smaller study populations. Data on outcome measures were poorly reported. Of the 11 trials with acceptable methods,<sup>19-23 25-30</sup> five provided sufficient data for the calculation of 95% confidence intervals.<sup>19 23 25 26 30</sup> Such calculation was possible for six of the nine remaining trials with unsatisfactory methods.

### Characteristics of trials

Table 2 outlines the study population, intervention, follow up, and reported results of the assessed trials. Again, the trials are ordered by the number of fulfilled validity criteria. In nine trials participation was restricted to narrowly defined diagnostic categories (for example, rotator cuff tendinitis),<sup>19 20 22 23 25 26 28 30 33</sup> whereas other trials included a wide variety of soft tissue disorders (for example, painful shoulder, peri-arthritis humeroscapularis). In eight trials, duration of symptoms at baseline was not specified as an entry criterion.<sup>23 27-28 30 35 37 38 40</sup> Another eight trials included patients who, at baseline, had had their symptoms for less than three months,<sup>19 21 22 29 31-33 36</sup> whereas in the four remaining trials duration of symptoms at baseline exceeded three months.

Ultrasound therapy was studied in six trials,<sup>19 23 28 29 38 39</sup> different methods of thermotherapy

in three trials,<sup>37 38 40</sup> and low level laser therapy in four trials.<sup>22 30 32 33</sup> Three trials concerned magnetotherapy,<sup>20 21 26</sup> three concerned manipulations or mobilisations,<sup>27 31 36</sup> two trials involved electrotherapy,<sup>28 35</sup> or cold therapy,<sup>31 39</sup> and one trial evaluated an exercise programme.<sup>25</sup>

Six trials compared various methods of physiotherapy,<sup>26 28 31 35 38 39</sup> nine trials compared physiotherapy with placebo treatment,<sup>19 20-22 25 29 30 32 33</sup> and 10 trials compared physiotherapy with another intervention (mainly analgesics, non-steroidal drugs, and steroid injections).<sup>23 25 27 31 32 37-41</sup> Furthermore, two trials included a control group without any treatment.<sup>21 31</sup> Results from long term follow up (at least two months after randomisation) were available from four trials.<sup>21 25 36 39</sup> Follow up in all other trials was restricted to assessment of outcome directly after completion of treatment, usually three or four weeks after randomisation.

### Effectiveness of treatment

The validity of four of the six trials that studied the effect of ultrasound therapy was acceptable, but none of these trials showed evidence in its favour.<sup>19 23 28 29</sup> Ultrasound therapy was no better than cold therapy and steroid injections,<sup>39</sup> non-steroidal anti-inflammatory drugs and acupuncture,<sup>23</sup> transcutaneous electrical stimulation,<sup>28</sup> and analgesics and iontophoresis.<sup>38</sup> Moreover, ultrasound therapy did not seem to be effective in placebo controlled trials.<sup>19 23 29</sup> The validity of two of the four trials that studied the effectiveness of low level laser therapy was acceptable.<sup>22 30</sup> Saunders could not find significant differences between active and placebo laser.<sup>22</sup> Our calculations of the results of Vecchio et al showed very small differences in favour of active low level laser therapy, though the authors, using different statistical methods, did not find significant differences.<sup>30</sup> The two other trials with unsatisfactory methods reported effects in favour of the short term effectiveness of low level laser therapy compared with placebo<sup>32 33</sup> or with non-steroidal drugs.<sup>32</sup>

Transcutaneous electrical stimulation did not seem to be more effective than ultrasound therapy<sup>28</sup> or than other electrical methods.<sup>35</sup> We could not find any placebo controlled trial on electrotherapy. The two placebo controlled trials on pulsed electromagnetic fields had acceptable validity and reported favourable results for treatment.<sup>20 26</sup> The results of Chard et al, however, were non-significant when they were analysed according to the intention to treat principle.<sup>26</sup> Magnetic treatment seemed to be ineffective when it was compared with no treatment.<sup>21</sup>

Cold therapy was no more effective than ultrasound therapy,<sup>39</sup> steroid injection,<sup>31 39</sup> mobilisations, or no intervention.<sup>31</sup> Different methods of thermotherapy were not more effective than placebo<sup>37 38</sup> or steroid injections and analgesics.<sup>40</sup>

Exercises were as effective as surgery in patients with a stage II impingement syndrome and were more effective than placebo laser therapy.<sup>25</sup> When they were compared to no intervention,<sup>31 36</sup> mobilisations and manipulations did not contribute to recovery nor were they superior to steroid injections<sup>27 31</sup> or cold therapy.<sup>31</sup>

**Table 1** Assessment of methods of trials of physiotherapy for shoulder disorders. Validity criteria for which bias must be considered likely, and validity and data display and extraction criteria for which incomplete information hampered assessment. Numbers refer to points in boxes

First author	Bias considered likely	Incomplete information for validity assessment	Incomplete data display for data extraction
Downing <sup>19</sup>	—	—	—
Binder <sup>20</sup>	—	2,3	5
Leclaire <sup>21</sup>	—	2,3	—
Saunders <sup>22</sup>	—	2,3	3
Berry <sup>23</sup> , Fernandes <sup>24</sup>	—	1,2,3	2
Brox <sup>25</sup>	7,8	2	5
Chard <sup>26</sup>	5	2,3,6	—
Dacre <sup>27</sup>	7	2,3,6	2,5
Herrera-Lasso <sup>28</sup>	4,7	1,2	—
Nykänen <sup>29</sup>	—	1,2,3,4	—
Vecchio <sup>30</sup>	—	1,2,4,5	—
Bulgen <sup>31</sup>	4,7	2,3,6	2,3,5
England <sup>32</sup>	—	1,2,3,4,6	5
Gudmundsen <sup>33</sup> , Hartvig <sup>34</sup>	8	1,2,3,6	—
Knüsel <sup>35</sup>	—	1,2,3,6,7	3,4,5
Thomas <sup>36</sup>	7	1,2,3,6,8	—
Biswas <sup>37</sup>	4,5,7	1,2,3,8	2,3,5
Delacerda <sup>38</sup>	7	1,2,3,4,6,8	3,4,5
Knorre <sup>39</sup>	1,7,8	2,3,4,5,6	5
Lee <sup>40 41</sup>	1,7	2,3,4,5,6,8	3,5

## Discussion

This systematic review, based on the reports of 20 randomised clinical trials, evaluated whether physiotherapy contributes to the extent and speed of recovery for patients with soft tissue shoulder disorders. It used an assessment of methods to minimise bias.

### Trial methods

The validity of the methods of 11 of the 20 assessed trials was satisfactory. One trial reported all the information needed for assessment of validity and data display and extraction.<sup>19</sup> Many trials did not provide sufficient information for at least two validity criteria. This poor reporting might hide flaws; thus it hinders the interpretation of trial results. This lack of information was most prominent for the randomisation procedure, baseline similarity of treatment groups, and cointerventions.

Schulz et al provided empirical evidence of bias for trials with inadequate concealment of treatment and lack of blinding.<sup>42</sup> Lack of prognostic comparability at baseline, withdrawals, and missing data are also related to success of treatment and therefore represent major sources of bias.<sup>43 44</sup>

### Effectiveness of treatment

Deficiencies in the presentation of data often hampered calculation of 95% confidence intervals. When we could calculate confidence intervals they were wide and included zero, even when trials had acceptable methods.<sup>19 23 26</sup>

Few of the assessed trials favoured the effectiveness of physiotherapy. The type of control treatment seemed unrelated to the study results. Because there were many small trials with negative results, statistical pooling of the results of trials with acceptable methods would have been useful. However, we considered that the few valid trials on the same methods of

**Table 2** Summary of treatments compared and results of trials of physiotherapy for shoulder disorders

First author	Treatments	Follow up	Result (No in group)	% Difference (95%CI)
Downing <sup>19</sup>	Continuous ultrasound Placebo ultrasound All received home exercises	No recovered at 4 weeks	7 (11) 4 (9)	20 (-23 to 63)
Binder <sup>20</sup>	Pulsed electromagnetic fields Placebo pulsed electromagnetic fields	No recovered at 4 weeks	* (15) * (14)	Significant differences Pulsed electromagnetic fields > placebo
Leclaire <sup>21</sup>	Magnetotherapy Placebo magnetotherapy All received heat and exercise	Mean (SD) pain (scale 0-4) at 12 weeks	1.5 (0.6); (22) 1.4 (0.7); (25)	No significant differences
Saunders <sup>22</sup>	Low level laser Placebo laser	Pain at 12 weeks	* (12) * (12)	No significant differences
Berry <sup>23</sup>	Ultrasound Tolmetin sodium and steroid injection Placebo tolmetin and steroid injection Placebo tolmetin and placebo ultrasound Acupuncture	No recovered at 4 weeks	6 (12) 5 (12) 6 (12) 9 (12) 5 (12)	8 (-32 to 48) v ultrasound 0 (-40 to 40) v ultrasound -25 (-62 to 12) v ultrasound 8 (-32 to 48) v ultrasound
Brox <sup>25</sup>	Exercises Placebo laser Arthroscopic resection of bursa and acromion	Median pain at 3 months; 6 months	15 (50); 25 (50) 15 (30); 15 (30) 25 (45); 25 (45)	-13 (-20 to -7) v exercises -5 (-10 to 0); -5 (-10 to 0) v exercises
Chard <sup>26</sup>	Pulsed electromagnetic fields 8 hours/day Pulsed electromagnetic fields 2 hours/day	No recovered at 4 weeks; 8 weeks	12 (25); 13 (25) 14 (25); 17 (25)	-8 (-36 to 20); -16 (-43 to 11)
Dacre <sup>27</sup>	Mobilisation Steroid injection Mobilisation and steroid injection	Pain at 3 months	* (20) * (22) * (20)	No significant differences
Herrera-Lasso <sup>28</sup>	Ultrasound Transcutaneous electrical stimulation All received heat and exercise	Pain at 6 weeks	* (15) * (15)	No significant differences
Nykänen <sup>29</sup>	Pulsed ultrasound Placebo ultrasound	Mean (SD) pain (scale 1-5) at 4 weeks	2.5 (0.7); (35) 2.4 (0.9); (37)	No significant differences
Vecchio <sup>30</sup>	Ga-As-Al laser Placebo laser All received exercises	Mean (SD) pain at 8 weeks	3.6 (0.9); (19) 1.8 (1.2); (16)	1.8 (1.1 to 2.5)
Bulgen <sup>31</sup>	Maitland mobilisations Ice packs; proprioceptive neuromuscular facilitation exercises Steroid injection No treatment All received medication and pendular exercises	Pain at 3 months	* (11) * (12) * (11) * (8)	No significant differences
England <sup>32</sup>	Infrared laser Placebo laser Naproxen tablets	Median pain reduction at 2 weeks	* (10) * (10) * (10)	2.5 (2 to 3) v laser 2 (1 to 3.5) v laser
Gudmundsen <sup>33</sup>	Ga-As laser Placebo laser	No recovered at 1 month	42 (47) 18 (44)	48 (31 to 65)
Knüsel <sup>35</sup>	Transcutaneous electrical stimulation constant current Constant voltage electrotherapy	No recovered at 3 weeks	19 (30) 21 (30)	7 (-15 to 29)
Thomas <sup>36</sup>	Forced manipulation No manipulation All received hydrocortisone injection	No recovered at 3 months	12 (15) 7 (15)	33 (1 to 65)
Biwas <sup>37</sup>	Diathermy Hydrocortisone injection Aspirin All received exercises	No recovered at 3 months	8 (17+n) 9 (18+n) 7 (12+n)	Size of group after randomisation unclear; 47 of 120 randomised patients reported
Delacerda <sup>38</sup>	Continuous ultrasound and thermotherapy Dexamethasone iontophoresis Analgesics and muscle relaxants	No recovered at 4 weeks	6 (8) 8 (8) 4 (7)	25 (-5 to 35) v ultrasound 18 (-29 to 65) v ultrasound 43 (6 to 80) v iontophoresis 2
Knorre <sup>39</sup>	Ultrasound Ice Triamcinolone injection	No recovered at 2 weeks; 12 weeks	14 (30); 15 (30) 15 (30); 15 (30) 12 (30); 11 (30)	10 (-15 to 35) v ultrasound 3 (-22 to 28) v ultrasound
Lee <sup>40</sup>	Infrared heat; exercises Hydrocortisone intra-articular injection; exercises Hydrocortisone tendon injection; exercises Analgesics	Pain at 6 weeks	* (17) * (15) * (18) * (15)	No significant differences

\*Data displayed graphically, no actual data presented.

treatment (for example, ultrasound therapy or low level laser therapy) were too heterogeneous with respect to administration (for example, intensity, duration, and frequency of administration), the compared treatment (for example, placebo, no treatment, or alternative control treatment), the selection of study populations (for example, regarding specific soft tissue disorders or symptom duration at baseline), and follow up (for example, timing of outcome assessment and choice of outcome measures) to merit statistical pooling.

Given the adequate methods of placebo controlled trials on ultrasound therapy, this method does not seem to be effective in treating patients with shoulder disorders. One placebo controlled trial with adequate methods reported superior effectiveness of pulsed electromagnetic fields. All other trials that reported significant results were small and had unsatisfactory methods. Thus there is insufficient evidence to draw conclusions on the effectiveness of low level laser therapy, heat treatment, cold therapy, electrotherapy, exercise, and mobilisations.



## Key messages

- Because of the small sample sizes and unsatisfactory methods of most trials, only a few randomised clinical trials of methods of physiotherapy in patients with soft tissue shoulder disorders allow firm conclusions on effectiveness of treatment
- When compared with placebo or another treatment, ultrasound therapy seems ineffective in patients with shoulder disorders
- Evidence is insufficient to support the effectiveness of low level laser therapy, heat treatment, cold therapy, electrotherapy, exercise, and mobilisation in such patients
- Future trials should focus on the effectiveness of exercise and mobilisation in comparison to analgesics, non-steroidal drugs, steroid injections, and advice and a wait and see policy
- Special attention should also be given to the principles of adequate design and conduct of trials and the standards of reporting

The purpose of treating patients with shoulder disorders is to increase the extent and speed of recovery. As ultrasound therapy is not effective, any further application in patients with shoulder disorders should be discouraged. This can be done by updating treatment guidelines or by withholding reimbursement for its use.

Future trials should show whether other methods of physiotherapy for shoulder disorders are effective. This should be particularly interesting for exercise and mobilisations, which have rarely been subjected to scientific scrutiny in randomised clinical trials despite being commonly used in patients with shoulder disorders. Priority should be given to a comparison of exercise and mobilisations with analgesics and advice and a wait and see policy. As there are some indications for their effectiveness, steroid injections and non-steroidal drugs are other relevant comparative treatments. During the design and execution of future trials specific attention should be given to the control of prevalent flaws, such as many withdrawals, many missing results, and a lack of blinding during treatment and assessment of outcome. Standards of reporting trials should prevent confusion about the validity of trial methods and ensure adequate data analysis and presentation of pertinent data.<sup>16 45</sup>

We thank Pieter Leffers and Paul Knipschild (department of epidemiology, Maastricht University, Netherlands) and Lex Bouter (Institute for Research in Extramural Medicine, Vrije Universiteit, Amsterdam, Netherlands) for their comments on the draft of this paper.

Funding: No external funding.

Conflict of interest: None.

- 1 Croft P. Soft-tissue rheumatism. In: Silman AJ, Hochberg MC, eds. *Epidemiology of the rheumatic diseases*. Oxford: Oxford University Press; 1993:375-421.
- 2 Van der Windt DAWM, Koes BW, De Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. *Ann Rheum Dis* 1995;54:959-64.
- 3 Lamberts H, Brouwer HJ, Mohrs J. *Reason for encounter-, episode- and process-oriented standard output from Transition project. Part I*. Amsterdam:

Department of General Practice/Family Medicine, University of Amsterdam: 1991.

- 4 Peters D, Davies P, Pietroni P. Musculoskeletal clinic in general practice: study of 1 year referrals. *Br J Gen Pract* 1994;44:25-9.
- 5 Grundemeijer HGLM, Brouwer HJ. De betekenis van fysiotherapie bij aandoeningen aan het bewegingsapparaat. *Huisarts Wetenschap* 1988;suppl 12:44-59.
- 6 Van der Windt DAWM, Van der Heijden GJMG, Scholten RJPM, Koes BW, Bouter LM. The efficacy of non-steroidal anti-inflammatory drugs (NSAIDs) for shoulder complaints. A systematic review. *J Clin Epidemiol* 1995;48:691-704.
- 7 Van der Heijden GJMG, Van der Windt DAWM, Kleijnen J, Koes BW, Bouter LM, Knipschild PG. Steroid injections for shoulder disorders. A systematic review of randomized clinical trials. *Br J Gen Pract* 1996;46:309-16.
- 8 Nitz AJ. Physical therapy management of the shoulder. *Phys Ther* 1986;66:1912-9.
- 9 Rey B, Gerber NJ. Shoulder pain trials. In: Schlapbach P, Gerber NJ, eds. *Physiotherapy: controlled trials and facts*. Rheumatology. Basel: Karger, 1991:91-8.
- 10 Dekker J, Van Baar M, Curfs EC, Kerssens JJ. Diagnosis and treatment in physical therapy: an investigation of their relationship. *Phys Ther* 1993;73:577-80.
- 11 Gentle PH, Herlihy PJ, Roxburgh IO. Controlled trial of open-access physiotherapy service. *Br J Gen Pract* 1994;34:371-6.
- 12 Miedema HS. *Reuma-onderzoek meerdere echelons (ROME): basisrapport*. Leiden: Nederlands Instituut voor Praeventieve Gezondheidszorg TNO, 1994.
- 13 Dickersin K, Scherer R, Lefebvre C. Identifying relevant studies for systematic reviews. *BMJ* 1994;309:1286-91.
- 14 Moher D, Jadad AR, Nichol G, Penman M, Tugwell P, Walsh S. Assessing the quality of randomized controlled trials: an annotated bibliography of scales and checklists. *Control Clin Trials* 1995;16:62-73.
- 15 Cho MK, Bero LA. Instruments for assessing the quality of drug studies published in the medical literature. *JAMA* 1994;272:101-4.
- 16 Standards of Reporting Trials Group. A proposal for structures reporting of randomized controlled trials. *JAMA* 1994;272:1926-31 (erratum: *JAMA* 1995;273:776).
- 17 Chalmers TC, Smith H, Blackburn B, Silverman B, Schroeder B, Reitman D, et al. A method for assessing the quality of a randomized control trial. *Control Clin Trials* 1981;2:31-49.
- 18 Eysenck HJ. Meta-analysis and its problems. *BMJ* 1994;309:789-92.
- 19 Downing DS, Weinstein A. Ultrasound therapy of subacromial bursitis. A double blind trial. *Phys Ther* 1986;66:194-9.
- 20 Binder A, Parr G, Hazleman B, Fitten-Jackson S. Pulsed electromagnetic field therapy of persistent rotator cuff tendinitis. A double blind controlled assessment. *Lancet* 1984;i:695-8.
- 21 Leclaire R, Bourgouin J. Electromagnetic treatment of shoulder periarthritis. A randomized controlled trial of the efficiency and tolerance of magnetotherapy. *Arch Phys Med Rehabil* 1991;72:284-7.
- 22 Saunders L. The efficacy of low-level laser therapy in supraspinatus tendinitis. *Clin Rehabil* 1995;9:126-34.
- 23 Berry H, Fernandes L, Bloom B, Clark RJ, Hamilton EB. Clinical study comparing acupuncture, physiotherapy, injection and oral anti-inflammatory therapy in shoulder-cuff lesions. *Curr Med Res Opin* 1980;7:121-6.
- 24 Fernandes L, Berry H, Clark RJ, Bloom B, Hamilton EB. Clinical study comparing acupuncture, physiotherapy, injection and oral anti-inflammatory therapy in shoulder-cuff lesions. *Lancet* 1980;i:208-9.
- 25 Brox JI, Staff PH, Ljunggren AE, Brevik JL. Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage II impingement syndrome). *BMJ* 1993;307:899-903.
- 26 Chard MD, Hazleman BL, Devereux MD. Controlled trial to investigate dose-response patterns to portable pulsed electromagnetic fields in the treatment of rotator cuff tendinitis. A review trial. *J Orthop Rheumatol* 1988;1:33-40.
- 27 Dacre JE, Beeny N, Scott DL. Injections and physiotherapy for the painful stiff shoulder. *Ann Rheum Dis* 1989;48:322-5.
- 28 Herrera-Lasso I, Mobarak L, Fernández-Domínguez L, Cardiel MH, Alarcón-Segovia D. Comparative effectiveness of packages of treatment including ultrasound or transcutaneous electrical nerve stimulation in painful shoulder syndrome. *Physiotherapy* 1993;79:251-3.
- 29 Nykänen M. Pulsed ultrasound treatment of the painful shoulder. A randomized, double-blind, placebo-controlled trial. *Scand J Rehabil Med* 1995;27:105-8.
- 30 Vecchio P, Cave C, King V, Adebajo AO, Smith M, Hazleman BL. A double-blind study of the effectiveness of low level laser treatment of rotator cuff tendonitis. *Br J Rheumatol* 1993;32:740-2.
- 31 Bulgen DY, Binder AI, Hazleman BL, Dutton J, Roberts S. Frozen shoulder: prospective clinical study with an evaluation of three treatment regimens. *Ann Rheum Dis* 1984;43:353-60.
- 32 England S, Farrell AJ, Coppock JS, Sthruethers G, Bacon PA. Low power laser therapy of shoulder tendonitis. *Scand J Rheumatol* 1989;18:427-31.
- 33 Gudmundsen J, Vikne J. Laser treatment for epicondylitis humeri and rotator cuff syndrome. *Nord Tidsskr Idrettsmed* 1987;2:6-15.
- 34 Hartvig P, Vikne J, Gudmundsen J. Does laser treatment help in tendinitis. *Tidsskr Nor Laegeforen* 1989;109:2184.
- 35 Knüsel O. Die transcutane elektrische Nervenstimulation beim Weichteilrheumatismus—Eine kontrollierte untersucherblinde Studie an 60 Patienten mit Levator-Scapulae-Syndrom. *Z Physikalische Med Balneol Med Klimatol* 1984;13:337-9.
- 36 Thomas D, Williams RA, Smith DS. The frozen shoulder: a review of manipulative treatment. *Rheumatol Rehab* 1980;19:173-9.
- 37 Biswas AK, Sur BN, Gupta CR. Treatment of periarthritis shoulder. *J Indian Med Assoc* 1979;72:276-7.

- 38 Delacerda FG. A comparative study of three methods of treatment for shoulder girdle myofascial syndrome. *J Orthop Sports Phys Ther* 1982;4:51-4.
- 39 Knorre B, Keitel W. Vergleichende Therapiestudie: Ultraschall, Kryotherapie und intraartikuläre Kortisonoide bei Veränderungen des Schultergelenkes aus entzündlicher Ursach. *Z Physiother* 1990;42:221-5.
- 40 Lee PN, Lee M, Haq AMMM, Longton EB, Wright V. Periarthritis of the shoulder. Trial of treatments investigated by multivariate analysis. *Ann Rheum Dis* 1974;33:116-9.
- 41 Lee PN, Haq AMMM, Wright V, Longton EB. Periarthritis of the shoulder: a controlled trial of physiotherapy. *Physiotherapy* 1973;59:312-5.
- 42 Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;273:408-12.
- 43 Altman DG, Doré CJ. Randomisation and baseline comparisons in clinical trials. *Lancet* 1990;335:149-53.
- 44 Ederer F. Patient bias, investigator bias and the double-masked procedure in clinical trials. *Am J Med* 1975;58:295-9.
- 45 Altman DG. Better reporting of randomised controlled trials: the CONSORT statement. *BMJ* 1996;313:570-1.

(Accepted 15 April 1997)

## Prevalence of HIV and injecting drug use in men entering Liverpool prison

Mark A Bellis, Andrew R Weild, Nick J Beeching, Ken J Mutton, Qutub Syed

See pp 18, 21, 61, 65

Sexual Health and Environmental Epidemiology Unit, Department of Public Health, University of Liverpool, Liverpool L69 3GB

Mark A Bellis, senior lecturer  
Andrew R Weild, research associate

Liverpool School of Tropical Medicine, Liverpool L3 5QA

Nick J Beeching, senior lecturer

Liverpool Public Health Laboratory, Liverpool L9 7AL

Ken J Mutton, consultant virologist

Communicable Disease Surveillance Centre (North West), Public Health Laboratory, Liverpool L9 7AL  
Qutub Syed, regional epidemiologist

Correspondence to: Dr Bellis (m.a.bellis@liv.ac.uk).

BMJ 1997;315:30-1

Studies in countries other than England and Wales suggest that a comparatively high proportion of people entering prison have a history of injecting drug use before imprisonment and that drug use does not always stop once people are incarcerated.<sup>1</sup> Consequently the sharing of injecting equipment by drug users in a Scottish prison led to the infection of at least 13 inmates with HIV.<sup>2</sup> Currently, little information is available on the number of drug users entering prisons in England and Wales, their HIV prevalence, or their levels of injecting drug use once incarcerated. Therefore, discussion about the potential for injecting related HIV transmission within these prisons often requires extrapolation from data gathered in other countries.<sup>3</sup> To examine the potential role of English prisons in drug related transmission of HIV and other bloodborne viruses we administered questionnaires to new prisoners at a large men's prison and tested them for HIV antibodies.

### Subjects, methods, and results

We defined new prisoners as men arriving at prison for the first occasion relating to their current remand (that is, awaiting trial or sentencing) or sentence. Over 10 weeks in early 1996, 969 such prisoners at reception to HM prison, Liverpool, were asked to complete a short, anonymous questionnaire on their drug related and sexual behaviour and provide a saliva sample.<sup>4</sup> Though participation was voluntary, compliance was high—921 (95.0%) subjects completed all or part of the questionnaire and 905 (93.4%) provided a matched saliva sample, of which one tested positive. Most participants (881/906; 97.2%) originated within the British Isles, and ages ranged from 21 to 70 years (median 28), 63.2% (577/913) of subjects being aged 30 or under. Prisoners on remand accounted for 43.2% (396/916) of the sample. Previously 47.2% (416/882) of subjects had been incarcerated before the age of 21 and 66.8% (588/880) had been in an adult prison.

### Comment

Of 219 subjects with a history of injecting drugs and incarceration, only 36 (16.4%; table 1) had ever injected in prison. Though this suggests that imprisonment

reduces injecting behaviour, for those who continue to inject while incarcerated levels of risk behaviour are substantially increased. Thus the prevalence of ever sharing injecting equipment rose from 31.5% (82/260) among all new arrivals with a history of injecting to 55.6% (20/36) sharing when injecting while incarcerated ( $\chi^2 = 8.08$ ;  $P < 0.005$ ). Furthermore, men who had ever injected as well as current injectors (that is, those who had injected in the past month) were disproportionately represented among those returning for second (26.0% ever, 19.7% current) or further sentences (42.0% ever, 29.9% current). Consequently, incarceration may reduce the numbers of subjects injecting drugs but only at the cost of increasing the risks of infection among those who inject while imprisoned and without necessarily preventing relapse into injecting on release.

Of roughly 7000 men received into HM prison, Liverpool, every year, over a quarter (table 1) may previously have injected drugs. In this survey only one such subject was HIV positive (an injecting drug user currently unaware of his infection), reflecting low levels of HIV in the local injecting communities.<sup>5</sup> However, the frequent exchange of subjects between such communities and the prison population means that drug use in prison cannot be taken in isolation. Indeed, prisons represent a valuable opportunity to educate drug users, familiarising them with safe injecting practice and the range of health services (community drugs teams, syringe exchange schemes) available, if not when incarcerated then certainly on release. Alternatively, if levels of HIV or other bloodborne viruses increase outside prison the high levels of sharing that occur when drugs are injected in prison may multiply

**Table 1** Summary of injecting drug use behaviour by new arrivals at HM prison, Liverpool. Figures are numbers (percentages) of subjects

Injecting drug use behaviour	Yes
Ever injected drugs	260/911 (28.5)
Shared injecting equipment	82/260 (31.5)
Injected recently (in past month)	177/260 (68.1)
Injected in prison	36/219†(16.4)
Shared injecting equipment in prison	20/36 (55.6)
First injected in prison	8/36 (22.2)

†219 represents injectors who had previous spells in prison.

numbers of infections and redistribute these among different drug using groups when inmates are released.

We are grateful for the support of Cathy James, Mike Jenkins, Norman Tucker, and Robert Lyons from Liverpool prison and to the Home Office for permitting this study, the prison inmates for participating, and Sheila Gore and Graham Bird for advice.

Funding: North West Regional Health Authority.

Conflict of interest: None.

- 1 Ford BT, Derrickson J. AIDS in prison: a review of epidemiology and preventive policy. *AIDS* 1992;6:623-8.
- 2 Yirrell DL, Robertson P, Goldberg DJ, McMenamin J, Cameron S, Leigh Brown AJ. Molecular investigation into outbreak of HIV in a Scottish prison. *BMJ* 1997;314:1446-50.
- 3 Curtis SP, Edwards A. HIV in UK prisons: a review of seroprevalence, transmission and patterns of risk. *Int J STD AIDS* 1995;6:387-91.
- 4 Johnson AM, Parry JV, Best SJ, Smith AM, DeSilva M, Mortimer P. HIV surveillance by testing saliva. *AIDS* 1988;2:369-71.
- 5 Morrison CL, Ruben SM. The development of healthcare services for drug misusers and prostitutes. *Postgrad Med J* 1995;71:593-7.

(Accepted 21 May 1997)

## Drug points

### Severe hypotension associated with netilmicin treatment

T Rygnestad, Department of Anaesthesiology, Regional and University Hospital, Trondheim, Norway

Cardiovascular side effects from aminoglycosides are rarely reported,<sup>1</sup> which might be the result of under-reporting. I report a case of severe hypotension associated with netilmicin treatment in a critically ill patient.

A 50 year old woman with pharyngeal cancer had an emergency tracheotomy. At operation she had no other known disease. She developed pneumonia and was artificially ventilated. *Streptococcus milleri* was found in cultures from the operation wound. She was given netilmicin 140 mg twice daily and metronidazole 500 mg and cefuroxime 1.5 g three times daily.

From the third postoperative day she had short hypotensive episodes lasting 5-10 minutes. Her systolic blood pressure measured in an intra-arterial line fell from 110-120 mm Hg to 60-80 mm Hg, which was accompanied by a fall in peripheral oxygen saturation on pulse oximetry of about 5-8%. However, she did not develop reflex tachycardia or show electrocardiographic changes or changes in central venous pressure. Vascular resistance was not measured. Her cardiovascular condition deteriorated and an infusion of dopamine (8 µg/kg/minute) was started to increase cardiac contractility. The hypotensive episodes

came immediately after the slow injection of netilmicin was started and lasted until about five minutes after it had finished. The same was observed when the regimen was changed to netilmicin 350 mg once daily, when the netilmicin was given as a slow intravenous infusion, and when it was given intravenously as three equal doses 10 minutes apart.

The antibiotic regimen was continued because the episodes were short and diuresis was adequate. Creatinine clearance was normal and stable. Netilmicin concentrations were within the recommended range. From the 14th postoperative day sedation was stopped. She no longer needed dopamine and the hypotensive episodes almost disappeared. She gradually recovered and had normal kidney function one week after discharge from intensive care.

This patient developed side effects when she was critically ill. In critically ill patients—for example, those with sepsis—many factors might cause hypotension. Side effects of netilmicin treatment might act in addition to factors such as septicaemia and heavy sedation. The lack of reflex tachycardia suggests a direct cardiodepressive effect. A direct vascular effect cannot be ruled out.

- 1 Keller H, Maurer P, Blaser J, Follath F. Miscellaneous antibiotics. In: Dukes MNG, ed. *Meyler's side effects of drugs*. 12th ed. Amsterdam: Elsevier, 1992: 637-71.

### Simvastatin and impotence

G Jackson, Cardiac Department, Guy's Hospital, London SE1 9RT

The benefits of lowering raised cholesterol concentrations are established in patients with documented coronary artery disease and those at high risk.<sup>1,2</sup> Inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase (statins) are highly effective agents with few reported adverse effects. However, as their use becomes more common, adverse effects may be increasingly recognised. Impotence, rarely volunteered or asked about, is an important adverse effect of drugs and not currently associated with simvastatin.

Five men with coronary artery disease developed impotence within one week of starting treatment with simvastatin 10 mg or having the dose increased to 20 mg (three men); they also had profound lethargy and inertia. Drug treatment for heart disease (aspirin alone in two patients) was not changed. Within one week of stopping simvastatin sexual function was restored. Two patients were rechallenged with simvastatin and impotence recurred and was resolved within a week. Alternative lipid lowering drugs (fluvastatin in four patients and fenofibrate in one) maintained similar degrees of reduction in cholesterol concentration and no sexual difficulties over 12-36 months of follow up.

Adverse effects on sexual function are not reported in the major trials of simvastatin or in the drug's data sheets.

The Australian Adverse Drug Reactions Committee has reported 42 cases of impotence associated with simvastatin, the onset being from 48 hours to 27 months after starting treatment.<sup>3</sup> Simvastatin was the only drug implicated in 35 cases, with four developing impotence on rechallenge.

Simvastatin may affect the central nervous system directly by passing through the blood-brain barrier or it may interact with other agents that might cause impotence. However, two of these five patients and 35 in Australia were not receiving any other drugs, which suggests an effect on the central nervous system.

Adverse effects on sexual function due to simvastatin are infrequent and should not detract from the strong evidence of the drug's effectiveness in reducing cardiac events. However, as the use of statins increases such individual problems may arise, and early recognition may lead to their alleviation. Furthermore, the benefits of lowering lipid concentrations can be maintained with alternative agents that may avoid impotence.

- 1 Scandinavian Simvastatin Study Group. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). *Lancet* 1994;344:1383-9.
- 2 Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, MacFarlane PW, et al, for the West of Scotland Coronary Prevention Study Group. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. *N Engl J Med* 1995;333:1301-7.
- 3 Boyd IW. Comment: HMG-CoA reductase inhibitor-induced impotence. *Ann Pharmacother* 1996;30:1199.