Funding: Dutch Ministry of Health, Welfare, and Sports and Health Care Information Centre (SIG).

Conflict of interest: None.

- 1 Aaron H, Schwartz WB. Rationing health care: the choice before us. *Science* 1990;247:418-22.
- 2 Lubitz J, Beebe J, Baker C. Longevity and Medicare expenditures. *N Engl J Med* 1995;332:999-1003.
- 3 Executive NHS. *Burdens of disease: a discussion document*. London: Department of Health, 1996.
- 4 Australian Institute of Health and Welfare. *Australia's health 1996*. Canberra: AIHW, 1996. Also on: http://www.aihw.gov.au/publications/h_online/ah96/index.html, 1996.
- 5 Moore R, Mao Y, Zhang J, Clarke K. *Economic burden of illness in Canada, 1993*. Ottawa: Minister of Public Works and Government Services, 1997.
- 6 Ministry of Health. *Annual overview of health care, 1997*. The Hague: SDU, 1996.
- 7 World Health Organisation. *International Classification of Diseases*. 9th ed. Geneva: WHO, 1977.
- 8 Polder JJ, Meerding WJ, Koopmanschap MA, Bonneux L, van der Maas PJ. *Costs of diseases in the Netherlands, 1994*. Rotterdam: Erasmus University,

Department of Public Health, Institute of Medical Technology Assessment, 1997.

- 9 Lindgren B. The economic impact of illness. In: Abshagen U, Munnich FE, eds. *Cost of illness and benefits of drug treatment*. Munich: Zuckschwerdt Verlag, 1990:12-20.
- 10 Koopmanschap MA, van Roijen L, Bonneux L. *Costs of diseases in the Netherlands, 1988*. Rotterdam: Erasmus University, Department of Public Health, Institute of Medical Technology Assessment, 1991.
- 11 Koopmanschap MA, van Roijen L, Bonneux L, Bonsel GJ, Rutten FFH, van der Maas PJ. Costs of diseases in an international perspective. *Eur J Public Health* 1994;4:258-64.
- 12 Groenenboom GKC, Huijsman R. *Elderly care in economic perspective: cost scenarios*. Utrecht: De Tijdstroom Steering Committee on Future Health Scenarios, 1995.
- 13 Murray CJL, Lopez AD. Global and regional descriptive epidemiology of disability. In: Murray CJL, Lopez AD, eds. *The global burden of disease and injury series*. Harvard: Harvard University Press, 1996:201-46.
- 14 Murray CJL, Lopez AD. Global mortality, disability and the contribution of risk factors. The global burden of disease study. *Lancet* 1997;349:1436-42.

(Accepted 19 February 1998)

Poverty, unemployment, and common mental disorders: population based cohort study

Scott Weich, Glyn Lewis

Abstract

Objective: To determine whether poverty and unemployment increase the likelihood of or delay recovery from common mental disorders, and whether these associations could be explained by subjective financial strain.

Design: Prospective cohort study.

Setting: England, Wales, and Scotland.

Subjects: 7726 adults aged 16-75 living in private households.

Main outcome measures: Common mental disorders were assessed using the general health questionnaire, a self assessed measure of psychiatric morbidity.

Results: Poverty and unemployment (odds ratio 1.86, 95% confidence interval 1.18 to 2.94) were associated with the maintenance but not onset of episodes of common mental disorders. Associations between poverty and employment and maintenance of common mental disorders, however, were much smaller than those of cross sectional studies. Financial strain at baseline was independently associated with both onset (1.57, 1.19 to 2.07) and maintenance (1.86, 1.36 to 2.53) even after adjusting for objective indices of standard of living.

Conclusions: Poverty and unemployment increased the duration of episodes of common mental disorders but not the likelihood of their onset. Financial strain was a better predictor of future psychiatric morbidity than either of these more objective risk factors though the nature of this risk factor and its relation with poverty and unemployment remain unclear.

Introduction

Symptoms of anxiety and depression are common, co-occur frequently, and are continuously distributed in the general population.^{1 2} At the top end of this distribution are disorders recognised by psychiatrists, with

an estimated community prevalence of about 15%.¹⁻³ These common mental disorders¹ account for one third of days lost from work due to ill health⁴ and one fifth of consultations in general practice in the United Kingdom.⁵ Those affected have increased mortality rates^{6 7} and clinically significant impairments in physical and social functioning.⁸

Common mental disorders are most prevalent among those with a poor standard of living,^{1-3 9 10} independent of occupational social class.^{9 11} Longitudinal findings, however, have been inconsistent. Despite reports of associations between low income,¹² few possessions,¹³ and onset of common mental disorders these risk factors have been more consistently associated with longer episodes.¹³⁻¹⁵ Unemployment is also associated with the prevalence,^{1 2 9 16 17} incidence,^{16 17} and maintenance¹⁶ of common mental disorders. Recent evidence suggests that the effects of unemployment and poverty on mental health may be mediated or modified by financial strain,^{9 18} although this has never been evaluated prospectively.

Over 12 months we investigated whether poverty and unemployment increased the likelihood of onset of or delayed recovery from episodes of common mental disorders, and tested whether these associations could be explained by greater subjective financial strain in people who are poor or unemployed.

Subjects and methods

Data were collected for the British household panel survey, an annual survey of individuals in private households in England, Wales, and Scotland. The design and primary aims of this survey have been described elsewhere.^{11 19} Only subjects who completed psychiatric assessments at two sets of interviews were included. The first set of interviews took place in 1991 (T1) and the second set (T2) 12 months later. The survey investigators complied with the ethical guidelines

University
Department of
Psychiatry, Royal
Free Hospital
School of Medicine,
London NW3 2PG
Scott Weich,
senior lecturer

Division of
Psychological
Medicine,
University of Wales
College of
Medicine, Cardiff
CF4 4XN
Glyn Lewis,
professor

Correspondence to:
Dr Weich
scott@rffsm.ac.uk

BMJ 1998;317:115-9

of the Social Research Association.¹⁹ Specific ethical approval was not sought for this secondary analysis, which was based on anonymous data supplied from the data archive of the Economic and Social Research Council in accordance with its regulations.

Common mental disorders were assessed with the general health questionnaire, comprising 12 items.²⁰ We followed previous studies in treating common mental disorders as a single dimension.^{3 21} The questionnaire was scored in two ways: by designating each item as absent or present (0 or 1) according to the method of the general health questionnaire²⁰; and according to severity (range 0 to 3) (the Likert method). Those scoring 3 or more (out of 12) by the general health questionnaire method were classified as cases.²⁰ Likert scores (range 0 to 36) more closely approximated a normal distribution and were used when the general health questionnaire score was treated as a continuous outcome.

To overcome likely colinearity between indices of standard of living, a poverty score comprising seven items was generated from variables previously judged to provide a comprehensive yet frugal assessment of each subject's standard of living.¹¹ One point was scored for each of the following: (a) annual household income (adjusted for household size and composition¹⁹) in the bottom fifth for region of residence (since the cost of living was expected to differ between regions); (b) no household access to car or van, (c) not saving from income (excluding money put by for bills but including life insurance, personal equity plans, share purchases, and holidays); (d) fewer than four domestic household appliances from a list of nine; (e) living in rented accommodation; (f) overcrowded accommodation (more than two household members per bedroom); and, (g) a home with two minor or any major structural problems such as dry rot. Where income sources could not be verified by documentary evidence missing data were imputed by the British household panel survey investigators¹⁹ using methods that minimised any tendency to overpredict associations with income.^{11 19} Items contributing to the poverty score were not weighted, given the absence of any rationale or method for doing so. Furthermore, cross sectional findings at T1 indicate that individual associations with the prevalence of common mental disorders differed little between items.¹¹

Subjective financial strain at T1 was assessed by asking: "How well would you say you are managing financially these days?", responses to which were coded as: (a) living comfortably or doing alright; (b) just about getting by; or, (c) finding it difficult or very difficult.

Potential confounding variables selected from the dataset of the British household panel survey were registrar general's social class by head of household based on current or most recent occupation,^{11 19} plus marital status, education, employment, ethnic group, household size, responsibility for dependent children under the age of 16, number of current physical health problems, and region of residence.

Statistical methods

Data were analysed in two ways. Firstly, the sample was stratified by case status at T1 and separate analyses were carried out for onset (proportion of non-cases at T1 who were cases at T2) and maintenance

(proportion of cases at T1 who were also cases at T2) of common mental disorders. Secondly, to evaluate the effects of exposures at T1 on change in psychiatric morbidity between sets of interviews without imposing an arbitrary case threshold, the general health questionnaire score at T2 was treated as a continuous outcome and adjusted for the general health questionnaire score at T1.

Univariate differences were tested using non-parametric χ^2 and Kruskal-Wallis tests as appropriate. Unadjusted and adjusted odds ratios and likelihood ratio χ^2 tests to assess confounding, effect modification, and departure from linear trends were calculated by means of logistic regression using statistical software (Release 4.0, Stata, TX). Regression analyses were conducted using the Huber-White sandwich estimator to control for the clustering of respondents within households.²²

Results

Overall, 5511 (73.6%) of enumerated private households participated at T1 comprising 10 264 individuals aged 16 and over. The general health questionnaire was completed by 9064 individuals (94.3% of those interviewed) aged 16-75 at T1, of whom 7726 (85.2%) were re-interviewed at T2. The prevalence of common mental disorders was 24.6% (95% confidence interval 23.7% to 25.5%) at T1 and 26.3% (25.3% to 27.3%) at T2. The rate of onset of a mental disorder was 17.5% (16.5% to 18.4%) and the rate of maintenance was 54.2% (51.9% to 56.5%). Spearman's rank order correlation coefficient for the general health questionnaire scores at T1 and T2 was +0.51 ($P < 0.0001$). Of the cases at T2, 1011 (49.7%) were also cases at T1. Poverty scores were skewed to the right at T1 with 6571 (72.5%) of subjects scoring ≤ 2 .

Non-participation was associated with low socioeconomic status at both sets of interviews. Compared with the 1% sample of anonymised records from the 1991 census, those living in very large households and in households with no access to a car or van were underrepresented at baseline to a statistically significant degree.¹⁹ Loss to follow up was associated with a higher mean poverty score (Kruskal-Wallis $\chi^2 = 44.8$, $df = 1$, $P = 0.0001$) and most individual indices of poverty, but not with financial strain ($\chi^2 = 2.63$, $df = 2$, $P = 0.27$). Those who were unemployed ($n = 588$) (response rate 78.6%) were significantly less likely than those in work at T1 to participate at T2 ($n = 5577$) (85.9%, $P < 0.0001$).

Associations that were highly statistically significant were found between financial strain at T1 and poverty score (analysis of variance $F = 880.96$, $df = 2$, $P < 0.0001$), unemployment ($\chi^2 = 496.3$, $df = 3$, $P < 0.001$), and case-ness at T1 ($\chi^2 = 599.6$, $df = 2$, $P < 0.0001$).

Onset of episodes of common mental disorders—A statistically significant association with the onset of common mental disorders was found for financial strain, but not for poverty score or unemployment at T1 (table 1). Adjusting for potential confounders did not alter this association, which was not modified to statistically significant degree by age, sex, general health questionnaire score, or household income at T1.

Maintenance of common mental disorders—There was a statistically significant, non-linear (likelihood ratio

Table 1 Unadjusted odds ratio (95% confidence interval) for onset and maintenance of episodes of common mental disorders by poverty score, unemployment, and financial strain at T1, adjusted for age, sex, general health questionnaire score at T1, social class (by head of household), other potential confounders,* and other variables in table†

Variable	No of subjects (%)	Onset		Maintenance	
		Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Poverty score:					
0	1653 (21.4)	1.00	1.00	1.00	1.00
1	2318 (30.0)	1.16 (0.96 to 1.40)	1.11 (0.90 to 1.36)	0.99 (0.73 to 1.33)	0.90 (0.65 to 1.24)
2-3	2677 (34.7)	1.17 (0.95 to 1.44)	1.06 (0.85 to 1.31)	1.21 (0.97 to 1.61)	1.21 (0.88 to 1.67)
≥4	1078 (14.0)	1.11 (0.86 to 1.43)	1.10 (0.80 to 1.50)	1.73 (1.26 to 2.37)	1.45 (0.97 to 2.18)
Unemployment‡	462 (6.0)	1.17 (0.85 to 1.62)	1.26 (0.85 to 1.88)	1.54 (1.13 to 2.10)	1.86 (1.18 to 2.94)
Financial strain:					
Living comfortably	4278 (55.5)	1.00	1.00	1.00	1.00
Just about getting by	2385 (30.9)	1.25 (1.07 to 1.45)	1.21 (1.01 to 1.44)	1.56 (1.25 to 1.95)	1.49 (1.15 to 1.94)
Difficult or very difficult	1048 (13.6)	1.92 (1.55 to 2.37)	1.57 (1.19 to 2.07)	2.02 (1.60 to 2.56)	1.86 (1.36 to 2.53)

*Household size, dependent children, education, ethnic group, marital status, number of physical health problems, and region of residence.

†Odds ratio for poverty score and unemployment not adjusted for financial strain at T1.

‡Compared with those in employment.

$\chi^2=8.10$, $df=3$, $P=0.04$) association between poverty score and maintenance of common mental disorders (table 1), which was partly confounded by age, sex, employment status, and general health questionnaire score at T1 (likelihood ratio $\chi^2=7.77$, $df=3$, $P=0.05$). Even after adjusting for these and other confounders, maintenance was significantly higher among those who were unemployed compared with those in work at T1, and among those reporting financial strain at T1 (table 1). The associations between maintenance and both poverty score (likelihood ratio $\chi^2=3.73$, $df=3$, $P=0.29$) and unemployment (likelihood ratio $\chi^2=5.72$, $df=2$, $P=0.06$) were confounded by financial strain at T1. No statistically significant interactions were found between financial strain and age, sex, general health questionnaire score or low income at T1.

Psychiatric morbidity as a continuous outcome—Statistically significant independent associations were found between general health questionnaire score at T2 and both poverty score and financial strain at T1, but not unemployment, after adjusting for general health questionnaire score at T1 and other potential confounders (table 2). On stratifying by general health questionnaire score at T1 the association between poverty score at T1 and general health questionnaire score at T2 increased with general health questionnaire score at T1. Among those with poverty scores of 4 or more at T1 ($n=1078$), the regression coefficient for general health questionnaire score at T2 increased from 0.05 (SE 0.29) ($P=0.86$) for those with general health

questionnaire scores in the bottom quarter of the study sample at T1 to 1.82 (SE 0.37) ($P<0.001$) for those with general health questionnaire scores in the top quarter. No statistically significant interactions were found between general health questionnaire score and either unemployment or financial strain at T1.

Discussion

Poverty and unemployment were associated with longer episodes of common mental disorders but not their onset. The observed effect sizes for the maintenance of such episodes were modest and smaller than expected given the strength of cross sectional associations.^{1-3 9-11} While the absence of associations between onset and either unemployment or poverty differs from several previous studies,^{12 17} these findings are consistent with studies in New Zealand and the United Kingdom.¹³⁻¹⁵ By contrast, financial strain at T1 was strongly associated with both onset and duration of episode.

Unemployment was associated with maintenance of common mental disorders but not with a statistically significant increase in general health questionnaire scores between sets of interviews. Previous studies have found that psychiatric morbidity increases during the first six months of unemployment and then plateaus,¹⁶ while finding work has the opposite effect.¹⁶ Thus, our finding may have been explained by the inclusion of both people who were

Table 2 Mean (SE) general health questionnaire score (GHQ) at T1 (Likert scoring method), and regression coefficients (SE), B, for general health questionnaire score at T1 and T2 by poverty score, unemployment, and financial strain at T1, adjusted for age, sex, social class (by head of household), other potential confounders*, other variables in table†, and general health questionnaire score at T1‡

	No of subjects (%)	Mean GHQ score at T1	B for GHQ score at T1	P value	B for GHQ score at T2‡	P value
Poverty score (v 0):						
1	2318 (30.0)	10.31 (0.09)	0.45 (0.14)	0.001	0.26 (0.14)	0.07
2-3	2677 (34.7)	10.75 (0.12)	0.69 (0.16)	<0.001	0.44 (0.16)	0.006
≥4	1078 (14.0)	12.43 (0.18)	1.75 (0.24)	<0.001	0.75 (0.22)	0.001
Unemployed (v employed)	462 (6.0)	12.86 (0.29)	1.72 (0.36)	<0.001	0.47 (0.35)	0.18
Financial strain (v comfortable):						
Just about getting by	2385 (30.9)	11.31 (0.10)	1.42 (0.13)	<0.001	0.47 (0.13)	<0.001
Difficult or very difficult	1048 (13.6)	14.01 (0.19)	3.75 (0.23)	<0.001	0.94 (0.22)	<0.001

*Household size, dependent children, education, ethnic group, marital status, number of physical health problems, and region of residence.

†Regression coefficients for poverty score and unemployment not adjusted for financial strain at T1.

unemployed long term at T1, and those who found work between sets of interviews among those people classified as unemployed.

Although confounding by psychiatric morbidity at T1 contributed to the discrepancy in the magnitude of cross sectional¹¹ and longitudinal socioeconomic gradients in rates of common mental disorders, it is difficult to distinguish definitively between the antecedents and consequences of these conditions, even in a cohort study. Some psychiatric morbidity at T1 may have been caused by earlier poverty or unemployment, and adjustment for baseline general health questionnaire score in longitudinal analyses may therefore underestimate the contribution of these exposures.¹⁵ Similarly, the possibility cannot be excluded that the large socioeconomic gradient in the prevalence of these disorders may be partly due to social selection operating over periods longer than 12 months.

Methodology

The study was limited by use of the general household questionnaire rather than a standardised clinical interview. Associations between poverty and common mental disorders are generally larger in studies using standardised clinical interviews.^{2,10} Since the general health questionnaire is sensitive to recent change in psychological functioning, false positives might have included individuals with mild or transient psychological disturbance, which should have biased associations towards the null. Although physical ill health also leads to false positives, all study findings were adjusted for the number of current physical health problems. Those in lower occupational grades²¹ may underreport psychiatric symptoms on the general health questionnaire compared with responses to a standardised clinical interview. While this may have led to underestimates of socioeconomic gradients in rates of common mental disorders it could not explain the discrepancy between cross sectional and longitudinal findings.

Though modest, non-participation at baseline was associated with low socioeconomic status while loss to follow up was greatest among those who were cases, unemployed or living in poverty, or both, at T1. Since being unemployed or living in poverty are both risk factors for common mental disorders, non-participation was most likely to have biased longitudinal associations towards the null. This was clearly not the case for financial strain at T1, which was not associated with non-response at T2. Finally, statistical power was greatly diminished even in this large study by stratifying the sample according to case status at T1, and this is reflected in confidence intervals which include potentially important associations.

Conclusions

Poverty and unemployment increase the prevalence of common mental disorders by maintaining episodes rather than by precipitating their onset. Financial strain was strongly associated with both onset and maintenance of common mental disorders and was neither confounded nor modified by more objective risk factors. Although it is most likely that financial strain was simply the most accurate measure of standard of living it may also represent an aspect of personality such as proneness to pessimism or worry. There is a

Key messages

- The prevalence of the most common mental disorders, anxiety and depression, has been shown to be consistently associated with unemployment and measures of poverty, independent of occupational social class
- Unemployment and poverty were associated with the maintenance of episodes of most common mental disorders but not their onset
- Financial strain was a powerful independent predictor of both the onset and maintenance of episodes of common mental disorders, even after adjusting for more objective measures of standard of living
- Over 12 months poverty and financial strain, but not unemployment, were associated with significant increases in psychiatric morbidity; the effect of poverty increased with the level of baseline morbidity
- Further research is needed to better understand the nature of financial strain and its relation with unemployment and objective measures of standard of living

need to better understand the nature of this risk factor and its relation with poverty and unemployment if we are to meet the major public health challenge of reducing the prevalence of these costly and disabling disorders.²³

This study was started while SW was studying for the MSc in Epidemiology at the London School of Hygiene and Tropical Medicine. The data were made available through the Economic and Social Research Council's data archive and were originally collected by its research centre on microsocial change at the University of Essex. Neither the original collectors of the data nor the archive bear any responsibility for the analyses or interpretations presented here. We thank Professor Anthony Mann for his help in obtaining financial support for this study, and Andrew Sloggett for his comments on the analyses and study findings.

SW was the principal investigator, initiated the study, discussed core ideas and contributed to the generation of study hypotheses, prepared the application for funding, obtained the dataset, undertook data management and analysis, and drafted the manuscript; he will act as guarantor for the paper. GL initiated the study, discussed core ideas and contributed to the generation of study hypotheses, and participated in the preparation of the manuscript.

Funding: Wellcome Trust (grant No 045048).

Conflict of interest: None.

- 1 Goldberg D, Huxley P. *Common mental disorders: a bio-social model*. London: Routledge, 1992.
- 2 Meltzer H, Gill B, Petticrew M. *OPCS surveys of psychiatric morbidity in Great Britain. Report No 1. The prevalence of psychiatric morbidity among adults aged 16-64 living in private households in Great Britain*. London: HMSO, 1995.
- 3 Blaxter M. *Health and lifestyles*. London: Routledge, 1990.
- 4 Jenkins R. Minor psychiatric disorder in employed young men and women and its contribution to sickness absence. *Br J Ind Med* 1985;42:147-54.
- 5 Williams P, Tarnopolsky A, Hand D, Shepherd M. Minor psychiatric morbidity and general practice consultations: the West London survey. *Psychol Med* 1986; monograph suppl 9:1-37.
- 6 Murphy JM, Monson RR, Olivier DC, Sobol AM, Leighton AH. Affective disorders and mortality. A general population study. *Arch Gen Psychiatry* 1987;44:473-80.
- 7 Lloyd KR, Jenkins R, Mann A. Long term outcome of patients with neurotic illness in general practice. *BMJ* 1996;313:26-8.
- 8 Wells KB, Golding JM, Burnam MA. Psychiatric disorder and limitations in physical functioning in a sample of the Los Angeles general population. *Am J Psychiatry* 1988;145:712-7.

- 9 Rodgers B. Socio-economic status, employment and neurosis. *Soc Psychiatry Psychiatr Epidemiol* 1991;26:104-14.
- 10 Blazer DG, Kessler RC, McGonagle KA, Swartz MS. The prevalence and distribution of major depression in a national community sample: the national comorbidity survey. *Am J Psychiatry* 1994;151:979-86.
- 11 Weich S, Lewis G. Material standard of living, social class and the prevalence of the common mental disorders in Great Britain. *J Epidemiol Community Health* 1998;52:8-14.
- 12 Bruce ML, Takeuchi DT, Leaf PJ. Poverty and psychiatric status. *Arch Gen Psychiatry* 1991;48:470-4.
- 13 Murphy JM, Olivier DC, Monson RR, Sobol AM, Federman EB, Leighton AH. Depression and anxiety in relation to social status. *Arch Gen Psychiatry* 1991;48:223-9.
- 14 Romans SE, Walton VA, McNoe B, Herbison GP, Mullen PE. Otago women's health survey 30 month follow-up. II: remission patterns of non-psychotic psychiatric disorder. *Br J Psychiatry* 1993;163:739-46.
- 15 Weich S, Churchill R, Lewis G, Mann A. Do socio-economic risk factors predict the incidence and maintenance of psychiatric disorder in primary care? *Psychol Med* 1997;27:73-80.
- 16 Warr P. *Work, unemployment and mental health*. Oxford: Oxford Science, 1987.
- 17 Fergusson DM, Horwood LJ, Lynskey MT. The effects of unemployment on psychiatric illness during young adulthood. *Psychol Med* 1997;27:371-81.
- 18 Turner JB. Economic context and the health effects of unemployment. *J Health Soc Behav* 1995;36:213-29.
- 19 Taylor MF, (ed), Brice J, Buck N, Prentice E. *British household panel survey user manual volume A: introduction, technical report and appendices*. Colchester: University of Essex, 1995.
- 20 Goldberg DP, Williams P. *The user's guide to the general health questionnaire*. Nfer-Nelson: Windsor, 1988.
- 21 Stansfeld SA, Marmot MG. Social class and minor psychiatric disorder in civil servants: a validated screening survey using the general health questionnaire. *Psychol Med* 1992;22:739-49.
- 22 Huber PJ. *Robust statistics*. New York: John Wiley, 1981.
- 23 Weich S. Prevention of the common mental disorders: a public health perspective. *Psychol Med* 1997;27:757-64.

Underreporting of suspected adverse drug reactions to newly marketed ("black triangle") drugs in general practice: observational study

Richard M Martin, Karan V Kapoor, Lynda V Wilton, Ronald D Mann

Data on side effects of newly launched drugs are limited,¹ highlighting the need for effective postmarketing surveillance. An inverted black triangle (▼) on product literature identifies new products. Suspected adverse reactions to these drugs, however minor, should be reported to the Committee on Safety of Medicines through the yellow card scheme.² Adverse reactions are underreported,³ and few doctors in the United Kingdom know the meaning of the "black triangle" symbol.⁴ We assessed the degree of underreporting of suspected adverse reactions to new drugs in general practice and determined if reporting varied when reactions were severe or previously unrecognised.

Patients, methods, and results

The Drug Safety Research Unit performs observational cohort studies (prescription event monitoring) on selected newly marketed drugs in general practice. All patients in England who have been dispensed selected new drugs are identified for these studies by the Prescription Pricing Authority. Questionnaires ("green forms") are subsequently sent to prescribers asking about clinical events, suspected adverse drug reactions, and events reported to the Committee on Safety of Medicines as suspected adverse reactions. For the 10 drugs we examined (acarbose, risperidone, fluvastatin, tramadol, gabapentin, famciclovir, lansoprazole, zolpidem, venlafaxine, and losartan) median exposure was 46 435 (interquartile range 24 524 to 55 735) patient months. Events recorded by general practitioners as suspected adverse reactions, and those stated as having been reported to the Committee on Safety of Medicines, were classified as serious or non-serious, using the definition published in the British National Formulary.² We determined whether the event was listed ("labelled") in the summary of product characteristics at the time of the study; events not listed were classified as unlabelled. Reports stating

"non-specific side effects" or intolerance were not classified. By calculating a risk ratio, using non-serious labelled events as the reference group, we determined the likelihood of each category of adverse reaction being reported to the Committee on Safety of Medicines.

There were 3045 events (in 2034 patients) reported as suspected adverse reactions on the green forms during the 10 studies. General practitioners indicated that they had reported 275 (9.0%; 95% confidence interval 8.0% to 10.0%) of these reactions to the Committee on Safety of Medicines: reporting was highest for serious unlabelled reactions (26/81; 32.1%) and lowest for non-serious labelled reactions (94/1443; 6.5%) (table). Serious unlabelled and non-serious unlabelled reactions were significantly more likely to be reported than were non-serious labelled reactions. According to general practitioners' responses, the proportion of serious labelled reactions also reported on yellow cards (7/64; 10.9%) was only slightly greater than that of non-serious labelled reactions.

Drug Safety Research Unit, Southampton SO31 1AA

Richard M Martin, clinical research fellow
Karan V Kapoor, research assistant

School of Medicine, Faculty of Medicine, Health and Biological Sciences, University of Southampton, Southampton S016 7PX

Lynda V Wilton, visiting honorary lecturer

Ronald D Mann, senior professorial fellow

Correspondence to: Dr Martin drmann@dsru.u-net.com

BMJ 1998;317:119-20

Suspected adverse drug reactions reported by general practitioners on green forms for 10 newly marketed "black triangle" drugs during prescription event monitoring studies 1994-7

Type of adverse reaction	Adverse drug reactions		Risk ratio (95% CI)
	No stated on green form	No (%) also reported to Committee on Safety of Medicines	
Non-serious:	2400	235 (9.8)	—
Labelled	1443	94 (6.5)	Reference
Unlabelled	957	141 (14.7)	2.3 (1.8 to 2.9)*
Serious:	145	33 (22.8)	3.5 (2.4 to 5.0)*
Labelled	64	7 (10.9)	1.7 (0.8 to 3.5)
Unlabelled	81	26 (32.1)	4.9 (3.4 to 7.2)*
Not categorised†	500	7 (1.4)	—
Total	3045	275 (9.0)	—

*P<0.0001.

†Insufficient information available for an assessment of severity or of status as labelled or unlabelled.