dose of depot neuroleptic.

The prevalence of non-psychotic symptoms during the course of schizophrenic illness has been a relatively neglected area of research interest. In a comparable population in which the PSE was also used to identify psychiatric symptoms reliably, Cheadle *et al* (1978) found a similar prevalence of 'neurotic' symptoms, which caused the patients considerable subjective distress. Such symptoms seem to increase during phases of psychotic relapse, but may remain a residual disability when the more overt schizophrenic symptoms are controlled. These results also confirm more recent observations by Knights *et al* (1979) and Johnson (1981). The prevalence of depression during the course of schizophrenic illness and its possible relationship to drug treatment has recently been investigated by Falloon *et al* (1978), (Knights & Hirsch, 1981) and Johnson (1981). Approximately half the patients in relapse or followed-up for six and 12 months after acute schizophrenic relapse experienced depression; in one study, more patients required in-patient admission for depression than schizophrenic relapse (Falloon *et al*, 1978). The tendency for depressive symptoms to remit, as florid symptomatology subsided and patients became established on antipsychotic medication, seemed to refute earlier suggestions (Helmchen & Hippius, 1967) that phenothiazines were a causative factor. Our study also found a high prevalence of depression, to which the main contributors were those patients in schizophrenic relapse; all cases of depression occurred in the neuroleptic treated group. It is very unlikely that any measure of depressed mood could have been confused with parkinsonism (Van Putten & May, 1978; Rifkin *et al*, 1975), since the patients were required to describe the symptoms in detail before a rating was made. The patients rediagnosed as manic-depressive or in whom the diagnosis of schizophrenia remained uncertain did not bias the results, since there was no correlation with diagnostic certainty.

To avoid potential statistical artefacts from the small numbers, an additional analysis was performed, using a categorical analysis of variance (Light & Margolin, 1971; Margolin & Light, 1974). This is a distribution-free test of association, applicable when there are two or more independent samples and the data are categorical and discrete. There is no size restriction and in contrast with the chi square test, an additional measure is given of the strength of association between independent and dependent variables; the results confirmed those obtained using the chi square test. The presence of all three depressive syndromes were significantly associated ($P < 0.05$) with: receiving antipsychotic drugs at the time of follow-up assessment, previous admissions with affective symptoms, and the previous prescribing of antidepressant medication. Although there was an apparent association between depression and receiving antipsychotic medication, no conclusion could be drawn about this because patients not receiving medication were a self-selected group. Although they did not have depression, there could be other reasons for this e.g. a different type of illness, or better prognosis. However, there is some evidence to suggest that in our sample, it tended to be the same patients who were more likely to experience mood disorder during schizophrenic relapse, to exhibit more overt affective symptoms as an indication for in-patient admission, and to have been prescribed antidepressant drugs during the follow-up period. Thus, the increased exposure to antipsychotic drugs may have indicated no more than the severity of illness and the clinicians' response to poorly controlled schizophrenic symptoms.

III. Relapse Postponement or Relapse Prevention? The Implications for Long-term Outcome

Summary: The relapse and admission histories revealed a positive correlation between number of schizophrenic episodes and time on maintenance medication, probably reflecting severity of illness. Relapse rates after drug discontinuation rose to 45% within 13 months. There were no differences of predictive value between those relapsing on or off medication. The relationship between relapse rates, drug treatment, and social outcome is complex; antipsychotic drugs may postpone relapse, and frequent relapses might inhibit improvement in social performance long after florid symptoms have been controlled by medication.

Parts I and II of this report defined the population of chronic schizophrenics which was studied and described the role of the maintenance clinic, the use of antipsychotic medication, problems that arose

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from poor patient compliance, and the prevalence of side-effects, neurotic symptoms, and depressive syndromes. It would appear that compliance problems are associated with increased relapse and admission rates, and that affective symptoms commonly contribute to the indication for admission. Depression was a major source of morbidity; the patients found to be depressed at follow-up tended to have had more admissions with prominent affective symptoms and were more likely to have received antidepressant drugs during the follow-up period.

This paper reports on relapse rates and on their relationship with maintenance neuroleptic therapy and long-term outcome.

Relapse and admission history

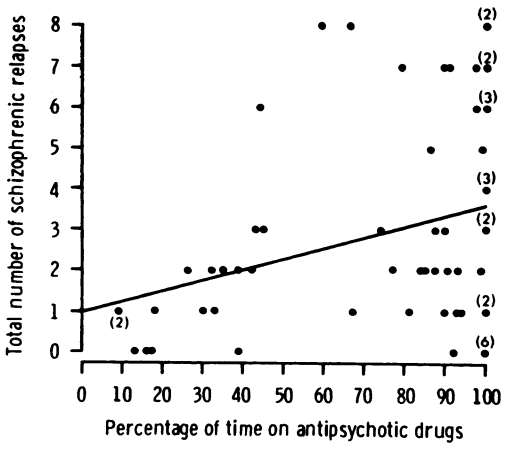
Of the total sample, 11 had remained in remission throughout and 24 had had no in-patient admissions. Fifty-two of the 63 patients with complete data on their relapse histories had a total of 172 episodes of schizophrenic illness (average 3.31); eight of those had had seven or more episodes, and two had been so floridly psychotic that discrete episodes of illness were difficult to identify in them (these two patients had both received depot neuroleptics continuously). A total of 94 in-patient admissions occurred in 40 patients, three-quarters of such admissions having been for less than three months. Transfer to day care as an extension of in-patient treatment was not counted in the duration figures, nor was such transfer counted as a day-patient admission. Thus, the 24 cases with 46 day-patient admissions were admitted to day hospitals as planned policy, and frequently as an alternative to in-patient care. Differences in the severity of illness episodes and in the role of day hospitals compared to acute psychiatric hospital wards probably account for the longer duration of day care (46% for more than three months).

Recorded reasons for in-patient or day-patient admissions were obtained from the hospital case notes; more than one reason could apply for each case. Florid psychotic symptoms accounted for most admissions (47%), with affective symptoms a close second (42%). Abnormal behaviour contributed to the indication for admission in 38%, and 7% were for social reasons alone; on nine occasions, the reason was not recorded or obscure.

Drug treatment and schizophrenic relapse

The relationship between neuroleptic therapy, relapse, and time was assessed in two ways. Firstly, percentage of time on medication was plotted against total number of schizophrenic episodes for each patient (Figure 3). The second method was to measure time to relapse after drug treatment ended.

The total number of relapses positively correlated with percentage of time on medication ($r = +0.31$, $P<0.01$), although a negative correlation might have been expected. The two 'continuously' psychotic patients were



• = 1 patient (numbers in brackets indicate more than one patient on the same spot).

FIG. 3 Number of schizophrenic relapses against percentage of time since end of trial on maintenance antipsychotic drug treatment ($P<0.01$, $n = 62$).

counted as eight relapses for the purposes of analysis, which produced a very slight under-estimate of relapse effect, whilst giving an advantage to drug treatment. Despite this, the result appears surprising if drug therapy is supposed to prevent relapse. The most likely explanation is that the more severely ill patients were more likely to remain on medication, even though such drug treatment was of limited benefit for some of them.

Secondly, the effects of drug discontinuation were assessed. Clinical records for each patient were carefully scrutinised for the dates when medication ceased and the onset of acute schizophrenic relapse (as defined earlier) began. The original intention was to date onset of relapse (not of admission or intensification of treatment) for all cases on all occasion, which would have permitted precise statistical analysis of the relationship between drug treatment and relapse. Although this proved to be possible in the vast majority of cases (in itself a tribute to the very high quality of medical records), it was not so for all cases on all occasions. For example, a consultant's letter supporting an application to a housing department described in detail the patient's relapse the previous year, but the onset could not be precisely dated.

Therefore, an alternative approach was adopted. The time to relapse was categorised, and this was possible for 62 patients on all occasions; 22 patients experienced one or more relapses within 13 months of drug discontinunation. The two patients who had been continuously psychotic were excluded from the analysis, for reasons given above. The numbers of patients relapsing within a specific interval of time, out of all those who remained drug-free for the same time-interval, were calculated. Some patient relapsed more than once when drug treatment ceased and some relapsed at different times, eg. five patients had a total of six relapses in three

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months, seven had eight relapses between them in four to six months, and 16 had 22 relapses between seven and 13 months. The cumulative relapse rate in those patients whose medication was discontinued rose from nearly 13% at four months to about 19% at six months, and reached a peak of 45% at seven to 13 months. This compares with a peak relapse at 3½ months during the original trial. Only 20 patients sustained a drug-free period longer than 14 months and of those, eight relapsed (40%).

The identification of drug responders and those who can safely come off medication is an unresolved issue. Although a retrospective follow-up study such as this could not be expected to answer such questions, an attempt was made to identify any differences between those patients who had received maintenance antipsychotic medication continuously since the original trial (n = 20—does not include two continuously psychotic patients) and those who relapsed within 13 months of drug treatment ceasing (n = 22). The two groups were compared on a number of variables: companionship, marital status, employment, admission status, prescription of oral antipsychotic drugs, time on injections during life, total number of illness episodes, age, out-patient relapses, in-patient and day-patient admissions, reasons for admissions (florid and affective symptoms, abnormal behaviour), and PSE score at follow-up assessment. There were no significant differences between the groups. Over the next 84 months to follow-up, 68% of patients relapsed whilst on antipsychotic drugs (Value A) while 63% of those exposed relapsed when off medication for up to 13 months (Value B).

Since the periods of exposure to the possibility of relapse are different for the groups on and off the drug, it is necessary to make certain assumptions about temporal features of the relapse process. The simplest model of time to relapse, on or off drug, is to assume that in a constant short time-interval, a constant proportion of those at risk will relapse; for this purpose, 'at risk' means not previously relapsed. The probability distribution resulting from this assumption is an exponential one, with possibly different parameters for time to relapse on and off drug. The values A and B could be analysed on this basis, and would lead to an estimate of relative risk of relapse off or on drug in a constant time period of about five.

In order to assess whether the exponential distribution is a realistic model for the phenomenon, the 'expected' relapse rates obtained from other studies may be examined, and compared with those observed here. On medication, 35% of patients would have been expected to relapse over 24 months (Value C), and without medication, 60-65% over 24 months (Value D). The relapse rates in A and C are compatible with the exponential model, but those in B and D indicate that the model may be untenable for the groups of patients off drug. Thus, the distributions of time to relapse may be different in the two groups, but if the 'expected' figures C and D are correct, then the conclusion must be that drug treatment postpones relapse.

Outcome

Chronic schizophrenia is characterised in the majority of cases by deterioration in personality and impairment of social functioning. Florid psychotic symptoms, abnormal social behaviour, and episodes of acute illness are important, but represent only some aspects of the condition (Wing & Brown, 1970).

For the initial trial, social performance was measured on a schedule which combined social behaviour and role performance, and the results have been described by Stevens (1973). However, the Social Behaviour Assessment Schedule was more appropriate for the follow-up study. The problem of comparing results from different instruments was overcome by using a method adopted by Brockington *et al* (1978). Two separate 100 millimetre linear analogue scales for occupational record and social

TABLE VIII

Relationship of SSR scores to other indicaters of illness severity

	Percentage of time on injection	*Inpatient admissions*	*Relapses*	*In Relapse*
Trial SSR	r = 0.31 *P = 0.015	r = 0.12 NS	r = −0.04 NS	r = 0.03 NS
Follow-up SSR	r = 0.42 P = 0.001	r = 0.25 P = 0.046	r = 0.41 P = 0.002	r = 0.30 P = 0.018
Following-up SSR (controlling for trial SSR)	r = 0.32 P = 0.014	r = 0.22 NS	r = 0.49 P = 0.000	r = 0.33 P = 0.010
Improvement*	Mann-Whitney U = 160.0 z = −2.48 P = 0.013	Mann-Whitney U = 254.0 z = −0.94 NS	Mann-Whitney U = 121.5 z = −3.01 P = 0.0027	χ^2 = 1.30 NS
Number of patients	61***	63	58****	63

*All probabilities are two-tailed

**Improvement = Difference between trial SSR and follow-up SSR, expressed as either "better" (n = 13) or "worse" (n = 50).

***Two cases excluded – not known

****One case (not known), two continuously psychotic, and two with more than eight relapses each excluded.

N.B. Correlation between trial SSR and follow-up SSR

r = 0.50, n = 63, P <0.001

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involvement, each with six cues, were independently rated by two of the follow-up investigators (DAC and RWB), after careful scrutiny of the raw data in both schedules. The means of the scores were taken as the Social State Rating (SSR), lower scores reflecting a higher level of social role performance. Inter-rater reliability of the SSR was assessed, and shown to be adequate: r = 0.86 ($P<.001$) and r = 0.90 ($P<.001$) at the trial and follow-up assessments, respectively; differences in scoring between raters were symmetrically distributed.

The relationship of SSR scores to other indicators of severity of illness (percentage of time on injection, number of inpatient admissions and numbers of relapses since the end of the trial, and whether in relapse at time of follow-up assessment) are explored in Table VIII. The two continuously psychotic patients and two with more than eight relapses were excluded from the relapse calculation, since social functioning is a somewhat meaningless concept at such a severity of mental illness. Trial and follow-up SSR scores were highly correlated (r = 0.50, $P<.001$), with a tendency for most patients to exhibit poorer social performance (higher scores) at follow-up. On a simple comparison of SSR scores, 50 were 'worse' and only 13 'better'. At the time of the original trial, there was a significant correlation between the percentage of time on injection and the SSR score, i.e. those with poorer social performance spent more time on injection. At follow-up, SSR score was significantly correlated with all four measures of illness severity. The strength of these correlations was little affected by controlling for the trial SSR (although the correlation with number of in-patient admissions was no longer significant). Those who were improved at follow-up spent significantly less time on injection than those who were worse (mean values of 53.3% and 79.7% respectively) and had significantly fewer relapses (mean values of 1.0 and 3.1, respectively). There was no significant association between improvement and the number of in-patient relapses or whether the patient was in relapse at follow-up.

Discussion

The role of neuroleptic drugs in controlling acute florid schizophrenic symptomatology and reducing relapse rates is well established (Davis, 1975; Hollister, 1978; Hirsch, 1980). Unfortunately, about one-third of patients are not well protected by drug therapy (Johnson, 1976, 1982). Drug discontinuation studies have supported the need for chronic schizophrenic patients to receive maintenance drug therapy for at least four years (Hogarty *et al,* 1976; Johnson, 1976, 1979a; Wistedt, 1981). Two non-blind studies of stabilised schizophrenic out-patients demonstrated relapse rates of 80 to 94% when relatively small doses of maintenance therapy were withdrawn (Capstick, 1980; Dencker *et al,* 1980) and Cheung (1981) reported an increased relapse rate in patients switched to benzodiazepines after between three and five years free of relapse. It has not proved possible to identify with any consistent degree of reliability chronic schizophrenic patients who can be safely withdrawn from maintenance medication.

The patients entering the original MRC trial were selected in respect of chronicity of illness and certainty of diagnosis. The relationship between relapse and drug treatment during the follow-up period was examined in a number of ways. The scattergram (Figure 3) shows a significant positive correlation between frequency of relapse and percentage of time on maintenance medication since the end of the trial. The most likely explanation is that the responsible clinicians were more likely to prescribe antipsychotic drugs to patients who they judged to be more ill. However, this scattergram may also be viewed in another way. It shows three overlapping groups of patients: those with few relapses and little drug treatment, those with numerous relapses and prolonged maintenance treatment, and a third group which had received prolonged maintenance therapy but experienced relatively few schizophrenic relapses. These groups might represent respectively the good prognosis cases, the drug non-responders, and the drug responders. The average monthly dose of medication is relevant in this respect, since it is conceivable that some of the non-responders may have benefited from higher doses.

During the original drug trial, the peak time to relapse was 3½ months after switching to placebo, with a roughly normal distribution over nine months, but the peak time to relapse for the patients discontinuing medication for whatever reason during the follow-up period was later (seven to 13 months). The explanation is obscure. It is possible that the 22 patients who stopped receiving medication were a biased sample in that the clinicians had selected out some better prognosis cases for elective discontinuation, or the illness may have spontaneously remitted. Prompt detection of relapse during a drug trial may also be easier than when compared to the reality of the clinical setting. The problems of interpretation of frequency of relapse over long periods of time have been discussed by Davis (1975) and by Johnson (1982): both concluded that the longer the time off drug, the more biased the sample towards better prognosis cases. Though the present results are very similar to those from some placebo-controlled and drug withdrawal trials, they are not directly comparable, since they reflect events in clinical practice rather than an aspect of study design. The inclusion criteria for the original trial would also influence these follow-up results, but they are compatible

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with a survival curve reported by Johnson (1979b).

In our study, 68% of the 20 patients on continuous maintenance treatment relapsed in the mean interval of 84 months from trial to follow-up, while 63% of the 22 patients whose medication was discontinued during the follow-up period relapsed in the first 13 months off drug. Comparison of the two patient groups on a number of demographic and clinical variables failed to identify any significant differences between them, but the effect of medication on slowing the rate of relapse is clear. As far as we are aware, no previous follow-up study has examined the relationship betwen maintenance therapy and relapse rates over such a prolonged period of time.

Direct comparison with results in the literature is difficult because of variations in patient samples, study design, drug treatment, and duration of follow-up, but the reported relapse frequency on drugs varies between four to 35% and on placebo between 29 to 80% (Johnson, 1982). It was possible to estimate the 'expected' relapse rates by using the results of other workers whose studies most closely compared to this one (Leff & Wing, 1971; Hogarty *et al*, 1974, 1976; Johnson, 1976; Rifkin *et al*, 1977) and a review by Gardos & Cole (1976). Pooling of these data produced figures in the range of 35% for the relapse rate on drug over 24 months, and 60–65% for relapse rate off drug over the same period; the most plausible mathematical model suggests that drug treatment postpones relapse. The notion of suppressing or delaying relapse is not new (Engelhardt & Freedman, 1970; Hogarty *et al*, 1976; Johnson, 1979a), but it could have implications for discontinuation of drug therapy, even for patients maintained on low dose schedules who exhibit very high relapse rates when medication was discontinued (Kane *et al*, 1979; Kane, 1981).

Irrespective of control of florid symptoms, the long-term outcome of schizophrenic illness tends to be measured in terms of social disability (Kraepelin, 1919). Using the method described above, a very high level of inter-rater agreement was obtained on social behaviour and role performance, and the mean Social State Rating (SSR) was used as an index of outcome. The most significant finding was the high negative correlation between improvement in SSR and total number of schizophrenic relapses since the end of the drug trial ($P < 0.0027$). The SSR is to a large extent a measure of role or social performance. In a previous study, the SBAS was used to assess social performance during a comparative drug trial (Barnes *et al*, 1983). Here, the social performance score continued to show improvement in both treatment groups over one year, even though all patients entering the trial had been well-controlled on maintenance therapy. The results suggested that when social performance is used as an outcome measure, it improves very slowly, and may continue to do so long after the resolution of florid symptomatology.

Such a relationship between drug treatment, acute relapse, and social performance may explain the findings from this follow-up study. Frequent relapses as a result of drug discontinuation or non-response may impede the slow improvement in role performance, inhibit a reasonable social recovery, and perhaps even contribute to the socially impaired state so characteristic of chronic schizophrenia. If our sample is representative, there would appear to be three types of chronic schizophrenic patient, though they merge into one another. In the first, the illness runs a relatively benign course, with a few relapses and little social deterioration. Neuroleptic drugs may be helpful in the acute phase, but may not be necessary as maintenance therapy. The second type is unresponsive to neuroleptics and the course of the illness is more malignant, with florid symptomatology and very marked social deterioration. Fortunately, this group is relatively small, even in such a chronically disabled sample of patients as recorded here. The third type, and the largest group in this sample, are patients who do show some response to maintenance neuroleptic drugs and, provided they comply with medical treatment, acute relapses are reduced and social deterioration is limited.

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