where the licensing authorities require more complete documentation even more information may be undisclosed.

Much of the information on adverse effects was of poor quality, for two reasons: the reports did not say how the adverse effects were defined and determined; and the incidence of adverse effects was often not calculated, nor was it related to the efficacy of the drug. Nevertheless, most reports contained some information on adverse effects, and possibly a skilled epidemiologist might be able to make good use of this. The unpublished reports contained more information on adverse effects than the published reports.

The results of this study also raise questions about the waste of clinical and research resources used in the sizable proportion of trials whose design made it unlikely that they would supply valuable information about the efficacy of the drug. This waste is deplorable when there is such a need for careful evaluation not only of new drugs but also of drugs already in use.

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General Practice Observed

Family trends in psychotropic and antibiotic prescribing in general practice

J G R HOWIE, A R BIGG

Summary and conclusions

A ten-year retrospective study of the consultations of 50 families with a city general practice was used to test the hypothesis that mothers who receive an excess of psychotropic drugs have children who receive an excess of antibiotics for episodes of acute respiratory illness. The children of the 10 mothers classed as high psychotropic users were seen twice as often with acute respiratory illness and received twice as many antibiotics as the children of the mothers who had received no psychotropic medication. The association between high psychotropic and high antibiotic use was not linked in time, and indeed the time of highest antibiotic use coincided with the time when the mother received fewest psychotropic prescriptions.

It is suggested that at many of these consultations the mother rather than the child should have been treated as the patient.

The prescribing of drugs in general practice is rightly regarded as a fundamentally important field for research work. Apart from the commonly discussed issues that include, for example, cost, quantity, and the risks of side effects and of interactions, many less tangible issues merit study. In particular the frequency with which general practice consultations result in a prescription (about two out of three consultations[1-3]), the high expectations of patients (both real and assumed[4]) that they will receive drugs, and the high (but variable) degree with which different doctors respond to these expectations are all factors which suggest that important influences in prescribing other than those of the presenting illness remain to be identified.

The most commonly prescribed group of drugs are the psychotropic drugs—one-sixth of all prescriptions[5]—and much has been written on their use.[6 7] When repeat prescriptions are excluded antibiotics become the drugs most commonly prescribed. It is widely accepted that—rightly or wrongly—antibiotics are often prescribed for reasons other than to reverse apparently relevant pathology, and published work has discussed some of these.[8 9] We examine a further hypothesis relating to the use of both psychotropic drugs and antibiotics—namely, that children who receive an excess of antibiotics for episodes of acute respiratory illness belong to mothers who receive an excess of psychotropic drugs. The work was mounted in the belief that demonstration of such a trend would reaffirm the importance of non-physical determinants of prescribing for physical illness in general practice, and show the degree to which psychological or social aspects of illness within one patient (or within his family or his environment) can overlap with the physical symptoms and signs to affect the making of diagnoses and decisions on management.

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Method

The study was based on retrospective examination of carefully maintained records in a three-partner Aberdeen practice with 5500 patients. The index patients were identified from the age-sex register and included all 50 mothers aged between 32 and 40 who had been registered with the practice throughout the period 1969-78 inclusive and whose husbands and children were also registered at the time of the investigation (1979). (The search started from the arbitrary maternal age of 35, chosen to ensure the recruitment of mature family units, and continued forwards and backwards until 50 families had been listed. The 50 mothers had 108 children.)

For each mother note was made of her age, of all contacts with the practice in each year from 1969 to 1978, and of all medicines prescribed. Antidepressants, minor anxiolytic and hypnotic drugs, and other psychotropic drugs were listed separately. Other aspects of health, including referrals to hospital, were also noted but are not described further in this paper. For each child age and all contacts with the practice for each year of the study were noted. Antibiotics prescribed were listed separately and note made of those apparently prescribed for acute respiratory illness.

The mothers were ranked according to the number of prescriptions for psychotropic drugs issued to them over the 10-year period of study. Twenty-two had received no psychotropic drugs and were categorised separately. The 28 who had received them divided conveniently into 10 mothers in a "high-user" group (11 or more prescriptions) and 18 mothers in a "low-user" group (1-8 prescriptions).

Results

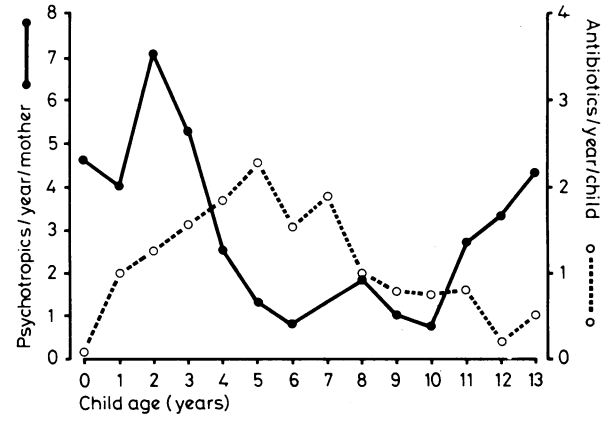
The main findings of the study are summarised in tables I and II.

TABLE I—*Distribution of mothers to categories of psychotropic drug use and background information regarding their age, parity, and annual number of contacts with their general practice*

Category of psychotropic drug use	Mothers		Mother's average total No of contacts per year with practice
	Average age	Average No of children	
High (n = 10)	37	1·8	8·5
Low (n = 18)	36	1·9	3·8
Nil (n = 22)	38	2·5	2·4

year period of study was 16 (mean 31; range 11-126). Eight had received anxiolytic more than antidepressant drugs and their children received antibiotics at the high rate of 1·5 per child year; the children of the two mothers who had been predominantly treated with antidepressants received antibiotics at the level of 0·4 per child year—below the average level for the children of non-takers of psychotropic drugs.

To examine the possibility that the high use of antibiotics for the children reflected illness which itself caused or justified the need for psychotropic treatment for the mothers, two further analyses were carried out. Firstly, for the 28 mothers who had received psychotropic treatment an attempt was made to assess whether the mother had received any psychotropic treatment in the same year as any of her children had received antibiotics. There was no measureable association in time between the prescribing of psychotropics and antibiotics. The second analysis is shown in the figure. For the 10 mothers



Relation in time between prescribing of psychotropic drugs to mothers classed as high users of psychotropic drugs and prescribing of antibiotics for acute respiratory illness to their children.

who had been classed as high-psychotropic users, the number of prescriptions they had received in each year was plotted against the appropriate age of each child; and the number of antibiotics prescribed for each child was also plotted against its age. It can be seen that the peak age for antibiotic use in the children (age 4-7) in fact overlaps the time of lowest prescription of psychotropic drugs to the mothers, while the psychotropic prescribing is highest while the child is younger (age 0-3) and again rises in later childhood.

TABLE II—*Relation between category of mothers (based on number of psychotropic drugs received) and their 108 children and the antibiotics they received for acute respiratory illnesses during 10-year period 1969-78*

Mother's category of psychotropic drug use	Children						
	No of children	Years at risk		No of RTIs presented		No of antibiotics prescribed	
		Observed	Expected	Observed	Expected	Observed	Expected
High	18	150	161·3	298	210·0	198	142·2
Low	35	320	313·7	407	408·3	310	276·4
Nil	55	498	493·0	555	641·7	345	434·4
		$\chi^2 = 0.969$		$\chi^2 = 56.766$		$\chi^2 = 44.536$	
		$0.50 > p < 0.70$		$p < 0.001$		$p < 0.001$	

RTI = Respiratory tract infection.

The mothers (and their children) in the three different categories of psychotropic drug use were of the same age distribution. The high-user mothers had many more contacts with the practice than the mothers in the other two groups, and even when contacts with the practice at which psychotropic medication had been issued were excluded, the high-user mothers still had twice as many contacts with the practice as did the non-users. Similarly the children of high-psychotropic users were presented significantly more often with respiratory illness than were the children of non-psychotropic users ($\chi^2 = 56.77$ $p < 0.001$) and, as antibiotics were prescribed at a constant rate to both groups, the children whose mothers were high psychotropic users received twice as many antibiotics as did the children of the non-user group, a highly significant increase ($\chi^2 = 44.54$ $p < 0.001$).

For the 10 mothers in the high-user psychotropic group, the median number of psychotropic drug prescriptions received over the 10-

Seven of the 10 high-users of psychotropic drugs lived in council housing as against 11 of the 22 non-users of psychotropic drugs. One father was a high-user of psychotropic drugs; his wife had received no psychotropic medication during the study period and his two children had received only one antibiotic prescription in 15 years "at risk."

Discussion

Practice records—The conclusions that can be drawn from any retrospective study are limited by the accuracy of the records available for study. The policy in the practice is to record all

clinical contacts at home and in the surgery as well as all the prescribing of repeat or other medication on the one record. All partners observe this policy as routine, and it seems improbable that any errors or omissions from the records would have selectively contributed to the trends described above.

Clinical implications—The finding that those mothers who consult more often receive more psychotropic drugs and in turn present their children with respiratory illness more often than average, is in accord with experience. The fact that these children then receive more than their share of antibiotics, although readily understandable, suggests that at many of these consultations the mother rather than the child should have been thought of as the patient. (It is interesting that the two mothers whose continuing problem appears to have been depression rather than anxiety did not reflect this general trend.) It goes without saying that to miss the basic reason for the consultation and prescribe unnecessary or inappropriate treatment not only risks drug side effects but fails to offer the treatment that is required and indirectly confirms the mother's anxiety and thus the tendency to consult (herself or with her child) again when not medically necessary. Although time for psychological assessment and health education is certainly at a premium during winter respiratory epidemics, the figures produced above show well the relation between behavioural and physical illness, and it seems reasonable to postulate that in the long run more time might be saved (and better care given) by treating the cause of the consultation rather than the complaint offered.

Theoretical implications—It is still fashionable to imply either that the clinical medicine of general practice has no distinctive characteristics or, on the other hand, that it is an art that cannot be taught (to postgraduates) or taught about (to undergraduates). It is equally reasonable to suggest that these two points of view are contradictory and mutually exclusive. One of the most important differences between the practice of medicine in general practice and in hospital is the *relative* frequency with which psychosocial features significantly affect the management of an apparently physical illness. In this study, of the 1260 acute childhood respiratory illnesses studied, 298 (24%) were in the children of the high-users of psychotropic drugs, and in these at least the influence of the mother must be seen as an important and inseparable part of the consultation. There are those in general practice who see their work primarily in somatic terms and others who put a substantially different—and sometimes extreme—emphasis on the non-physical components of illness and its presentation. Further studies of the type reported in this paper should enable the proper balance to be better defined and in turn assist the description and thus the teaching of the "art."

We thank Drs J Gauld, I Ross, and R Strachan for their interest and for access to their practice records.

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What is Cornelia de Lange syndrome and what advice should be given to a childless couple whose child died of this condition a few hours after birth?

The more constant features of Cornelia de Lange syndrome include: short stature of prenatal onset, mental retardation, a low-pitched cry in infancy, microcephaly, bushy eyebrows, synophrys and curly eyelashes, small nose and anteverted nostrils, thin lips with downward curving of the angle of the mouth, micrognathia, hirsutism, small hands and feet, and proximal implantation of thumbs. It is diagnosed from the presence of the features given above and others less consistently present. There is no specific diagnostic test. There have been a few reports of two siblings being affected, but the recurrence risk is probably only about 1%.

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Are the results of safety tests on saccharin, using animals, valid in advising the use of this substance in man? Can saccharin be used safely in low carbohydrate diets?

This question raises several very difficult areas connected with toxicological testing of food additives. Screening with animals or some other type of biological assessment is a necessary safety measure before a food additive can be used. This testing, however, necessitates feeding the additive at several dose levels, some of which would be very much greater than those which would be consumed by man on a per kg body weight basis. The carcinogenetic activity of an additive is particularly difficult to assess at very low incidence rates because large numbers of test animals are required and tumours may arise spontaneously.

The concern with the safety of saccharin arose from studies where a very high level of intake of saccharin produced a low incidence of bladder tumours. The laws relating to the use of food additives in the USA are dogmatic in rejecting the use of an additive which at *any* level of consumption has been associated with the development of tumours. The evidence for the involvement of saccharin in producing tumours is not unequivocal—consumption of diets containing 50 000 ppm (5%) has reportedly not produced any excess of tumours in dosed rats compared with controls. On balance, the evidence at present suggests that the risks from ingesting saccharin at normal levels of consumption are very low indeed.

As there still seems to be some doubt whether the fourth or fifth Korotkoff sound is indicative of arterial diastolic pressure, would not a needle in the brachial artery inserted just below the sphygmomanometer cuff and connected to an oscillograph give the required information?

There is doubt whether muffling (Korotkoff, phase 4) or disappearance of sounds (phase 5) is a more accurate indicator of diastolic blood pressure.[1] The tendency in Britain and Ireland has been to use the fourth phase, whereas the USA has generally favoured the fifth phase. The controversy continues, but phase 5 is now more generally accepted because the results are closer to those with direct intra-arterial measurement, and there is better agreement among observers. The disadvantage in choosing the fifth phase is that in high-output states the disappearance of sounds may be greatly below muffling, and sometimes the sounds do not disappear at all. When this occurs the fourth phase should be taken. The controversy might be best solved if both phases were recorded. Phase 5 correlates best with the diastolic pressure measured through an intra-arterial catheter, a technique that is not only feasible but is often used to obtain continuous blood pressure measurement in selected patients.[2]

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