

Chloromycetin is among the important products that have run the gauntlet of newspaper evaluation. Perhaps the dramatic qualities of the antibiotic, itself, have contributed to this condition. A relatively few articles, however, have accused Chloromycetin of being associated with certain blood dyscrasias. On the other hand, intensive investigation by the Food and Drug Administration, carried on with the assistance of a special committee of eminent specialists appointed by the National Research Council, resulted in unqualified sanction of continued use of Chloromycetin for all conditions in which it had previously been used.

A sensible caution against indiscriminate use, which we have incorporated into our advertising and labeling, is a welcome addition to our literature and to the label on Chloromycetin products, and in our opinion, would be appropriate in those on any potent chemotherapeutic agent. Actually, such caution is an assurance that the full benefits of well-tolerated Chloromycetin will be available and free from misuse.

(2-PP10)

Here is the breakdown of the recent survey made by the Food and Drug Administration covering 539 patients. It should be borne in mind that this survey was specifically made for the purpose of ascertaining, if possible, the degree of involvement of Chloromycetin in the development of blood dyscrasias. You will notice that there are three categories, "A", "B", and "C". These three categories relate to: "A" those cases in which Chloromycetin was the only drug given; "B" those in which Chloromycetin was given in combination with other drugs; and "C" those cases in which Chloromycetin was not involved.

(3-PP10)

On this page, Doctor, we have reduced to percentage the salient points which we noted from the tabulation I have just shown you.

Several interesting factors are obvious from these data. The number of cases of blood dyscrasias found in this survey apparently associated with Chloromycetin alone is only about 10 per cent of the total cases surveyed.

In this survey specifically intended to find the facts on Chloromycetin, 341 patients out of a total of 539, more than 60 per cent of the total were of cases in which this antibiotic was not involved.

(4-PP10)

Are the broad-spectrum antibiotics important factors in the incidence of blood dyscrasias? Of course, it is logical to use Chloromycetin as an example, because it has been the subject of intensive and thorough investigation. An investigation, incidentally, in which Parke-Davis wholeheartedly cooperated. Here is a chart showing the increased use of Chloromycetin from the time of its introduction. Notice the steady, continued and rapid rise which now amounts to many millions of doses, comprising several millions of courses of therapy.

(5-PP10)

Here, Doctor, we have plotted the mortality from aplastic anemia as reported by thirty States for the years of 1949, 1950, 1951. These figures, compiled by Parke-Davis from data obtained from the thirty States in which these figures were available for the three year period, revealed a specific mortality per 100,000 of 0.41 in 1949; 0.42 in 1950; and 0.43 in 1951.

(6-PP10)

Now, on this page we have plotted the two curves superimposed on the same set of coordinates: A. Chloromycetin curve; B. Mortality from aplastic anemia. The lack of parallelism leads to the impression that there is little relation between the two factors that, were Chloromycetin an important cause, would be expected to show parallelism at least.

(7-PP10)

Up through October, 1952, 59 published papers, reporting on experience involving more than 1700 patients, have presented data in which thorough blood studies had been made on each patient before, during, and following therapeutic courses of Chloromycetin. Doctor, is it not significant, that in not one of these 1700 patients was there any evidence of blood dyscrasia following administration of the antibiotic?