

TABLE 1.—OUTCOME OF BLOOD DYSCRASIA ATTRIBUTED TO TOXIC EFFECTS OF CHLORAMPHENICOL OR PHENYL-BUTAZONE; RESULTS OF FOLLOWUP SURVEY OF 154 PATIENTS

Outcome	Chloramphenicol			Phenylbutazone			Chlor- am- pheni- col and phenyl- buta- zone	Total
	Number cases ²	Range ³	Median	Number cases ²	Range ³	Median		
Recovery.....	47 (37)	1 week-7 year.	1½ month....	18 (72)	2 weeks-4 years.	1 month....	2	67
Still under care.....	19 (15)	6 months-6 years.	4 years.....	4 (16)	1-5 years....	4½ years.....		23
Death.....	50 (40)	1 day-3½ years.	1½ month....	3 (12)	2 weeks-2 years.	10 months..	1	54
Unknown.....	10 (8)							10
Total.....	126 (100)		9 months....	25 (100)		1 year.....	3	154

¹ Interval=period between diagnosis of blood dyscrasia and outcome.² Figures in parentheses are percentages.³ Range=shortest to longest interval.

Questionnaires for each reported case were then mailed to the 126 physicians. These forms were designed to elicit information on the outcome of the blood dyscrasia and on disorders which occurred subsequent to the onset of the dyscrasia. When leukemia was reported as one of these disorders, further data on the drug reaction and its course were requested from records of the registry and the reporting physician.

During the course of this study four of the responding physicians called our attention to a total of six patients who had *not* previously been registered at the AMA or FDA, but in whom leukemia developed following use of chloramphenicol or phenylbutazone. These patients were not included in the survey, but pertinent data submitted on these patients are summarized in a separate section below.

RESULTS OF THE SURVEY

Of 126 physicians sent questionnaires, 39 did not reply; ten returned forms which were not completed; and 77 sent completed questionnaires. Five physicians who did not complete the questionnaires said they were unable to recall cases previously reported; four had departed from the area or the original hospital; and one physician had died. In a few instances, a reply was received from an associate of the physician who originally reported the case to the registry. The 77 physicians who returned completed questionnaires (43% of the original roster of reporting physicians) provided followup data on 154 patients with bone marrow depression (66% of the total cases originally reported). Of these cases, 126 were attributed to chloramphenicol, 25 to phenylbutazone, and three to both drugs combined. The patients with toxic reactions to chloramphenicol consisted of 46 males, 77 females, and three with sex unrecorded; the median age at diagnosis was 38 years for males, and 19 years for females. The phenylbutazone reactions occurred in eight males and 17 females, with median ages of 51 and 48 years, respectively. Sixteen of the 77 physicians who returned questionnaires were from countries other than the United States.

Outcome of Blood Dyscrasia.—Table 1 summarizes the results of the marrow depression among the 154 cases in the survey. The median period of observation was nine months for the chloramphenicol group, and one year for the phenylbutazone series. For each outcome category there were no significant differences between the two drugs in the distribution of time intervals since diagnosis of the blood dyscrasia. Furthermore, there was a similar proportion of patients who were still being treated for toxic effects from each drug, at median intervals of 4 and 4½ years, respectively, following diagnosis. The chloramphenicol series, however, had a much higher proportion of deaths, while the phenylbutazone group had a greater frequency of recovery. These differences persist even if the patients with toxic reactions to chloramphenicol who were lost to follow-up (8%) are assumed to have recovered. Table 2 specifies the type of blood dyscrasia under treatment at the time of survey. Tables 3 and 4 show the reported causes of death.