UNIVERSITY OF MARYLAND
SCHOOL OF MEDICINE
DEPARTMENT OF SOCIAL AND PREVENTIVE MEDICINE

DIVISION OF CLINICAL INVESTIGATION
600 Wyndhurst Avenue
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~~pc RP & return today.~~
R? update?
no answer necessary — meeting held in April w/ each detail ...

Dear Henry:

The enclosed tables provide the information on baseline prevalence of individual ECG Codes by treatment group that you requested in your memorandum of January 12. Table 1 provides information on the percent of patients with individual ECG abnormalities at baseline, based on the initial readings of the ECGs and presented in the 1966 progress report. Table 2 provides the information which was presented in Cornfield's paper and in the phenformin monograph and gives the percent of patients with specified ECG abnormalities at baseline by treatment group based on the present reading program. These readings were obtained by your technician graders following the revised Minnesota Code.

As I understand the controversy the major focus has been on the one line in the 1966 progress report "one or more major ECG abnormalities" compared to the line in the published report "any significant ECG abnormality." It is clear that these two lines have summarized the findings for a different set of ECG abnormalities. We have made an attempt to obtain a line comparable to the line in the progress report "one or more major ECG abnormalities" using the readings from the current program. In the 1966 progress report, one or more ECG abnormalities included the following: S-T depression junction or segment, inverted T-wave, A-V ventricular conduction defects, intraventricular conduction defects, significant arrhythmias and large Q-waves compatible with infarction. An attempt has been made to obtain a comparable combination from the current reading program and in that analysis we have included the following codes: 1-1-1 through 1-1-7, 1-2-3, 1-3-6; 4-1 through 4-3; 5-1, 5-2; 6-1, 6-2, 6-4, 6-5; 7-1, 7-2, 7-4; 8-2 through 8-6, and 8-9. These results are given in Table 3. This is our best guess as to the comparable set of codes, but of course, we need your confirmation that the set is comparable.

I do not know when the new reading program was undertaken but all UGDP ECGs have now been read by your technician graders according to the revised Minnesota Code. The results for the first grading program, that is, the readings based on the enclosed form performed by you and Dr. Liebow, were included only in the 1966 progress report.

It would be a considerable amount of work to retrieve the initial gradings for individual patients and I do not believe it would be productive. However, as you know as part of the FDA audit, the baseline ECGs for deceased patients and a small sample of surviving patients were taken for assessment within the FDA. This involved a total of 159 ECGs. It would be useful if you reviewed these ECGs in anticipation of the report of the independent reading of these ECGs at the FDA. These ECGs are being sent to you under separate cover.

It is my understanding that Dr. Osborne spoke to you about storing or retaining all of the original UGDP ECGs in your Reading Center. If that arrangement is acceptable with you, we will start to arrange for the transfer of these materials to Minnesota.

I enjoyed visiting with you in Puerto Rico and I look forward to hearing from you concerning the thoughts outlined above. Best regards.

Sincerely yours,

Genell

Genell L. Knatterud, Ph.D.
Professor and Deputy Director

GLK:wmr

Enclosures

cc: Dr. Ron Prineas
Dr. Christian Klimt