DEPARTMENT OF THE ARMY
MADIGAN ARMY MEDICAL CENTER
TACOMA, WASHINGTON 98431-5000

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REPLY TO
ATTENTION OF

HSHJ-CI

20 October 1992

SUBJECT: Minutes of the Clinical Investigation Committee, 16 Oct 92

1. The meeting convened at 1300 hours, 16 Oct 92

2. a. Members present:

COL Dan C. Moore, MC	Chairman
COL Marvin S. Krober, MC	Representative, Dept Pediatrics
COL Barbara Turner, AN	Representative, Dept Nursing
LTC Robert E. Jones, MC	Chief, Clinical Studies Svc, DCI
LTC John P. Kugler, MC	Representative, Dept Fam Practice
MAJ Frederick Burgess, MC	Representative, Dept Surgery
MAJ Richard Gomez, MC	Representative, Dept Pathology
MAJ Andrew Guertler, MC	Representative, Dept Emer Med
MAJ Douglas Powell, VC	Chief, Lab Animal & Surg Svc, DCI
MAJ Bernard J. Roth, MC	Representative, Dept Medicine
MAJ Robert Stewart, MS	Chief, Microbiology, DCI
CPT Curtis S. Hansen, MS	Representative, Pharmacy Service
CPT Jeffrey Hansen, MS	Representative, Clin Psychol Svc
CPT Rodger K. Martin, MS	Chief, Bioresearch, DCI
CPT Katherine Moore, MS	Chief, Biochemistry, DCI
Troy Patience, DAC	Statistician, DCI
Nancy Whitten, DAC	Recorder, non-voting member

b. Members absent:

Representative, Dept OB/GYN
Representative, Dept Radiology

c. Non-members present:

COL Ronald Cooper, MC	Chief, Infectious Disease Svc
MAJ Michael W. Peterson, MC	Resident, Emergency Med
CPT James P. Guevara, MC	Resident, Pediatrics
CPT Jan Vanderlinde, MC	Resident, Emergency Med
Lori Loan, R.N.	Nursing Research Service

3. The minutes of the previous meeting (18 Sep 92) were approved as written.

4. New protocols -

a. The Effect of Calcium Administration on Albuterol's Ability to Lower Serum K+ in a Hyperkalemic Swine Model by MAJ Michael W. Peterson, MC

The issues discussed were:

(1) Has it been shown that albuterol will lower the potassium in the pig model and, if so what dose will be required? Dr. Peterson stated that it is known that albuterol will lower the potassium in people, horses, and dogs, but it has not been shown in pigs. The first two pigs will be used to do a pilot study to provide this information. He noted that several people had brought it to his attention that there is no reason why he will have to euthanize the pigs, but rather let them recover and use them in the actual study; therefore using 7-9 pigs rather than 9-11.

(2) Figure 1 - mg should be changed to meq

(3) The dose of Telazole; Dr. Burgess stated that 10 to 12 mg/kg would be a very high dose of Telazole for the pigs. Dr. Powell stated that the dose should read 10-12 mg/pound.

(4) How the lab will handle the blood samples since there will be 400-500 samples. Dr. Peterson stated that he had discussed this with the lab and the samples will be batched.

(5) How to avoid hemolysis of the samples. Dr. Peterson stated that the samples would be centrifuged immediately and the serum frozen until the samples are run.

(6) How the pH values will be run. Dr. Peterson stated that these will be run by the Clinical Investigation Lab immediately.

(7) Since only 7 pigs are being studied, how to do the randomization in order to make sure that they don't come up with unbalanced treatment groups; i.e., three pigs that start with one treatment and only one that starts with another treatment.

DECISION: APPROVE 16; DISAPPROVE: 0

STIPULATIONS: (1) on Figure 1 change mg to meq
(2) change the dose of Telazole to mg/pound
(3) consult with Troy Patience and redesign the randomization to meet his approval

b. A Double-Blind, Placebo Controlled, Parallel Group, Multi-center Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium Avium Complex Disease in HIV-Infected People by COL Ronald H. Cooper, MC

The issues discussed were:

(1) Will MAMC be limited to 10 subjects and will it be able to provide 10 subjects. Dr. Cooper stated that MAMC could enter as many patients as they want to, and he thought 10 was a reasonable figure. Since this is a triservice study, an adequate number of subjects does not necessarily depend on MAMC.

(2) Since this population has fairly advanced disease, will the patients survive for the 18 month follow-up and will they stay on active duty or at least stay in this area for the follow-up. Dr. Cooper stated that these will be medically retired people at this stage and that most of them will stay in this area in order to receive treatment. He added that two years would be a reasonable average life expectancy for the subjects.

(3) Funding: Dr. Cooper stated that the medications will be supplied by the manufacturer through the Jackson Foundation and that MAMC will receive no funds for doing the study.

DECISION: APPROVE 16; DISAPPROVE: 0

STIPULATIONS: None

c. A Randomized Controlled Trial of Penicillin to Evaluate the Clinical Response in Group C Streptococcal Pharyngitis by CPT James P. Guevara, MC

The issues discussed were:

(1) Is there a benefit to the children and can a placebo be justified? Dr. Guevara stated that at present the standard of care at MAMC is not to treat these patients. Therefore, the treatment group would be receiving a potential benefit from the treatment, and he felt that the placebo would be justified because treatment was not being withheld. Also, there would be a benefit because the subjects would be seeing a physician more often than with standard care.

(2) Include the scoring index in the protocol.

(3) Will an equal number of males and females be entered; no both sexes will be asked to enter and a convenience sample will be used.

(4) The fact that fever will be a parameter that is looked at separately. How will it be explained to the parents when to give an antipyretic or not to give one at all. Dr. Guevara stated that they will ask the parents not to give an antipyretic for the first 72 hours; however, if the child is obviously very sick with a fever of 100 to 105 then he could not ethically justify withholding the antipyretic. He felt that giving the child an antipyretic would not necessarily mean that the data could not be entered in the analysis. Dr. Roth suggested giving the parents a cut off score of perhaps 102 so that they would not face the dilemma of whether or not to give the child an antipyretic. Then the number of times that an antipyretic was given could be counted and placebo versus active therapy could be compared. COL Turner asked if giving an antipyretic was standard treatment in the clinic. Dr. Krober stated that it is generally the decision of the physician because some physicians do not like the routine use of antipyretics and therefore don't routinely prescribe them for fever. Dr. Dan Moore stated that the investigators need to know if an antipyretic was given and how many times so that when temperatures are looked at the investigator would have some idea of what might be affecting the child's condition other than the penicillin. Dr. Krober stated that only the study physicians would be seeing the patients so there should be some way to account for this.

(5) A study physician will be available on Saturday and Sunday to see the subjects whose 48 hour checkup is due on those days.

(6) The placebo and the drug will both be given in suspension form. The PI has discussed the placebo with the Pharmacy who is unable to make it. The PI has discussed this with a couple of drug companies who have shown some interest, but will not have an answer for 60 to 90 days.

(7) There will be one group of patients diagnosed immediately on rapid strep and one group that is negative on rapid strep but positive on culture. Therefore there will be a 24 hour difference in the time of the start of therapy between the two groups. Dr. Guevara stated he did not plan to randomize the group separately. Dr. Moore stated that it could possibly turn out that by a fluke in randomization more of the late culture positive ones would be in one group and more of the rapid strep ones in the other group who would end up with different symptom scores because the late group was already improving at the time they entered the study and this could skew the results. Dr. Krober stated that since they do not have much data on the natural history of Group C strep it is possible that the 24 hours could make a difference.

DECISION: APPROVE 15; DISAPPROVE: 0 ABSTAIN: 1 - Dr. Krober, AI

STIPULATIONS: (1) change plan to state how it will be determined if an antipyretic was given and how often and
(2) state the advice given to the patients
(3) stratify the randomization by method of diagnosis
(4) include scoring index
(5) determine how placebo will be obtained and obtain appropriate approval for that

10. The meeting adjourned at 1440 hours.

Nancy J. Whitten

NANCY J. WHITTEN, DAC
Recorder

Dan C Moore COL MC

DAN C. MOORE, M.D.
COL, MC
Chairman

APPROVE/~~DISAPPROVE~~

L M Burger

LESLIE M. BURGER, M.D.
Brigadier General, MC
Commanding

26 Oct 92
Date