



Fall Newsletter - October 1996

**A Word from the Medical Director**

Hypertension is a highly prevalent condition in the United States adult population, affecting at least 43 million people. Evidence suggests that hypertension, diabetes, and stroke disproportionately affect individuals in the Southeast. Although awareness and treatment has improved over the last two decades, only 25 percent of all hypertensives have attained blood pressure levels <140/90 mm Hg. Many factors influence the effectiveness of prescribed anti-hypertensive drug therapy.

At Parke-Davis, we are committed to high-quality research, which has practical implications for the clinician in the general community. We first began conceptualizing the study design for A-TIME last year. With input from interested researchers and thought leaders in the academic community, a study that examined the effect of Quinapril in controlling blood pressure based on titration intervals of fast versus slow was designed. In addition, we wanted to investigate whether differences in titration intervals impacted the number of therapeutic agents required for blood pressure control.

It was clear that we would require the assistance of a Data Coordinating Center to assist with the design of the protocol, case report forms, and the management of the data collection and analysis. We chose The Bowman Gray School of Medicine, based on their interest in the project and their reputation for excellence in epidemiology and clinical research. As you are aware, Dr. John Flack of the Hypertension Center at Bowman Gray, is our principal investigator.

It was important to us to have the ability to perform sub-group analyses for those populations that have historically been under-researched. Therefore, we planned on enrolling sufficient numbers of Hispanics, African Americans, diabetics, and women into the trial to perform these analyses.

We are now two-thirds of the way through the Accupril Titration Interval Management Evaluation, and we can certainly see the light at the end of the tunnel. I would like to applaud all investigators and the Data Coordinating Center for maintaining high standards of good clinical research as well as a high level of enthusiasm.

We are counting on you. You should be aware and proud of the fact that this data will be a necessary contribution to the literature on the pharmacological treatment of hypertension.

Best regards and continued well wishes for the completion of the patient enrollment.

Elizabeth Attias-Yon, Sc.D.  
Medical Director, Parke-Davis

**ATIME ABSTRACT**  
**Treatment of Hypertension**  
**A Re-evaluation of the Paradigm**  
**by John M. Flack, M.D., M.P.H.,**  
**Principal Investigator**

BP thresholds trigger therapeutic interventions that do not differ according to the age, race, ethnicity or gender of the individual. Further, therapeutic BP targets should be <140/90 mm Hg in most hypertensives unless the patient is unable to tolerate BPs this low.

A general therapeutic strategy should be adopted for the hypertensive whose therapeutic interventions, both drug and non-drug, are based on individual characteristics as opposed to inadequate hypertension treatment. Anti-hypertensive drugs of any drug class should not be denied to individuals in any race or ethnic group based on a blanket presumption of a lack of hypotensive efficacy. The majority of *individuals* in any ethnic or racial group will manifest a favorable BP response to various antihypertensive agents within any drug class.

A general therapeutic strategy should be adopted for hypertensive patients where therapeutic interventions, both drug and non-drug, are based on individual characteristics as opposed to immutable group (i.e., race) designations. Adequate BP control, coexisting medical conditions, and long-term tolerability should be central considerations when selecting initial drug therapy as well as when prescribing additional antihypertensive medication(s) for all hypertensive patients.

**Protocol Reminder**

The ATIME study is a mandatory titration study. If a patient returns for a follow-up visit and blood pressure does not meet protocol target of <140/90, the dose of Accupril must be titrated up as per the protocol flow titration schedule (see page 9, ATIME Investigator's Binder for more details).

**Important Telephone Numbers**  
If you have questions regarding the study, please contact Mizpah Shepherd at the Coordinating Center.  
ATIME Coordinating Center      800-BP-STUDY  
ATIME fax                              800-611-1274

**Reminders From the  
Data Coordinating Center**

Patient recruitment is one of the most challenging yet enjoyable periods of a clinical trial. At this time, we think about potential participants and try to enroll as many patients as possible. The following tips will ensure that your efforts are successful:

- Carefully evaluate potential participants for exclusions.
- Make sure all inclusion criteria are met. It is helpful to have pocket cards with eligibility criteria. Include information on the cutpoints for year of birth and blood pressure.
- Make sure the patient understands what is expected during study participation.
- Keep a master log of all enrollees with name, study ID, titration schedule and date of next appointment.
- Send the case report forms to the coordinating center immediately after randomization, by fax or mail. Don't wait until the patient has completed all visits.

**Notice: Serious Adverse Event**

Please call Michael Kilbaner at 800-223-0432 for all serious adverse event reporting.

**A Few Words on Submitting Forms**

As always, your attention to the detail work required by the forms of the ATIME study is critical to the validity of the research conducted. Please follow these submittal guidelines.

**For patient enrollment**

To ensure proper patient enrollment, please send the following forms immediately following week 0 visit:

Labwork

Week -2 CRF (This visit cannot be combined with week 0)

Week 0 CRF

Sociodemographic data

Concurrent Med CRF

*Reminder:* Average blood pressure will be used to determine entry eligibility. BP must meet the following guidelines: SBP<170/DBP 90-104 or SBP 140-169/DBP <105 at **week 0 not at week -2**. Age range for this trial is 21-75 years old.

**For patient completion**

Please send in end-of-study case report forms when each patient has completed the trial.

**Mail forms, if more than 15 pages, to:**

Hypertension Center  
ATIME  
Bowman Gray School of Medicine  
Medical Center Boulevard  
Winston-Salem, NC 2751-1032

**Fax forms, if less than 15 pages, to:**

800-611-1274

**Meeting Date to Remember**

12th International Interdisciplinary  
Conference on Hypertension in Blacks  
July 20-24, 1996 — London, England  
For more information, please call ISHIB  
at 404-875-6263.

**Patient Enrollment Facts and Figures**

As of October 22, 1996  
3,204 patients enrolled  
398 sites have enrolled at least one patient  
ATIME top 5 recruitment sites  
Site 695, Dr. Ronald McCoy, AL  
Site 424, Dr. Alberto Lee, Charleston, WV  
Site 432, Dr. Gregory Papas, New Castle, DE  
Site 242, Dr. Laurence Neufeld, Tampa, FL  
Site 920, Dr. George Sutton, Daphne, AL

**ATIME Study**  
International Society on  
Hypertension in Blacks  
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