

## MSH DATA ANALYSIS AND MANUSCRIPTS

*Analysis topics are numbered as in previous issues of this report. **Recently received proposals are denoted by an asterisk (\*)**. If a publication has resulted from the analysis, the topic title is the title of the published paper. Authors, as they appear in the publication, are listed next. If the topic was additionally presented at a meeting or published as an abstract, the citation is provided where available.*

### MAINLINE RESULTS

- M-01 Design of the Multicenter Study of Hydroxyurea in Sickle Cell Anemia. Charache S, Terrin ML, Moore RD, Dover GJ, McMahon RP, Barton FB, Waclawiw M, Eckert S, and the MSH Investigators. 1995; *Controlled Clinical Trials*: 16:432-446.
- M-02 Baseline Results  
Charache S, and the MSH Investigators.  
Published abstract: *Blood Suppl 1 to 82(10):365a (1993)*.
- M-03 Effect of Hydroxyurea on the Frequency of Painful Crises in Sickle Cell Anemia (Data through June 1994). Charache S, Terrin ML, Dover GJ, Moore RD, Barton FB, Eckert S, McMahon RP, Bonds D, and the MSH Investigators, 1995; *New Engl J Med* 332:1317-1322. Abstract presented at AAP 5/5-8/95.
- M-04 Fetal Hemoglobin, Hydroxyurea and Sickle Cell Anemia: Clinical Utility of a Hemoglobin “Switching” Agent. Charache S, Barton FB, Moore RD, Terrin ML, Steinberg MH, Dover GJ, Ballas SK, McMahon RP, Castro O, Orringer EP, and the MSH Investigators, 1997; *Medicine* 75(6):300-326.
- M-05 Fetal Hemoglobin in Sickle Cell Anemia: Determinants of Response to Hydroxyurea. Steinberg MH, Lu ZH, Barton FB, Terrin ML, Charache S, Dover GJ, and the MSH Investigators. 1997; *Blood* 89(3) 1078-1088.  
Published abstract: *Blood 86 (Suppl 1): 418a, 1995*.
- M-06 Treatment Effect on Quality of Life and Demographics (see A-05)  
Terrin, Ballas, Waclawiw, Ewart, Barton, Bonds, and the MSH Investigators.
- M-07 Treatment Effect on Daily Pain  
Smith, Ballas, Barton, and the MSH Investigators.
- M-08 Cost and Economics of Hydroxyurea Treatment  
Moore, Ballas, Charache, Dover, Terrin, Castro, and the MSH Investigators.  
Published: *AJ Hematology* 64: 26-31, 2000.
- M-09 Chest Syndrome  
Vichinsky, Castro, Ballas, Dover, Embury, Terrin, Orringer, Pegelow, and the MSH Investigators. Writing group meeting 7/24/95 (Baltimore). Results distributed 8/4/95. Draft manuscript 4/95.

- M-10 Keeping the Blind in a Clinical Trial  
Barton, Moore, Terrin, Charache, Koshy, and the MSH Investigators.  
Published abstract: Treatment guesses by patients and investigators in a double-blind clinical trial. 1996. *Controlled Clinical Trials* 17:40S.
- M-11 Effect of Discontinuation of Hydroxyurea on Effectiveness  
Swerdlow and the MSH Investigators.
- M-12 Long-term effects of hydroxyurea usage on laboratory measurements\*  
Kutlar, Eckman, B. Barton
- M-13 Analgesia Usage in Sickle Cell Patients\* (Combined with old D-04: Analgesia)  
Ballas, Smith, Castro, Bellevue, B. Barton and MSH Investigators  
D-04 Proposal received 12/15/93; approved 01/31/94.  
Poster presentation at the National Sickle Cell Meeting, Mobile AL, March 1996.
- M-14 Quality of Life  
Ballas, Barton, Pegelow, Waclawiw, Koskhy, Eckman, Swerdlow, Terrin, Bonds, and the MSH Investigators.  
Abstract published: *Controlled Clinical Trials* 15(35): 120S, 1994
- M-15 Effect of Hydrxyurea on Mortality and Morbidity in Adult Sickle Cell Anemia  
Steinberg, Barton, Castro, Pegelow, Ballas, Kutlar, Orringer, Bellevue, Olivieri, Eckman, Varma, Ramirez, Adler, Smith, Ataga, Carlos, DeCastro, Bigelow, Saunthararajh, Telfer, Vichunsky, Claster, Bridges, Waclawiw, Bonds, Terrin. *JAMA* 289(13): 1645-1651, 2003.  
Published abstract: *Blood* 96(11): 485a. 2000.
- M-16 Combined with D-22
- M-17 Long-term Mortality in Sickle Cell Patients using Hydroxyurea\*  
Eckman, B. Barton
- M-18 Exposure to Hydroxyurea and Pregnancy Outcomes in Patients With Sickle Cell Anemia.  
Samir K. Ballas, M.D., FACP, William McCarthy Ph.D, Nan Guo, BS, Laura DeCastro, M.D., Rita Bellevue, M.D., Bruce A. Barton, Ph.D., Myron A, Waclawiw, Ph.D., and the investigators of the Multicenter Study of Hydroxyurea in Sickle Cell Anemia.  
Published: *JNMA* 10/09 vol. 101.no. 10
- M-19 Pulmonary Hypertension in Sickle Cell Patients using Hydroxyurea\*  
Castro, Ataga, B. Barton
- M-20 Developmental Outcomes of Offspring of Adults Treated With Hydroxyurea on the Multicenter Study of Hydroxyurea. F. Daniel Armstrong, Ph.D, Martin Steinberg, M.D., Samir Ballas, M.D., Kenneth Ataga, M.D., Myron Waclawiw, Ph.D., Abdullah Kutlar, M.D., Paul Swerdlow, M.D., and William McCarthy, Ph.D. for the Multicenter Study of HydroxyureaExtension Investigators.  
Published abstract: *ASH* 2009 (PN) 1543
- M-21 Cytogenetic Abnormalities in Sickle Cell Patients\*  
Kutlar, B. Barton

- M-22 Dense cells and Reticulocytes in Sickle Cell Patients\*  
Ballas, Dover, B. Barton
- M-23 Sickle Cell Genetic Markers: Geographic distribution and Relation to Pain Outcomes in Multicenter Study of Hydroxyurea. Samir K. Ballas, M.D., William McCarthy, Ph.D., Robert Bauserman, Ph.D. Oswaldo L. Castro, M.D., Myron A. Waclawiw, Ph.D.  
Published abstract: ASH 2009 (PN) 2592
- M-24 Patterns of Anagesic Utilization in the Multicenter Study of Hydroxyurea. Samir K. Ballas, William McCarthy, Ph.D., Robert L. Bauserman, Ph.D., Oaswaldo Castro, M.D., Paul Swerdlow, M.D. Myron A. Waclawiw, Ph.D., Bruce A. Barton, Ph.D.  
Published Abstract: ASH 2009 (PN) 2577
- M-25 Definition of Responders to HU Therapy: Revisited  
Samir K. Ballas, M.D., William F. McCarthy, Ph.D., Robert L. Bauserman, Ph.D., Faramarz Valafar, Myron A. Waclawiw, Ph.D., Bruce A. Barton, Ph.D. Abdullah Kutlar, M.D.  
Published abstract: ASH 2009 (PN) 1513

#### DATABANK STUDIES

- D-01 Rank Statistics for Analysis of a Clinical Trial  
McMahon, Terrin, Barton and the MSH Investigators.  
Published abstract: *Cont Clin Trials* 13:420, 1992.
- D-02 Measurement of Pain in Sickle Cell Anemia  
Proposal received 9/17/92; approved 10/27/92.  
Published abstract: *Blood Suppl 1 to 82(10):475a (1993)*.  
Abstract authors: Swerdlow, Ballas, Smith, Barton, Terrin, and the MSH Investigators  
Poster: Sickle Cell Centers Meeting, New York, NY, 3/94.  
Manuscript authors: Smith, Barton, et al.
- D-03 Measurement of Health Quality of Life  
Barton, Terrin, Charache, Koshy, Swerdlow, Ewart and the MSH Investigators.  
Proposal received 12/03/93; approved 12/13/93.  
Published abstract: *Cont Clin Trials* 15:120S, 1994.
- D-04 Combined with M-13
- D-05 Unusual Alpha Globin Gene Haplotypes in Sickle Cell Anemia.  
Lu ZH, Steinberg MH,\* and the MSH Investigators.  
Proposal received 12/23/93; approved 01/31/94.  
Presented at Sickle Cell Centers Meeting, New York, NY, March 1994.
- D-06 Clinical Manifestations of Sickle Cell Disease  
Ballas and the MSH Investigators.  
Received 6/7/93; approved 7/20/93.

- D-07 Dosage Titration and Toxicity Monitoring in the MSH  
Handy, Barton, Moore, McMahon, Eckert, Terrin, Dover, Charache and the MSH Investigators.  
Proposal received 11/94; approved 11/94.  
Published abstract: *Controlled Clin Trials*: 17:67S, 1996.
- D-08 Combined with M-23
- D-09 A Surrogate End Point for Sickle Cell Crisis from Pain Diaries  
Swerdlow, Smith, and the MSH Investigators.  
Proposal received 12/12/94. Draft manuscript July 1997.
- D-10 Defining a Sickle Cell Crisis  
Charache, Ballas, Heyman, Terrin, Moore, Embury, and the MSH Investigators.
- D-11 Blood Transfusions in the MSH  
Dover, Ballas, Moore, Barton, Pegelow, Castro, Orringer, and the MSH Investigators.
- D-12 Description of Patients Who Refused Hydroxyurea Treatment  
Embury, and the MSH Investigators.
- D-13 An Extension of Stochastic Curtailment for Incompletely Reported and Classified Data on Recurrent Outcomes. McMahon RP, Waclawiw M, Geller NL, Barton FB, Terrin ML, and Bonds DB, 1997; *Controlled Clin Trials* 18:420-430. (Also 1996 *Contr Clin Trials* 17:72S).
- D-14 Iron Deficiency and the Response to Hydroxyurea  
Castro, Ballas, Barton, and the MSH Investigators.
- D-15 Genitourinary Complications of Sickle Cell Disease  
Burnett (Urology, JHU) and the MSH Investigators.  
Proposal received May 1995.
- D-16 Adverse Effects of Hydroxyurea on Liver and Kidney Function  
Bellevue, Ballas, and the MSH Investigators.  
Proposal received May 1995.
- D-17 Non-response to Hydroxyurea Therapy  
Ballas, Orringer, and the MSH Investigators.  
Proposal received May 1995.
- D-18 Ascertainment of the Primary End Point in a Multicenter Clinical Trial  
Barton FB, Terrin ML, Moore RD, McMahon RP, Charache S, and the MSH Investigators.  
Proposal received June 1995.  
Published abstract: *Controlled Clin Trials*: 17:67S (1996).
- D-19 Technicon Data  
Steinberg ML, Ballas SK, Narla M, Dover GJ, and others.  
Proposal received July 1996.

- D-20 Factors Affecting Compliance  
Earles A, Jones S, Barton F.  
Proposal approved July 1996.
- \*D-21 Leg Ulcers and Hydroxyurea  
Kutlar A, Ballas SK.  
Received 5/98; discussed by Executive Committee 5/98.
- D-22 Pattern of Utilization of Health Care Facilities by Adult Patients with SS. (combined with old M-16: Utilization of the Emergency Room for Painful Crises in Sickle Cell Disease\*)  
Smith, Ballas, et al.
- D-23 Impact of Hydroxyurea on Employment Among Patients With Sickle Cell Anemia. Smair K.  
Ballas, M.D., Robert L. Bauserman, Ph.D, William McCarthy, Ph.D., Myron A. Waclawiw, Ph.D., Bruce A, Barton, Ph.D. Abstract: ASH 2009 (PN)
- D-24 N-Terminal Pro-Brain Natriuretic Peptide Levels and Risk of Death in Sickle cell Disease  
Machado, Anthi, Steinberg, Bonds, Sachdev, Kato, Taveira-DeSilva, Ballas, Blackwelder, Xu, Hunter, Barton, Waclawiw, Castro, Gladwin, for the MSH Investigators.

#### ANCILLARY STUDIES

- A-01 Anthropometry  
Hackney AC, Heizer W, Hoffman E, Jones S, Strayhorn D, Orringer EP.  
Proposal received 10/08/91; approved 12/17/91.  
Published abstract (ASH, 1995): *Blood Suppl 1 to 86:141A (1995)*.  
Effects of hydroxyurea on the body weight, body composition and exercise performance of patients with sickle-cell anemia. 1997; *Clinical Science* 92:481-486.
- A-02 Effects of Hydroxyurea on Red Blood Cells in Sickle Cell Anemia  
Orringer.  
Proposal received 10/08/91; approved 12/17/91. Data file sent 7/26/95.  
Poster presented at National Sickle Cell Meeting, Mobile AL, March 1996.
- A-03 Visual Function and Ocular Microvasculature (WITHDRAWN)
- A-04 Rheological Effects of Hydroxyurea on Sickle Cell Erythrocytes  
Ballas SK, Marcolina MJ.  
Proposal received 5/28/91; approved 8/01/91.  
Published abstract (ASH 1995): *Blood* 86 (Suppl 1) 140a.  
*BrJ Hematol* 105:491-496, 1999.
- A-05 Quality of Life (see M-06)  
Cohen, Ferrans, Koshy\*. Changed to Ballas et al.  
Proposal received 7/18/91; approved 2/24/92. Data files sent June 1996.
- A-06 Parvovirus and aplastic anemia (WITHDRAWN)
- \*A-07 Development of Multivariate Predictive Model of Painful Episodes in Sickle Cell Anemia

Orringer EP and Root M.  
Received 1/98; approved 4/98.

\*A-08 Analysis of DNA Mutations Associated with Hydroxyurea Therapy  
Ware RE.  
Received 10/97; approved 4/98.