

PRELIMINARY REPORT
OF THE
BEST PRACTICES DEVELOPMENT CONFERENCE
FOR THE MANAGEMENT OF
ACUTE AND CHRONIC PAIN
IN ADULTS WITH SICKLE CELL DISEASE

September 25 – September 27, 2006

Dallas, Texas

Supported by National Heart Lung and Blood Institute
National Institutes of Health
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I. AGENDA

Day 1, September 25, 2006

Session 1: Noon-6:00 p.m.

Introductions and Charge to Panel

1:00 p.m. Welcome, Introductions, and Charge to the Panel
James Eckman, M.D., Conference Chairman
Kathryn Hassell, M.D.

State-of-the-Art Lectures:

1:30 p.m. New Revelations about Sickle Cell Pain – The PiCES Study
Wally R. Smith, M.D.

2:15 p.m. Sickle Cell Pain in the Emergency Department

Introduction:
Pain, Sickle Cell Disease and Emergency Departments
Knox Todd, M.D.

The American Pain Society Guideline and Analgesic Management
in the Emergency Department – Results from a Multi-Center
Project
Paula Tanabe, R.N.

The Emergency Department Treatment of SCD: The Evidence
Bernie Lopez, M.D.

Management of Acute Sickle Cell Pain Episode in the Emergency
Department: Impact of an Algorithmic Pathway for Pain
Management
Victoria Thornton, M.D.

3:30 – 3:45 p.m. Break

3:45 p.m. Acute Sickle Cell Pain in the Inpatient Setting

Management of Acute Sickle Cell Painful Crises in the Hospital
Samir Ballas, M.D.

Healthcare Disparities & Sickle Cell Disease:
Inpatient Management
Kristi Woods, M.D.

5:00 p.m. Chronic Sickle Cell Pain

Chronic Pain Pathology Management in Sickle Cell Disease
Lennette Benjamin, M.D.

Chronic Pain in Sickle Cell Disease: Basic Principles of
Assessment and Management
Marsha Treadwell, M.D.

Nutrition and Pain in Sickle Cell Disease
Maciej Buchowski, Ph.D.

The Psycho-Spiritual Impact on Patient's Well-being
Rev. Violet Dease, M.Div., M.S.W.

6:00 p.m. Challenges to Implementation of Best Practices

A Qualitative Assessment Of Sickle Cell Needs In Rural Georgia
Communities: A Patient's Perspective
Melissa S. Creary, MPH

Adult Sickle Cell Pain Management: Opportunities for
Improvement
James Eckman, M.D.

7:00 p.m. Adjourn

Day 2, September 26, 2006

Session 1: 8 a.m. - 1 p.m.

Specific Best Practices Development: Open Full Panel Discussion

8:00 a.m. Emergency Department Practices
Led by Knox Todd, M.D.

9:30 a.m. Break

10:00 a.m. Inpatient Practices
Led by Samir Ballas, M.D.

1:30 p.m. Lunch

Session 2: 2:00 p.m. – 6 p.m.

- 2:00 p.m. Chronic Pain Management
Led by Lennette Benjamin, M.D.
- 4:30 p.m. Break
- 4:45 p.m. Implementation Strategies
Led by James Eckman, M.D.
- Evening Preparation of summary of materials and slides for presentation
Drs. Eckman and Hassell

Day 3, September 27, 2006

8 a.m. – 11:30 a.m.

8:00 a.m. Presentation, discussion and review of best practices and
implementation strategies in each area
Full Panel

10:30 a.m. Discussion of slides to be present at the SCDAAs Public Forum

Noon Presentation of meeting summary to the SCDAAs “Meeting Unmet Needs” forum for
public commentary and feedback

II. PANEL MEMBERS

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Meeting Chair and Chair, Implementation Panel

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III. CONFERENCE OBJECTIVES AND GOALS

“Best Practices Development Conference for the Management of Acute and Chronic Pain in Adults with Sickle Cell Disease” represents the first in a series designed to address challenging areas in the clinical management of adults with sickle cell disease. The overall goals of the program series include:

1. Establishing a panel of experts in sickle cell disease, appropriate associated specialists (emergency medicine, pain medicine, psychology), primary care providers, sickle cell disease patients and members of the community to review available management recommendations, experience and observations
2. Assembling the panel before an audience of all interested providers at an annual conference to present management recommendations, research priorities and quality assurance outcomes measures for discussion and consensus development
3. Preparing a conference proceedings and appropriate publications to disseminate management recommendations, and devising strategies to facilitate awareness and acceptance amongst providers and patients.

The sentinel symptom of sickle cell disease is acute, severe pain which may require potent narcotic analgesic intervention. A number of treatment recommendations and algorithms have been developed and may be routinely employed in day-hospitals and other settings where some sickle cell disease patients receive care. However, a large number of adults with sickle cell disease seek care in other settings including emergency departments and hospitals served by primary care providers. Implementation of treatment recommendations in these settings can be erratic due to lack of familiarity with the disease, provider biases, and other challenges.

As importantly, adults with sickle cell disease can develop severe chronic pain. Poor adaptation to recurrent pain events, inadequate nutrition and drug addiction may complicate management of chronic pain. There are few guidelines or recommendations regarding the evaluation of prolonged or chronic pain in sickle cell patients. Optimal pain management may be achieved by the integration of non-opiate therapies including anti-inflammatory and anti-depressant medications, oral opiates, and non-pharmacologic approaches, based on the recognition of the sources chronic pain.

In fulfilling the programmatic goals listed above, utilizing the approach detailed in the Methodology section, the objectives of this conference are to:

1. Develop best practices recommendations that can be utilized as the basis for institution-specific acute and chronic pain management pathways in various care settings, including:
 - a. emergency department
 - b. inpatient hospital services, especially on general medical services
 - c. outpatient settings, especially by primary care providers
2. Create work products that will result in a quality improvement plan to establish best practices for the treatment of sickle cell pain
3. Identify strategies for the successful dissemination and implementation of best practices in collaboration with representative partners, including:
 - a. professional societies (specialty, emergency medicine, primary care)
 - b. agencies (health care services, governmental)
 - c. patient advocacy groups

IV. METHODOLOGIES

The topic of best practices in the management of sickle cell pain was divided into four areas of focus: Acute Pain Management in the Emergency Department, Acute Pain Management in the Inpatient Setting, Chronic Pain Management, and Best Practices Implementation Strategies. Chairpersons were selected for each section and panel members were chosen by these chairs to obtain input from a variety of professionals (physicians, nurses, psychologists, medical social workers, clergy) from multiple disciplines (hematology, emergency medicine, hospital medicine, nutrition, pharmacology, psychology, religion/spirituality, health services delivery). Those affected by sickle cell disease were also included on the panel.

The follow tasks were be completed by panel members prior to the actual conference:

1. Review of the available literature. In some cases, formal searches of available medical literature were supported by research library support staff (emergency medicine) or grant support staff (acute pain management)
2. Solicitation of input from other resources and experts with in care networks, sites of practice, or agencies.
3. Preparation of a 20-30 minute presentation about the state-of-the-art in their area of expertise/experience
4. Development of proposed specific best practices for management of acute and chronic sickle cell pain in various care settings.
5. Identification of areas in need of further research.
6. Development of strategies for dissemination and implementation of consensus results, and measures of quality assurance and outcomes.

The conference was held from September 25-27, 2006 in conjunction with the annual national Sickle Cell Disease Association of America meeting in order to permit attendance at both meetings and input from stakeholders.

On Day 1 of the conference, guest speaker Wally Smith, M.D., principal investigator for the PiCES Study, presented data regarding the nature and frequency of sickle cell pain in adult patients. State-of-the-art lectures were presented and reviewed by panel member to serve as background and a basis for subsequent discussion.

On Day 2, the chair of each focus area led the full panel through the development of an outline of best practices. The outline was organized into six areas:

Scope: specification of the target population and site of implementation

Terminology: commonly used terms and their definition/meaning in the context of the practice setting

Assessment: important elements related to pain, including physical/medical comorbidities, psychosocial considerations, health care utilization

Treatment: best practices in the management of pain which may serve as a tool for development of specific treatment pathways

Coordination: opportunities for integration of practices into overall management strategies

Monitoring: recognition of beneficial and harmful effects of intervention

Outcomes: indicators of successful implementation and effective therapy

Implementation: mechanisms to promote broad adoption of best practices and development of specific pathways at sites of practice

Discussion and input from the panel was captured by a note taker using a flipchart for easy reference, and by professional meeting support staff from American Institutes of Research, who created two electronic documents, one with summarized text and the other a bulleted outline. Audience members included adult hematologists, nurses, clinical care coordinators and members of sickle cell support groups from various parts of the country (e.g. California, New York, Colorado, Ohio, Vermont), who actively participated in all discussions.

Through the evening of Day 2, Dr. Eckman and Dr. Hassell compiled information from all sources into a final outlined proposal of best practices in each of the four sections. They also created a brief summary slide set for presentation to the public SCDAAs forum.

On Day 3, the outline of each section was presented to the full panel for further discussion. At the completion of this session, the slide set was reviewed and revisions made as suggested by panel members.

Dr. Eckman presented a summary of the conference to the “Meeting Unmet Needs” public session of the Sickle Cell Disease Association of American National Meeting, after which public commentary was invited. There were an estimated 200 attendees to this session. Feedback and commentary from this forum was noted and will be incorporated into the final proceedings.

V. SUMMARY OF PRESENTATIONS AND RECOMMENDATIONS

PRESENTATIONS

1. New Revelations about Sickle Cell Pain – the PiCES Study Wally R. Smith M.D.

Dr. Smith, the Principal Investigator of the PiCES Study, presented information regarding the pain experiences of adult patients with sickle cell disease as characterized by long-term daily diary reporting. His study noted

- Pain in sickle cell disease is the rule rather than the exception: 55% of patients had pain on more than half their days, 30% essentially daily
- Much of sickle cell pain is not called a “crisis” by patients
- Utilization of the health care system is the exception rather than the rule for response to pain in sickle cell disease: only 3.5% of days did patients utilize
- Current pain terminology and measurement in sickle cell disease may lead to misclassification, distorted communication, undertreatment

2. Pain, Sickle Cell and Emergency Departments Knox H. Todd, M.D.

Dr. Todd introduced the Emergency Medicine Panel and outlined an approach to the development of Best Practices, encompassing the scope of the practice, pathway principles, assessment, treatment, coordination of care, monitoring, outcomes and implementation.

3. The American Pain Society Guidelines and Analgesic Management in the Emergency Department – Results of Multi-Center Project Paula Tanabe, R.N.

Ms. Tanabe summarized the results of her multi-center study which demonstrated that during a study of 612 ED visits for sickle cell pain by 159 unique patients that the median time to initial analgesia of 90 minutes, which is 4.5 times the recommended time frame by the American Pain Society. Factors that impacted this delay included lower triage priority levels, female gender and lack of i.v. access, and also likely reflected attitudes and perceptions of ED providers, overcrowding, knowledge deficits, and need for individualized and general care pathways.

4. The Emergency Department Treatment of SCD: The Evidence Bernie Lopez, M.D.

Dr. Lopez reviewed the few small studies and case series available in the literature, usually derived from academic University-based practices, noting the “benefit” of interventions was characterized as decreased number of ED visits, less need for rescue narcotics or amount of narcotics used. Despite common application, there were no data that demonstrated benefit from intravenous fluids or oxygen therapy, and no clear

scientific evidence justifying a particular dose, route or type of narcotic analgesic. He concluded significantly more research is needed to improve pain management in sickle cell disease in the ED.

5. Management of Acute Sickle Cell Pain Episode in the Emergency Department: Impact of an Algorithmic Pathway for Pain Management
Victoria L. Thornton, M.D.

Dr. Thornton presented the experience in the Duke ED observation unit where the application of an acute pain management medication protocol, utilizing patient-controlled analgesia, improved patient satisfaction with physician and nursing care to 98% and 81%, respectively. Analgesia was delivered within 60 minutes to 84% of patients, and the majority of patients were assigned an ESI triage category of 2.

6. Management of Acute Sickle Cell Painful Crises in the Hospital
Samir K. Ballas, M.D.

Dr. Ballas discussed the types and typical course of sickle cell painful episodes, and the tailoring choice and route of treatment based on careful assessment and communication between the patient and members of the care team. Therapy may include opioid and nonopioid as well as adjuvant medications, titrated to “relief” using maintenance and breakthrough coverage. Consideration of chronic medication use and gradual tapering of acute interventions should be based on frequent reassessment.

7. Healthcare Disparities & Sickle Cell Disease: Inpatient Management
Kristi F. Woods, M.D., M.P.H.

Dr. Woods outlined racial and ethnic health care disparities that impact on the management of sickle cell disease and proposed strategies for eliminating them, including legal, regulatory and policy interventions, quality data collecting and monitoring, research, advocacy and exposure.

8. Chronic Pain Pathology: Management in Sickle Cell Disease
Lennette Benjamin, M.D.

Dr. Benjamin characterized the factors contributing to chronic pain in sickle cell disease and the need to individualize therapy based on a multi-disciplinary construct incorporating biopsychosociocultural features and specific characteristics of different pharmacologic interventions. She emphasized the need to acknowledge the impact of provider beliefs on the implementation of well-established principles of opioid and nonopioid medication administration as outlined in the 1999 American Pain Society Sickle Cell Pain Management monograph.

9. Chronic Pain in Sickle Cell Disease: Basic Principles of Assessment and Management
Marsha J. Treadwell, Ph.D.

Dr. Treadwell focused on the pain experience, stress response and social and economic impacts of chronic pain in sickle cell disease patients, noting correlates of frequent pain to include negative self concept, anxiety, depression, poor school/work performance, social isolation, decreased participation in activities of daily living and diminished self-efficacy. Negative provider factors, including over- or undertreatment, negative views of patients, underestimate of daily pain and overestimates of addiction, adversely impact management. After thorough assessment of the pain experience, goals of management emphasize control of pain, improvement in function, improved health-related quality of life and avoidance or minimization of therapeutic toxicity.

10. Nutrition and Pain in Sickle Cell Disease
Mac Buchowski, Ph.D.

Dr. Buchowski presented a summary of his review of the nutrition literature as it relates to sickle cell disease, noting multifactorial micronutrient deficiencies, growth delay and altered metabolism have been recognized. These micronutrients may play an important role in the regulation of inflammation and oxidative stress, which are recognized to impact the pathophysiology of sickle cell disease. Appropriate fluid repletion was discussed as a way to prevent or shorten crisis. He reviewed dietary components, including isoflavons, anthocyanins, lipids, and sucrose, which may modulate pain mechanisms and called for more extensive research into the underlying mechanisms and therapeutic applications.

11. The Psycho-Spiritual Impact on Patient's Well-Being
Rev. Violet L. Dease, M.Div., M.S.W.

Reverend Dease defined spirituality and religiosity, identifying both as having significant positive impact on the general well-being, functional ability, health, and overall life satisfaction, noting this may be a particularly important aspect of life for patients with sickle cell disease. She recommended the recognition of the role and inclusion of religion and spirituality in a plan of care, citing studies demonstrating benefit in acute and chronic illnesses.

12. A Qualitative Assessment of Sickle Cell Needs in Rural Georgia
Communities: A Patient's Perspective
Melissa S. Creary, M.P.H.

Ms. Creary presented the results of her qualitative cross-sectional study to investigate the local needs of the sickle cell community in rural areas, utilizing focus groups and a brief questionnaire. She found that patients were generally knowledgeable about their disease, that pain management was very important to them and may be unaware of what they don't know. However, patients will use information if they know of its existence, and will access healthcare if the provider was perceived as having knowledge and a positive attitude toward sickle cell disease. She recommended priority be placed on increasing patient and provider knowledge; recognition of stigma, which

affects utilization; open dialogue and cultural competency training of providers; and further research in this area.

13. Adult Sickle Cell Pain Management: Opportunities for Improvement
James R. Eckman, M.D.

Dr. Eckman emphasized the role of provider perceptions and attitudes regarding pain in adults with sickle cell disease, but also noted that patients also develop perceptions about pain management based on their own coping skills as well as their interactions with the health care system. He discussed the problems of pseudoaddiction and hyperalgesia, as well as the challenges of limited resources and funding for an adequate multidisciplinary pain team approach. He summarized the overall problems in this area, and charged the panel with the task of identifying the best approaches to acute and chronic pain management in the inpatient and outpatient setting, identification of the appropriate providers, strategies for evaluation, dissemination and implementation, and funding for initiatives and research in this important area.