SICKLE CELL DISEASE
TREATMENT DEMONSTRATION PROGRAM

MODEL PROTOCOL AND COMPENDIUM OF RESOURCES

OCTOBER 2014

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INTRODUCTION

Between 2010 and 2014 Nine Sickle Cell Disease Treatment Demonstration Program (SCDTDP) funded grantee networks from across the United States applied the principles of collaborative learning and improvement science to improve processes and systems of care for individuals living with sickle cell disease. The National Institute for Children’s Health Quality (NICHQ) served as the National Coordinating Center during this period.

This model protocol includes recommendations regarding the highest-leverage changes that led to process improvements across five dimensions of sickle cell care listed below in the Hemoglobinopathy Learning Collaborative, sponsored under the auspices of Health Resources and Services Administration (HRSA) and funded by the SCDTDP:

1. Acute care
2. Medical home/care coordination
3. Screening and follow up
4. Transition of care
5. Hydroxyurea

The purpose of this model protocol is to provide clinicians, nurses, allied health professionals, community-based organizations and public health agencies with recommendations and strategies to improve care provided to individuals with sickle cell disease and trait. The National Coordinating Center strongly encourages organizations to develop an integrated advisory committee interested in sickle cell disease care comprised of multiple stakeholders including patients, parents, family members, community health workers or patient navigators, physicians, nurses and allied health professionals. These advisory committees should review these recommendations and consider testing and adapting some of these changes in their respective settings.

The majority of the recommendations result from a synthesis of changes implemented across the grantee networks that led to process improvements. NICHQ also reviewed and included some recommendations from existing published clinical practice guidelines and consensus statements related to the care of individuals with sickle cell disease. Lastly, the model protocol includes guidance from expert panels consisting of health care professionals with expertise in hematology, pediatrics, newborn screening, genetics and public and community health convened by NICHQ for the SCDTDP and the Sickle Cell Disease Newborn Screening Program (SCDNBSP). A systematic assessment of the quality of evidence associated with each recommendation was beyond the scope of the project, and some recommendations may highlight areas where future research is warranted given a limited existing evidence base. The model protocol was reviewed by representatives from all of the SCDTDP grantee networks, including patients and family members of patients, as well as the SCDTDP Oversight Steering Committee and HRSA program staff.
ORGANIZATION OF MODEL PROTOCOL AND COMPENDIUM OF RESOURCES

The model protocol includes a section for each of the dimensions of sickle cell care in which grantee networks worked: acute care, care coordination and self-management, screening and follow up, transition and hydroxyurea. This [model protocol] is not a comprehensive listing of changes for every dimension of sickle cell care but rather includes recommendations on the topics where SCIDTP grantee networks focused their efforts during the funding period. Each section includes an overview of the specific topic, including rationale for why it is important to improve this dimension of sickle cell care, and a discussion of the recommendations for high-leverage changes. The resources listed in each section of the model protocol were used by teams as they implemented the high-level changes in their organizations. The companion compendium of resources includes educational materials for patients and providers such as clinical algorithms, standardized order sets, and patient tracking tools.

ACUTE CARE

Acute vaso-occlusive episodes, often referred to as pain crises, are unpredictable bouts of pain that are the most common reason for emergency department visits and hospitalizations for patients with sickle cell disease. Timely and appropriate use of oral or parenteral analgesia (i.e., pain medication) can result in pain relief, reduce hospitalizations and reduce the development of chronic pain syndromes. Both pediatric and adult patients with sickle cell disease experience prolonged periods of waiting for pain medications in the emergency department despite the existence of detailed guidelines and quality indicators related to the management of pain crises. Emergency department visits and hospitalizations account for a significant proportion of health care expenditures in this population.

An important component in improving key processes in the management of pain crises in the emergency department is forming a multidisciplinary group comprised of patients and family members, providers from the emergency and hematology departments, and other physicians, nurses, nurse practitioners, psychologists, pharmacists and allied health professionals such as community health workers. Key responsibilities for this team include identifying a physician and/or nurse “champion” from the emergency department, inviting individuals with sickle cell disease to review performance data and provide ideas to inform the initiative, openly sharing data with affected individuals and emergency department staff, and offering trainings and educational materials to nursing and physician staff.

**Recommendations:**

1. Rapidly triage patients and assess recent use of pain medications and quality and location of patient’s pain. Use age-appropriate pain assessment tool to assess intensity of pain.
2. Analgesia should be rapidly started within 30 minutes of triage or within 60 minutes of registration.
3. Use standard order sets for management of sickle cell pain in acute care settings such as the emergency department and, when appropriate, use individual pain treatment plans to facilitate timely, effective and safe management of pain crises.
4. Reassess in regular intervals (e.g. 30 minutes) after each dose of pain medication for pain relief and side effects.
5. Regularly assess patient and family satisfaction with and experience of care in acute care setting.
6. Regularly track performance on timeliness of assessment and reassessment of pain and administration of pain medications to assess impact of process improvements.
7. Consider initiating patient-controlled analgesia for patients who will be admitted to the hospital for pain management.
8. Consider use of intranasal fentanyl as a short-term intervention to relieve pain when intravenous access is difficult or until intravenous access is obtained.
TABLE 1: High-leverage changes and resources tested by grantee networks in acute care

<table>
<thead>
<tr>
<th>Change Idea</th>
<th>What is it? (Definition) Why do we use it? (Rationale)</th>
<th>Resources</th>
</tr>
</thead>
</table>
| Pain assessment charts       | Since pain is often subjective and personal, pain assessment charts help patients describe the amount of pain an individual is feeling. Numerical and picture-based charts allow patients to communicate their pain more clearly so that interventions can be planned accurately. | Illinois SCDTDP Pain Chart  
Wong-Baker FACES Pain Rating Scale© |
| Standard order sets          | Standard order sets are a group of medical orders used to standardize diagnosis and treatment for specific medical conditions such as sickle cell pain based on clinical practice guidelines. These order sets communicate best practices, reduce variation and potential for medical errors, and enhance workflow. In this context, the order set standardizes the timeframes for triage, medication administration, and reassessment of pain with the goal of expediting patient care and decreasing delays in critical interventions such as administration of pain medication. Standard order sets can be paper-based or embedded in an electronic health record system. | California SCDTDP Sickle Cell Initial Order Set  
Massachusetts SCDNBSBP Pediatric ED VOE Protocol  
New Jersey SCDTDP ED Algorithm  
Tennessee SCDNBSBP Checklists for Pain, Acute Chest, Stroke and Iron Overload |
| Pain action plans            | Individual pain action plans list pain medication and doses that have been previously effective for that individual. Tailoring pain treatment to the individual facilitates faster and more effective pain management. Care plans should be developed and finalized with patients and their families based on their desired level of engagement. | California SCDTDP (English and Spanish) Pain Action Plan  
Massachusetts SCDNBSBP Adult ED Individualized Pain Plan  
Pennsylvania SCDNBSBP Pain Action Plan |
| Patient satisfaction surveys | Surveys allow individuals to let clinic staff know which parts of care worked well and which were less than ideal. Obtaining feedback from patients and families allows improvement teams to determine what areas need to be addressed more urgently than others. | Massachusetts SCDNBSBP Pediatric ED Satisfaction Survey  
Massachusetts SCDNBSBP Adult ED Satisfaction Survey |
| Patient-controlled analgesia pumps | A computerized pump which contains a syringe of pain medication prescribed by a physician is connected directly to a patient's intravenous line. Patient-controlled analgesia pumps allow patients to control the timing of intravenous administration of their own pain medication, resulting in timely pain relief. | Massachusetts SCDNBSBP PCA Handout |
| Intranasal fentanyl          | Opioid analgesic administered intranasally (a squirt into the nose) to allow for rapid administration of first dose of pain medication while awaiting IV access or if IV access is difficult. This medication comes in a liquid preparation and is not available over the counter. Further studies are being conducted to assess the impact of this medication on subsequent doses of parenteral analgesia. | Massachusetts SCDNBSBP Intranasal Fentanyl handout  
California SCDTDP ED Protocol for IN Fentanyl |
MEDICAL HOME/CARE COORDINATION

Care for persons with sickle cell disease is often fragmented, spanning multiple providers and often multiple institutions. This results in many persons with sickle cell disease not having a medical home that coordinates their care. A patient-centered medical home is an approach to providing comprehensive primary care for children, adolescents and adults that is patient- and family-centered, comprehensive, coordinated, accessible and committed to quality and safety. The location of the medical home for individuals with sickle cell disease may vary based on patient and family preferences, and proximity to primary care and specialty care providers. One study highlighted that many children with sickle cell disease did not have care that met the standards for a patient-centered medical home. Additional literature has also shown that patients who receive comprehensive care had fewer emergency department visits and hospitalizations. Coordination between primary and specialty care is crucial to the provision of high quality care for patients with sickle cell disease, as the lack of regular ambulatory care may lead to increased health care utilization in acute care settings (including increased reliance on the emergency department, particularly among transition-age youth (ages 12-25) and adults) as well as missed opportunities for preventive care. Lack of outpatient hematology follow up after hospital discharge is a known risk factor for 30 day readmission among individuals with sickle cell disease.

One particularly important area of care coordination is the promotion of chronic illness self-management, which is crucial to improving outcomes for children and adults with sickle cell disease. Patients and families have a central role in managing their own or their child’s health. Engaging in healthy behaviors such as adhering to prescribed medications, eating a nutritious diet, drinking plenty of fluids, staying active, avoiding extreme temperatures and managing stress levels can lead to fewer instances of complications such as pain crises, and thus improve outcomes and overall quality of life. Knowing how to manage mild complications at home and when to appropriately seek health care also contributes to improved quality of life and may lead to lower health care utilization costs.

Improvements in the realm of care coordination are essential and will require both leveraging pre-existing relationships within networks and developing new relationships to expand and extend clinical and psychosocial services. In turn, these efforts will improve processes to increase the speed and ease with which patients are able to access health services, as well as address some of the psychosocial issues that are often seen in this population, including mental health issues, unemployment, and homelessness. Ultimately, improvements in the coordination of care across multiple systems and networks and in the provision of primary and specialty care will enhance the quality life of individuals with sickle cell disease.

RECOMMENDATIONS:

1. Develop an individualized care plan collaboratively with patient and/or family to facilitate communication of patient’s current treatment plan.
2. Develop health maintenance tool to monitor and track patients’ preventive screenings and vaccinations related to their care. Patients can be contacted to come in for requisite screenings and/or vaccinations.
3. Develop process for co-management between primary care provider and specialty provider; specifically outline which provider is responsible for each element of a patient’s care.
4. Incorporate care team huddles or meetings each week to review patients’ charts and/or care coordination tool and plan care that needs to be provided at upcoming medical visits.
5. Share tools such as health passports or patient diaries with patients that can be used to record, track and manage their treatment and care. Patients can also use this to coordinate care among clinicians.
6. Consider use of community health workers or patient navigators to assist with coordinating patient care.
7. Consider providing patients with self-management training such as the Stanford University Chronic Disease Self-management Program (CDSMP).
<table>
<thead>
<tr>
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<th>Resources</th>
</tr>
</thead>
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| Individualized care plans         | A medical summary that is a shared document including the patient/family perspective and values. This summary includes a listing of patient demographic information including patient and family (if applicable) contact information, sickle cell genotype, past medical and surgical history, medications, medication and food allergies, baseline lab results, pain management plan (home, emergency department, inpatient setting), treatment algorithms for pain, asthma action plan, provider information (primary care provider and sickle cell team members), pharmacy information, health insurance information, and disability level (if applicable). |                                                                                                                                                                                                 | Illinois SCDTDP Patient Needs Assessment form  
Ohio SCDTDP electronic health record tool (sickle cell disease-specific EPIC template “SMART Phrase”)  
http://www.medicalhomeinfo.org/how/care_delivery/#care                                                                                                                                   |
| Health maintenance tracking tool  | This tool provides a strategy for providers to track the care that patients receive and ensure that patients are up to date with their preventative care (e.g. screenings and vaccinations). This tool could be a paper-based checklist or embedded in the electronic medical record. This tool can be used during pre-clinic team meetings or huddles which is when the care team assembles at a predetermined time to look ahead on the schedule and anticipate the needs of the patients coming to the clinic on a particular day. |                                                                                                                                                                                                 | Illinois SCDTDP adult patient tracking log, care coordination checklist and screening tool  
New York SCDNBSP Well Sickle Checklist  
New Jersey Health Maintenance Checklist                                                                                                                                                       |
| “Health passport”/patient diary   | Patient-centered tool that includes a patient’s medical history and contact information for care providers used to facilitate communication between patient and providers. Patients can track their symptoms and interventions at home and use the data to consult with providers. |                                                                                                                                                                                                 | New York SCDNBSP patient event diary  
Ohio SCDTDP electronic health record tool (sickle cell disease-specific EPIC template “SMART” Phrase)                                                                                       |
| Patient navigators/community health workers | A patient navigator or community health worker is a member of the healthcare team who helps patients navigate and understand the healthcare system and get timely care. Navigators help coordinate patient care and can improve access to health care and social services such as insurance, housing, and employment. |                                                                                                                                                                                                 | Maryland SCDTDP (Urban Health Institution Community Health Worker program and the iHOMES program)  
Colorado SCDTDP Patient Navigators                                                                                                                                                    |
| Patient self-management training  | Self-management programs like the Stanford University Chronic Disease Self-Management Program train patients to deal with problems related to living with a chronic disease, appropriate exercises to enhance flexibility and endurance, use of medications, communication with health care providers and evaluating new treatments. Such programs build confidence, empowerment and decision-making skills among patients. |                                                                                                                                                                                                 | Stanford Chronic Disease Self-Management Program  
New York SCDNBSP Handout: Well Sickle Care Screening - Why needed?  
California SCDTDP Handout: What is Comprehensive Care in Sickle Cell Disease?  
California SCDTDP Surveys (Barriers to Care, Iron Overload, Chelation Adherence, Improving School Success)  
Tennessee SCDTDP online training modules                                                                                                                                            |
| Provider education to enhance patient self-management | The ACCEPT program (Advancing Communication and Care by Engaging Patients in Training) trains providers to integrate self-management support strategies (such as goal-setting) into routine clinical care. |                                                                                                                                                                                                 | Ohio SCDTDP and Ohio SCDNBSP’s ACCEPT Training Materials, including overview and follow-up                                                                                                                   |
SCREENING AND FOLLOW UP

Early studies documented that the early administration of penicillin prophylaxis reduced the incidence of pneumococcal infections by 84 percent and reduced mortality from such infections in children with sickle cell disease.20 This finding provided the rationale for newborn screening and early diagnosis (in the newborn period) to ensure prompt treatment of affected individuals.20 The result of screening performed in the neonatal period has immediate implications for the infant found to have the disease, but also longer-term implications for both the child and other family members, such as the ongoing need for genetic counseling and education.21

Only since May 1, 2006, have all U.S. states and the District of Columbia required and provided universal newborn screening for sickle cell disease, which also identifies sickle cell trait, despite a national recommendation to this effect in 1987.22,23 Each state has developed a newborn screening program that meets the needs and resources of the state. For sickle cell disease and sickle cell trait, some states have well-developed follow-up programs in which nurses, program specialists or community-based organizations contact families of infants with positive newborn screening results and, as necessary, arrange confirmatory testing and follow up with specialists and genetic counselors.24 Other states rely on the primary care provider to arrange for confirmatory testing, provide education to parents and refer patients to specialists.25 Variation also exists in the process of screening individuals who are not screened as infants including pregnant women and immigrants.

NICHQ encourages organizations involved in the care of individuals with sickle cell disease to partner across their communities to incorporate screening genetic counseling and education into their outreach activities. This will expand the reach to diverse populations such as recent immigrants who were not screened in the newborn period.

RECOMMENDATIONS:

1. State newborn screening programs should communicate results to patients or families and primary care providers.

2. Parents or caregivers of patients with confirmed diagnosis of sickle cell disease should receive genetic education about sickle cell disease.

3. Patients with confirmed diagnosis of sickle cell disease should be seen by a hematologist within three months of diagnosis.

4. Patients with confirmed diagnosis of sickle cell disease (SCD-SS and SCD-Sbeta zero thalassemia) should have prophylactic antibiotics initiated within three months of diagnosis to prevent invasive pneumococcal disease.

5. Patients with SCD-SS and SCD-Sbeta zero thalassemia who are younger than five years of age should be prescribed prophylactic antibiotics to prevent invasive pneumococcal disease.

6. Offer genetic education to individuals of reproductive age with sickle cell disease and sickle cell trait to allow for informed decision making. Consider developing electronic medical record prompts and other methods to alert providers that genetic counseling is needed during adolescence.

7. Consider conducting community outreach activities (such as health fairs, public service announcements, or social media posts) to encourage screening for sickle cell disease and sickle cell trait for individuals who were not screened in the newborn period.
### Table 3: High-leverage changes and resources tested by grantee networks in screening and follow up

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<thead>
<tr>
<th>Change Idea</th>
<th>What is it? (Definition) Why do we use it? (Rationale)</th>
<th>Resources</th>
</tr>
</thead>
</table>
| Educational and counseling strategies | Educational and counseling strategies include providing counseling and education over the phone, group clinic visits for newborns with sickle cell disease, and electronic health record prompts to remind providers to counsel sickle cell disease patients. Education entails information about genetics of sickle cell disease, managing pain crises and other sickle cell related complications, reproductive implications and health maintenance strategies. Education should be age-appropriate and occur throughout the lifespan for individuals with sickle cell disease and trait. | Missouri SCDTDP Screening and Trait Counseling Education Booklet and Presentation  
Tennessee SCDTDP Genes for Teens and Genes for Parents of Children with Sickle Cell Disease  
Massachusetts SCDBSP Parent’s Guide to Sickle Cell Disease |
| Pre- and post-tests             | Questionnaires to assess patient/family knowledge before and after counseling. Administer pre-tests before offering education and post-tests immediately after as well as 3-6 months later to assess retention of knowledge. | Illinois SCDTDP pre- and post-tests  
Illinois SCDBSP pre- and post-tests |
| Sickle cell trait toolkit       | This toolkit was developed by grantee network teams to help providers counsel individuals and families recently diagnosed with sickle cell trait. Toolkit provides educational materials about sickle cell trait and sickle cell disease that can be reviewed by families on a periodic basis. | Screening Affinity Group Sickle Cell Trait Counseling Resource Packet |
TRANSITION OF CARE

Because of great strides over the past few decades in care for individuals with sickle cell disease, these individuals are now living longer, transitioning from pediatric to adult care as they grow older. As patients transition from pediatric care to adult care, they experience a variety of challenges including leaving a familiar provider and environment, being seen by a provider who may not have knowledge of sickle cell disease, establishing independence from caregivers, and having adequate health insurance. Multiple factors may contribute to high mortality during the period immediately following transition from pediatric to adult care including disease progression, lack of routine care and adherence to treatment. In addition to increased mortality, young adults with sickle cell disease utilize emergency care services more often and have less frequent care maintenance visits during the transition years. Planned and coordinated transition from pediatric care to adult care is critical in ensuring no interruption in care continuity and improving health outcomes and overall quality of life of individuals with sickle cell disease.

RECOMMENDATIONS:

1. Develop a registry or listing of transition age youth in sickle cell program.
2. Establish a transition clinic/program to facilitate transition to adult care for patients 12 years and older that includes an agreed-upon transition policy posted in a visible place (e.g., waiting room, exam room, office).
3. Incorporate individual transition readiness assessments or checklists to prepare patients for transition of care.
4. Connect families, in advance of transition, with community and social services for planning and care coordination.
5. Consider scheduling a joint visit between the patient, pediatric hematologist or physician and adult hematologist or physician prior to transfer of care.
**Change Idea** | **What is it? (Definition)** | **Why do we use it? (Rationale)** | **Resources**
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Transition clinic | A transition clinic/program allows providers, patients and families to prepare for the transfer of care from pediatric to adult settings. Ideally, the process of preparing for transition to adult care begins in early adolescence. In developing a clinic, the first step is developing a transition policy. Clinics/programs must develop a method (e.g., registry) of tracking and monitoring transitioning patients, assessing readiness, and transferring care. Transfer is complete if the patient continues to attend visits with an adult provider. | **New Jersey SCDTDP Transition Policy**
Transition readiness assessment | Tools used to assess adolescents’ knowledge and self-efficacy in various knowledge domains including medical, cognitive, emotional, psychosocial, and academic. Skills assessed vary by age and patients should demonstrate increased autonomy over time. Assessments should be administered at the start of the transition period and throughout the process. Results should be used to inform the education individual patients receive during the transition process. | **California SCDTDP Transition Intervention Program—Readiness for Transition Assessment**
**Tennessee SCDTDP Readiness Assessment for Academic, Emotional, Medical and Psychosocial domains**
**New Jersey SCDTDP Autonomy Preparation Questions**
**Colorado SCDTDP Patient Activation Assessment**
**Colorado SCDTDP Changing Roles Assessment and Action Plan**
Sickle cell disease specific transition curriculum | The comprehensive curriculum covers all ages of the transition period (12-21 years of age) and includes recommendations of educational content for providers, patients and parents. The curriculum is organized into three main sections by age group, and each age group consists of three domains: medical, social, and academic. Use of the curriculum will ensure that all topics are covered throughout the transition planning process. Each domain includes guidelines for topics, suggested methodology, and techniques to measure efficacy. The curriculum can be used as a resource in both the medical and the community setting, and would be especially effective in organizing the work in partnerships. | **Transition Affinity Group Sickle Cell Disease Transition Curriculum**

**TABLE 4:** High-leverage changes and resources tested by grantee networks in transition of care

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**HYDROXYUREA**

Hydroxyurea is the only therapy approved for sickle cell disease by the Food and Drug Administration. This medication results in a decline in sickle cell-related complications such as pain crises, acute chest syndrome and associated emergency department visits and hospitalizations. By reducing the frequency of these complications of sickle cell disease, hydroxyurea can improve the quality of life for patients. Hydroxyurea has been found to lower the costs associated with care for patients with sickle cell disease. While outpatient costs have been found to be higher, they are outweighed by the savings from fewer hospitalizations.

Use of hydroxyurea varies greatly from region to region and provider to provider, highlighting a substantial opportunity to improve care by making hydroxyurea accessible to more patients. One important barrier to the use of hydroxyurea is poor understanding of the clinical benefits, side effects, and long-term consequences of its use. Patients can obtain information from many diverse sources, some of which may be unreliable. Additional barriers to hydroxyurea use are focused at the health system level (e.g., insurance coverage) and provider level (e.g., knowledge, self-efficacy).

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**RECOMMENDATIONS:**

1. Discuss hydroxyurea (including side effects, benefits, and monitoring protocol) with patients with HbSS and Hb Sbeta zero Thalassemia and their families and incorporate patient preferences and values in decision making.
2. For adults with HbSS, treat with hydroxyurea if individual has three or more pain crises annually, has recurrent acute chest syndrome or severe pain impacting quality of life.
3. For infants older than nine months and children and youth, consider hydroxyurea treatment to prevent sickle cell-related complications.
4. Consider use of text/SMS messaging and other technologies to enhance adherence to hydroxyurea.
<table>
<thead>
<tr>
<th>Change Idea</th>
<th>What is it? (Definition)</th>
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<th>Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient education</td>
<td>Videos, brochures, handouts and other information sources can be used with patients and families to convey information about hydroxyurea and clarify misconceptions about this treatment.</td>
<td></td>
<td>Massachusetts SCDBSP – Keeping you Healthy with Sickle Cell Disease</td>
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<td>New Jersey SCDTDP – The Best Hope for Sickle Cell (video)</td>
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<td>Tennessee SCDBSP – Family Guide to hydroxyurea</td>
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<td>Decision support</td>
<td>Tools to guide patients and families through the process of evaluating the risks and benefits of hydroxyurea therapy can help facilitate the conversation and allow patients and families to feel more informed before making a decision.</td>
<td></td>
<td>Massachusetts SCDBSP hydroxyurea Dosing Guidelines</td>
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<tr>
<td>tools</td>
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<tr>
<td>Text/SMS messaging</td>
<td>Tool to send electronic message to patient’s cell phone to remind patient to take medication (e.g., hydroxyurea).</td>
<td></td>
<td>Tennessee SCDTDP - Scheduled Instant Messaging Over the Network (SIMON)</td>
</tr>
</tbody>
</table>
REFERENCES


