Supporting Statement

Sickle Cell Disease Treatment Demonstration Program - Quality Improvement Data Collection for the Hemoglobinopathy Learning Collaborative

1. **Justification**
2. **Circumstances Making the Collection of Information Necessary**

The Health Resources and Services Administration (HRSA) is requesting that the Office of Management and Budget (OMB) review and approve three data collection forms for the quality improvement data collection strategy of the Sickle Cell Disease Treatment and Demonstration Program (SCDTDP). The purpose of the quality improvement data collection strategy is to measure progress in meeting the goals of the SCDTDP and to implement a system to monitor the progress of HRSA’s Maternal and Child Health Bureau (MCHB) funded activities in improving care and health outcomes for individuals living with sickle cell disease and sickle cell trait. This is a new activity.

In 2004, Congress enacted and the President signed into law P.L. 108-357, the American Jobs Creation Act of 2004. Section 712 of P.L. 108-357 authorized a demonstration program for the prevention and treatment of sickle cell disease. The legislation was enacted to (1) create an optional medical assistance program for individuals with sickle cell disease for treatment and education, genetic counseling and other services to prevent mortality and decrease morbidity from sickle cell disease, and (2) to create a demonstration program under the direction of the HRSA. Please refer to Appendix A for a copy of the America Jobs Creation Act of 2004. Section 712 of P.L. 108-357.

The SCDTDP, which is administered by MCHB’s Genetic Services Branch of the Division of Services for Children with Special Health Needs, provides grants to federally-qualified and nonprofit health care centers. These grants help to establish geographically distributed regional networks that work with comprehensive sickle cell disease centers and community-based support organizations to provide coordinated, comprehensive, culturally competent, and family-centered care to families with sickle cell disease and sickle cell trait.

Under the authorizing legislation, a National Coordinating Center (NCC) was also established for the demonstration program to: (1) collect, coordinate, monitor, and report on best practices and findings regarding the activities of the demonstration program; (2) identify a model protocol for eligible entities with respect to the prevention and treatment of sickle cell disease; (3) identify educational materials regarding the prevention and treatment of sickle cell disease; and, (4) prepare a final report on the efficacy of the demonstration program based on evaluation findings.

The SCDTDP will work to address the unique challenges faced by patients with SCD and to develop strategies to improve care and outcomes for patients with SCD. Individuals with SCD suffer significant morbidities such as frequent pain episodes, pulmonary complications (e.g. acute chest syndrome), and stroke. Persons living with this condition also experience complications related to chronic organ damage, psychosocial issues and on occasion early death. Variation exists in both the provision of care and outcomes for individuals living with sickle cell disease across multiple care sites and regions in the United States.[[1]](#footnote-1) Studies suggest that well established therapies (e.g. hydroxyurea) and screening modalities (e.g. transcranial doppler) are underused in SCD.[[2]](#footnote-2)-[[3]](#footnote-3)[[4]](#footnote-4)[[5]](#footnote-5)[[6]](#footnote-6)[[7]](#footnote-7)

The medical care for individuals with SCD is heterogeneous and occurs primarily in three venues: 1) primary care practices, 2) hematology programs and 3) acute care settings such as emergency departments (ED) and inpatient units. This care is also supplemented by services provided by community based organizations, public health agencies and social service programs. Care for persons with sickle cell disease is often fragmented and spans multiple institutions resulting in many persons with sickle cell disease not having a medical home that coordinates their care. Furthermore, the number of hematology specialists with expertise in the care of persons of sickle cell disease has dwindled over recent years resulting in a dearth of specialty providers, particularly adult providers available to care for this population. Strategies for effective transition of adolescents with sickle cell disease to adult care are essential. Thus, new models of care for individuals with sickle cell disease that effectively integrate primary care, subspecialty care and social service supports are necessary.[[8]](#footnote-8) In this context, integrated networks of primary care providers, community health centers, community organizations interfacing with hematology providers can play a pivotal role in ensuring persons with sickle cell disease receive high quality, coordinated, culturally appropriate, and patient centered care. The SCDTDP was created to address these issues and provides a unique opportunity to measure quality of care in these settings in order to develop strategies to improve care and outcomes for patients with SCD.

1. **Purpose and Use of Information Collection**

The goals of the SCDTDP are to (1) improve coordination and service delivery for individuals with sickle cell disease (2) improve access to services and (3) improve and expand patient and provider education. In order to achieve these goals and objectives, the NCC is facilitating the Hemoglobinopathy Learning Collaborative (HLC). The HLC offers consumers, health care providers and community-based organizations the first nationwide opportunity to apply quality improvement (QI) strategies to improve the care of individuals with sickle cell disease (SCD) and sickle cell trait (SCT) across the United States. The Breakthrough Series (BTS) Learning Collaborativeis being usedto drive the aims for the HLC. A BTS Learning Collaborative is a vehicle for refining and spreading changes known to be effective for improving care and outcomes for defined populations. Teams gather regularly via webinars and face-to-face Learning Sessions to compare their current performance and assess gaps from their project goals. With the assistance of faculty experts in the science of improvement and clinical practice, teams share ideas and strategies about how to improve, learn about essential improvement techniques, and prioritize possible actions in terms of impact and feasibility.

The HLC uses a process known as the Model for Improvement, a widely used approach to Quality Improvement (QI) used in health care settings.[[9]](#footnote-9) This QI approach uses a structured process for grantee teams, who henceforth will be referred to as improvement teams, to build upon small tests of change at their site while measuring and reporting on the impact of those changes on key process and outcome measures. These measures include outcome measures (ex. health status and health care utilization of the SCD population) and process measures (ex. care system processes). An example of an outcome measure would include the average number of ED visits per SCD patient in the last 12 months. While an example of a process measure would be the average time from triage to administration of parenteral analgesic (pain medicine) for SCD patients presenting at the ED with acute pain. The QI data collection and entry forms capture data elements that will be used in calculating these key HLC QI outcome and process measures. Please refer to Appendix B for a detailed list of all QI measures and the connection between the data collection and entry forms and how they will be used to calculate the QI measures.

Collection of these QI measures is integral to the improvement process and the data will be used to:

1. Monitor and drive improvement. The data will allow teams to determine if the changes they are testing are leading to improvement and enable the NCC to provide network teams with feedback on their performance and improvement. For example, teams focusing on improving care in acute care settings will use measures such as time to administration of pain medication to assess if the change of implementing pain protocols improves performance on this measure.
2. Identify changes proven most effective at improving care for individuals with SCD and sickle cell trait. As the collaborative model is built around an “everyone learns, everyone teaches” framework, the most effective changes can then be shared throughout the collaborative as teams share their data and expertise via regular meetings, webinars and the project listserv.
3. Refine a common model protocol with respect to the prevention and treatment of sickle cell disease.
4. Provide HRSA/Congress information on overall progress of the program.

The HLC QI data collection strategy incorporates measures developed through a rigorous evidence-based process and implemented through a common, standardized data entry and reporting system, called Research Electronic Data Capture (REDCap), built expressly to support this work. Measures were identified and narrowed from a previously published set of pediatric SCD measures based on the RAND consensus development process.[[10]](#footnote-10) The scope of the measurement set was expanded to include adult aspects of SCD care. All measures were evaluated by an expert panel and a group of grantee representatives for validity and feasibility. Once finalized, measures were translated to QI data collection and entry forms that improvement teams will use to collect data. The QI data collection and entry forms capture data elements that will be used in calculating the HLC QI measures. Please refer to Appendix B for more detail on the connection between the data collection and entry forms and the QI measures that will be calculated.

QI data will be collected from medical chart review on a monthly basis to monitor and drive improvements in care intended to affect outcomes and to inform collaborative activities. The nine SCDTDP improvement teams will complete up to three QI data collection and entry forms for a sample of 20 patients with SCD or sickle cell trait who were seen in their network that month. When collecting data for improvement efforts the definition of required sample size is less well defined than it may be in a research focused effort. Sample size in improvement work must balance the resources required to collect the measure with the utility of the information obtained by the sample, providing just enough information to make sensible judgments about next steps and guide work. The measures are utilized primarily for learning, to increase the degree of belief that the changes are leading to improvement, not to collect all possible points of data. The selection of 20 patients per month has frequently been used for improvement work and will aid teams in expediting their improvement effort efforts while minimizing monthly burden.

A general overview of each form is described below. More detailed information on the data collection items and instruments are provided in Appendices C through E.

**Data collection procedures and instruments:**

Each of the improvement teams will complete the QI data collection and entry forms on a monthly basis throughout the duration of the program. All teams will complete the participant profile form once for each patient whose chart is reviewed. Depending on the area of focus in each setting, teams can choose to complete the acute care form, ambulatory care form, or both.

These QI data collection and entry forms include:

* The Participant Profile form will be used to collect demographic and basic health information, such as gender, year of birth, genotype, screening information and care sites, for each SCD/sickle cell trait patient sampled. Over time, this information will provide a comprehensive view of SCD patient population sampled within these networks. This form will be completed once for all patients whose chart is reviewed.
* The Acute Care Visit form will assess care in the acute care setting, such as in the ED, day hospitals or acute care clinics for treatment of pain and fever episodes. Examples of care processes assessed include, time to triage, assessment of pain, time to administration of first parenteral analgesic and/or antibiotics. This form will only be completed by those teams who are focusing their improvement projects in clinical settings like the emergency department or infusion clinics.
* The Ambulatory Care Visit form will assess care given in ambulatory care settings of primary care and/or Hematology offices. Examples of care processes assessed include provision of routine health screenings, coordination of care, and hydroxyurea use. This form will only be completed by those teams who are focusing their improvement projects in primary care and/or Hematology office settings.

Data elements on these forms will be collected via medical chart review and directly entered into a secure, web-based data collection tool, called Research Electronic Data Capture (REDCap), by a project team member from each of the improvement teams. In order to familiarize the improvement teams with the REDCap system, they were given a user-guide and attended an in-person training session on the system. Each team also has a project manager, from the national coordinating center, assigned to them and this individual is a point of contact for any technical questions that may arise during the use of the REDCap system. Moreover, the REDCap system will be maintained by our informatics team at Boston Medical Center. Please see section 10 for further detail on aspects of the technical standards for this system.

Each month teams will test changes to improve key process and outcomes within their organization. Ideas for effecting changes in the system are evaluated serially using a practical adaptation of the experimental paradigm, the Plan-Do-Study-Act (PDSA) cycle. PDSA cycles test changes, initially on a very small scale, in order to quickly identify promising ideas and adapt and develop them to into robust, reliable standard processes. Measuring the impact of those changes using the key QI process and outcome measures is vital to determining if team’s changes are leading to improvement.

We are not conducting a random sampling of medical chart reviews. Teams will use a judgment sample, relying on their process knowledge to select a useful sample for learning about process performance and the impact of their changes. Collecting a judgment sample of 20 patients each month will save time and resources while ensuring teams are able to accurately track their networks performance over time.

By reporting on a monthly basis, teams are more readily able to track and reassess their performance on quality measures. In addition, they are able to receive timely feedback on their performance and any small tests of change that they have implemented at their site. This is done with the goal of monitoring and driving improvements of outcomes for individuals with sickle cell disease and sickle cell trait. Through this process teams are able to examine the range of influences on these quality measures in order to increase the degree of belief that the changes are leading to improvement. This is a crucial aspect of improvement work. Specific details about calculation of burden hours for each of the proposed QI instruments are outlined in Section 12.

**Respondents:**

The respondents for the QI data collection will be a project team member from each the nine improvement teams. To note, these improvement teams consist of an interdisciplinary team that includes integrated networks of primary care providers, community health centers, and community based organizations interfacing with hematology providers within their given sites. These individuals will perform medical chart reviews on a monthly basis for twenty patients seen at their respective network sites. Hence, respondents are being asked to complete data collection twelve times annually. This process would yield 20 medical chart reviews per network per month, for an annual total of 240 medical chart reviews completed per network (2,160 for the TDP as a whole). The measurement strategy of collecting a sample of 20 patients per month will save time and resources while ensuring teams are able to accurately track the performance of their networks over time and build confidence that the changes they are making are leading to improvement. Specific details about calculation of burden hours, for each of the QI instruments used, are outlined in Section 12.

**Analysis:**

De-identified data obtained from medical chart reviews will be entered directly into a secure web-based data collection tool called Research Electronic Data Capture (REDCap). The data entered into REDCap will be aggregated via a custom measure generator that will calculate and export the QI outcome and process measures to the Improvement Lab (ILab) or other reporting tools to be viewed in time series chart format by improvement teams and the NCC to track performance. Please refer to Appendix B for more detail on the connection between the data collection and entry forms and the QI measures that will be calculated.

These measures will be used to assess the teams’ performance and improvement on quality measures. In the context of the SCD Collaborative, teams are designing and refining local systems and processes to reliably deliver evidence based care to patients with SCD. The teams, as well as the Collaborative faculty and leadership, will rely on these quality measures to assess the reliability of care, and the degree of improvement achieved by the teams. In addition, the data collected will be necessary for the preparation of the annual report to HRSA, as well as the final Congressional report, detailing the results of this program as required by federal legislation.

1. **Use of Improved Technology and Burden Reduction**

In an effort to reduce respondent burden, an electronic data and reporting system will be utilized.

Using web based QI data collection and entry forms, the SCDTDP improvement teams will collect QI data through medical chart review. By using an electronic method and programmed branching logic, respondents are able to answer only questions that are applicable to each patient as opposed to all possible questions that could be asked. This selective question sequence was done to decrease respondent burden. The data will be used to inform the improvement teams’ work in their health care setting. All of the web based data collection tools will utilize secure interfaces.

Electronic data will be encrypted and transmitted using Secure Socket Layer (SSL) technology. SSL is a file and data encryption protocol. If electronic data exchange/messaging are used, an HL7-compliant interface will be available.

1. **Efforts to Identify Duplication and Use of Similar Information**

The data to be submitted on the proposed collection forms are unique and are not available elsewhere in any other manner. The SCDTDP is a unique demonstration program that provides the opportunity to improve care and outcomes locally, develop and test best practice models and address the requirements of the legislation. Efforts to identify duplication and use of similar information are done through the following manner:

* The Strategic Project Director attends relevant national meetings including, National Heart Lung and Blood Institute National Blood Disorder Coordinating Committee meeting; Sickle Cell Disease Association of America (SCDAA) annual convention and American society of Hematology meeting and other adhoc meetings with other federal and non-federal entities focused on SCD.
* The Strategic Project Director and HRSA Program Officer consult with other federal agencies, providing a bi-directional interface between the SCDTDP and relevant national efforts to both accelerate improvements and avoid duplication.
* Scanning existing literature identified few quality indicators for individuals with sickle cell disease. We are working with Dr. C. Jason Wang, a well respected health service researcher in this field and faculty member on this project, to adapt the previously published pediatric quality indicators for SCD and use them for the SCDTDP.[[11]](#footnote-11)

Through our various partnerships, we are able to keep abreast of the work and additional metrics being developed for SCD. While we want to minimize duplication, we are poised to learn and share ideas within these partnerships. For example, we intend to use NHLBI guidelines for SCD care once they are finalized and available for use.

1. **Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this study.

1. **Consequences of Collecting the Information Less Frequently**

Respondents are being asked to report quality improvement data to the NCC on a monthly basis throughout the duration of the program. [[12]](#footnote-12) This frequent data reporting is needed in order for teams to track their improvement and for the NCC to give timely feedback to improvement teams on their performance and improvement. This is an important component of the Hemoglobinopathy Learning Collaborative (HLC) as defined by the Sickle Cell Disease Treatment Demonstration Program (SCDTDP). Moreover, less frequent assessments will not provide sufficient timely feedback to inform program design, activities and improvements nor the required data specified by the legislation noted above. However, there are no legal obstacles to reduce the burden.

1. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The data are collected in a manner consistent with guidelines contained in 5 CFR 1320.5. There are no special circumstances requiring deviation from these guidelines.

1. **Comments in Response to the Federal Register Notice/Outside Consultation**

The 60-day Federal Register Notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on May 31, 2012, vol. 77, No. 105; pp. 32127-32128. Additionally, no comments were *re*ceived.

Prior to the publication of the 60-day Federal Register notice, the HLC data collection strategy incorporated measures developed through a rigorous evidence-based process and implemented through a common, standardized data entry and reporting system built expressly to support this work. The measures were established using the RAND/UCLA Appropriateness Method, a modified Delphi method. The process included a comprehensive literature review with ratings of the evidence and two rounds of anonymous ratings by an expert panel, with panelists meeting face-to-face in April 2011 to discuss the indicators between the two rounds. The expert panel was nominated by leaders of various U.S. academic societies and the National Heart, Lung and Blood Institute. A group of grantees, the Technical Working Group (TWG), were also engaged in the process to offer feedback on the measures and the feasibility of data collection recommended by the expert panel. After the data collection and entry forms were developed, the TWG tested the feasibility of data collection and provided feedback. The names, titles and contact information for both the expert panel and TWG are listed in Appendices F and G.

1. **Explanation of any Payment/Gift to Respondents**

Respondents will not be remunerated or compensated.

1. **Assurance of Confidentiality Provided to Respondents**

The project team will undertake the following to ensure privacy to the extent allowed by law:

1. Individuals will be assigned a project ID number. The linkage between project ID number and patient/client name will be kept at sites and not reported to the NCC.
2. All NCC personnel with access to data will undergo Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPPA) training and certification.
3. No personal health information will be collected or reported on the QI data collection and entry forms.
4. Electronic data will be encrypted and transmitted using Secure Socket Layer (SSL) technology. SSL is a file and data encryption protocol.
5. Publicly accessible reports will only provide aggregate data.

Moreover, IRB approval for the QI measures was obtained for the NCC Data Coordinating Center at Boston Medical Center on May 30, 2012. This includes a Data Use Agreement, which represents a formal agreement between the investigator and “covered entities” (improvement teams) that hold the health information.

1. **Justification for Sensitive Questions**

There are no questions of a sensitive nature being asked of respondents.

1. **Estimates of Annualized Hour and Cost Burden**

The data managers from the nine improvement teams will complete the QI data collection and entry forms on a monthly basis throughout the duration of the program. Data will be collected using three electronic QI data collection and entry forms: the Participant Profile form, the Acute Care Visit form, and the Ambulatory Care Visit form. These data managers will complete the relevant forms for each of the twenty patients whose chart is reviewed on a monthly basis. Each form was pre-tested with 4 respondents, including two improvement teams at two separate intervals for feasibility and the estimates of burden are based on the results of those assessments.

The average annual burden is shown below:

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| --- |
| **Exhibit 12.A Estimated Annualized Burden of Hours** |
| **Type of Respondent** | **Form Name** | **No. of Respondents** | **No. Responses per Respondent[[13]](#footnote-13)** | **Average Burden per Response (in hours)** | **Total Burden Hours** |
|  |  |  |  |  |  |
| **Improvement project team member** | Participant Profile | 9 | 12 | 5 | 540 |
| **Improvement project team member** | Acute Care Visit  | 9 | 12 | 10 | 1080 |
| **Improvement project team member** | Ambulatory Care Visit | 9 | 12 | 10 | 1080 |
| **Total** |  | 27 | 12 | 8.334 | 2700 |

Exhibit 12.A

The estimated cost to the improvement project team members completing the medical chart review is presented in Exhibit 12.B. The burden cost is based on the average hourly wage rates from the 2011 National Occupational Employment and Wage Estimates from the Bureau of Labor Statistics for all occupations available at: <http://www.bls.gov/oes/current/oes_nat.htm>;

|  |
| --- |
| Exhibit 12.B Estimated Annualized Burden Costs |
| **Type of Respondent** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Costs** |
|  |  |  |  |
| **Improvement project team member**  | 540 | $21.74 | $11,739.60 |
| **Improvement project team member**  | 1080 | $21.74 | $23,479.20 |
| **Improvement project team member**  | 1080 | $21.74 | $23,479.20 |
| **Total** | 2700 | -------------------- | $58,698.00 |

1. **Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs**

There are no capital or startup costs associated with data collection.

1. **Annualized Cost to Federal Government**

The cost of the contract to gather data as part of the Sickle Cell Disease Treatment Program is approximately $99,315 annually as well as the cost for one FTE GS-14 at 40% time at $65,000 to oversee the project. The total annual costs for this collection of information are approximately $164,315. The estimated cost for three years is $492,945.

1. **Explanation for Program Changes or Adjustments**

This is a new data collection.

1. **Plans for Tabulation, Publication, and Project Time Schedule**

Project Time Table

Data collection will be conducted over a 19 month period beginning in approximately February 2013, pending OMB approval. A final report presenting the findings of this OMB submission and the previously approved OMB application (OMB Number: 0915-0344) for the SCD demonstration program will be presented at the conclusion of the project. Manuscripts for publication in peer reviewed journals may be prepared depending on the decisions of the Technical Working Group. Exhibit 16.A below demonstrates the proposed timeline for the QI data collection.

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| **Exhibit 16.A Proposed Project Timeline** |
| **Activity** | **Time Schedule** |
| Receipt of OMB approval  | Estimated January 2013 |
| SCDTDP Quality Improvement Data Collection and Entry Forms Utilized | January/ February 2013 |
| Implementation of NCC data collection protocols | January/ February 2013 |
|  Data submission | Monthly (February 2013) through the funded period 2011-2014 |
| Data Analysis and Technical Assistance | Monthly (February 2013) through the funded period 2011-2014 |
| Annual Report to HRSA/MCHB | Annual (June) through the funded period 2011-2014 |
| Final Report to HRSA/MCHB | September 2014 |
| Congressional report | September 2014 |

1. **Reason(s) Display of OMB Expiration Date is Inappropriate**

The expiration date will be displayed on all instruments.

1. **Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification. The project complied with CFR 1320.9.

**Appendices (provided separately as pdfs)**

Appendix A: Copy of the 108th Congress of the United States of America. American Jobs

 Creation Act of 2004. (Bill no H.R. 4520)

Appendix B: Measurement Bank- shortened

Appendix C: Participant Profile Form, annotated

Appendix D: Acute Care Form, annotated

Appendix E: Ambulatory Care Form, annotated

Appendix F: SCDTDP Expert Panel Members

Appendix G: SCDTDP Technical Working Group (TWG)

1. Davis H, Green PJ, Moore RM, Jr. Geographic differences in mortality of young children with sickle cell disease in the United States. *Public Health Rep*. Jan-Feb 1997;112(1):52-58. [↑](#footnote-ref-1)
2. Charache S, Terrin ML, Moore RD, et al. Effect of Hydroxyurea on the Frequency of Painful Crises in Sickle Cell Anemia. *N. Engl. J. Med*. May 18, 1995; 332(20):1317-1322. [↑](#footnote-ref-2)
3. Steinberg MH, Barton F, Castro O, et al. Effect of hydroxyurea on mortality and morbidity in adult sickle cell anemia: risk and benefits up to 9 years of treatment.[see comment][erratum appears in JAMA.2003 Aug 13;290(6):756]. *JAMA*. Apr 2. 2003; 289(13):1645-1651. [↑](#footnote-ref-3)
4. Zimmerman SA, Schultz WH, Davis JS, et al. Sustained long-term hematologic efficacy of hydroxyurea at maximum tolerated doses in children with sickle cell disease. *Blood*. March 15, 2004; 103(6):2039-2045. [↑](#footnote-ref-4)
5. Hoppe C, Vichinsky E, Quirolo K, van Warmerdam J, Allen K, Styles L. Use of hydroxyurea in children ages 2 to 5 years with sickle cell disease. *J. Pediatr. Hematol. Oncol*. Jul-Aug 2000; 22(4):330-334. [↑](#footnote-ref-5)
6. Hoppe C, Vichinsky E, Quirolo K, van Warmerdam J, Allen K, Styles L. Use of hydroxyurea in children ages 2 to 5 years with sickle cell disease. *J. Pediatr. Hematol. Oncol*. Jul-Aug 2000; 22(4):330-334. (12):932-938. [↑](#footnote-ref-6)
7. Ritho J, Liu H, Hartzema AG, et al. Hydroxyurea use in patients with sickle cell disease in a Medicaid population. *Am J Hematol.* 2011 Oct; 86(10):888-90. [↑](#footnote-ref-7)
8. Grosse SD, Schechter MS, Kulkarni R, Lloyd –Puryear MA, Strickland B, Trevathan E. Models of comprehensive multidisciplinary care for individuals in the United States with genetic disorders. *Pediatrics*. Jan 2009; 123(1):407-412. [↑](#footnote-ref-8)
9. Institute for Healthcare Improvement. The Breakthrough Series: IHI’s Collaborative Model for Achieving Breakthrough Improvement. *Diabetes Spectrum*. April 2004; 17(2):97-101. [↑](#footnote-ref-9)
10. Wang CJ, Kavanagh PL, Little AA, et al. Quality-of-care indicators for children with sickle cell disease. *Pediatrics*. 2011 Sep; 128(3):484-93. [↑](#footnote-ref-10)
11. Wang CJ, Kavanagh PL, Little AA, et al. Quality-of-care indicators for children with sickle cell disease. *Pediatrics*. 2011 Sep; 128(3):484-93. [↑](#footnote-ref-11)
12. Institute for Healthcare Improvement. The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement. *Diabetes Spectrum.* April 2004; 17(2):97-101. [↑](#footnote-ref-12)
13. This burden table has been revised from the one published in the 60-day notice to reflect the accurate count of responses per respondent. The number 12 reflects the number of times a respondent will be approached for data collection annually not the total number of data collection forms completed as was previously reported. [↑](#footnote-ref-13)