Supporting Statement

Part B

Improving Sickle Cell Transitions of Care through Health Information Technology Phase 1

Version 3: *March 7, 2013*

Agency of Healthcare Research and Quality (AHRQ)

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Part B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

This data collection effort will be qualitative in nature and will not require complex statistical sampling methods. Because the important factors and variables are not yet known regarding problematic health care transitions for patients with SCD, qualitative research is necessary to generate hypotheses that may be amenable to quantitative testing at a later stage.

Focus Groups. There are three clinical sites participating in patient, parent/caregiver and provider focus groups and one non-clinical site participating in the IT developer focus group. As with qualitative research in general the results are not intended to be generalizable or statistically significant and, as such, low recruitment rates should not invalidate the results of the data collected. Nevertheless, the team will seek to engage focus group participants from each of the sites that generally reflect the populations affected by sickle cell disease in that community as well as reflect the providers who serve those patients. Information about their views will provide valuable information to AHRQ on stakeholder priorities and needs that will be used to inform the design and functionality of an HIT-enabled tool. Thus selection does not consist of formal statistical sampling, but rather inclusion of an appropriately diverse group of respondents to ensure valid identification and saturation of themes that emerge from focus groups. Identifying clinical site and participant characteristics in the final reports will allow the team to contextualize findings and may enable other organizations or users of the research to assess the potential usability and acceptability of findings.

Ten focus groups will be conducted with up to ten participants in each group. Table 1 below describes the focus group breakout per research site. Justification for the assignment of each group to a particular site, and the patient population size of each site, can be found in Attachment 13. Due to differences among the policies and regulations of each facility, recruitment approaches for each of the focus group sites may differ slightly. Overall, staff from the clinical settings will conduct purposive sampling from existing eligible patient populations for each patient and parent/caregiver focus group to which the facility is assigned. Nomination of potential participants for the patient and parent/caregiver focus groups will be made by providers serving the target patient population including physicians, social workers, and nurse practitioners. A total sample of eligible families will be compiled. In order to simplify recruitment, and reduce the travel and time commitments for recruits, the team will target initial recruitment on patient-caregiver dyads and will augment this approach by individual patients or caregivers as needed using the broader eligible patient sample as a basis.

Provider participants will be identified by the study team based on participant profile criteria that targets providers representing diversity in the following key characteristics: length of time practicing medicine, gender, specialty, and health technology experience. Leveraging established contacts within each clinical setting, the study team will invite identified providers to participate.

IT developer participants will be identified by the study team based on participant profile criteria that targets participants representing diversity in the following key characteristics: technology platform expertise (e.g., smartphones, EHR, web portals, health information exchange, HIT solutions for vulnerable populations or transitions), as well as academic and private sector

experience. To minimize costs and enhance the likelihood of strong participation, the team will primarily recruit individuals from the Northeast region, an area with a strong representation of HIT expertise.

Table 1: Focus Group Allocation by Site

	Site				
Focus Group Type	CCHMC	CNMC	Nemours	Lewin & NICHQ	**Total**
Provider	10	10			20
Parent/Caregiver	10	10	10		30
IT Developer				10	10
Patients 9-13	10				10
Patients 14-17			10		10
Patients 18 & older		10			10
Patients mixed ages		10			10
Total	30	40	20	10	100

Key Informant Interviews. Interview participants will be identified based on four recruitment categories: attorneys (focusing on privacy and security of health information technology); representatives from the Office of the National Coordinator for the Health Information Technology Office of Chief Scientist and other policy makers; State Medicaid Directors; and, patient advocates. Potential participants will be identified by the study team leveraging existing contacts and relationships to engage eight participants for interviews evenly distributed across the four recruitment categories.

2. Information Collection Procedures

As described above, the primary data collection activities will include an environmental scan, focus groups (including brief demographic questionnaires) and key informant interviews. This approval request is for the focus groups portion only. Data collection procedures have been designed to maximize response, minimize burden on the respondents, and promote accuracy and completeness of responses. Described below are the specific data collection procedures proposed for the focus groups. Through recruitment, the team will collect basic demographic information from all eligible patients, parents/caregivers, providers and IT Developers who agree to participate by giving informed consent. Identifiable personal health information will not be collected. This basic information will encompass fundamental demographics about participants that will allow the team to contextualize findings.

Focus group moderator guides have been developed for the qualitative data collection efforts. Guides have been developed for each of the core stakeholder segments of patients 9-13 (Attachment 1), patients 14-17 (Attachment 2), patients 18 and older (Attachment 3), patients mixed ages (Attachment 4), parents/caregivers (Attachment 5), providers (Attachment 6), and IT Developers (Attachment 7). These guides will be used by the moderators to guide the focus group discussions. Not all questions or probes will apply to every focus group participant and, as such, the moderator will use the guide as a framework allowing for some flexibility and spontaneity depending on responses received. Each guide includes a core set of questions followed by potential

probes and follow-on questions that may be asked pending participant responses. Questions are designed to be open ended to allow participants the greatest freedom in responding and the generation of ideas that emerge from the participants themselves rather than the investigators. In this way, the team will maximize the breadth of information available from diverse respondents as well as allow some comparisons and integration across groups and sites.

A co-moderation model will be used for focus groups with each moderator having a distinct role. The lead moderator is responsible for facilitating the group, setting the tone and responding to participants. The co-moderator is responsible for clarifying vague responses, recording key issues to drive the discussion, facilitating the inclusion of late participants, and encouraging reluctant participants to engage actively. Focus groups will be up to two (2) hours in length, with the exception of the IT Developer group which will last up to four (4) hours, and all groups will be conducted in person. Focus groups will be digitally audio-recorded and summarized in writing but without any use of the participants' names. Recordings of each focus group will be managed by the partner site coordinating that group. Focus group summaries and any additional notes will be stored on secure computer servers at The Lewin Group.

3. Methods to Maximize Response Rates

To increase participation in the focus groups, clinical partners were chosen with both broad expertise in treating pediatric and adult sickle cell disease patients and ready access to pools of potential participants. Many of the partners also bring extensive experience conducting focus groups and are familiar with successful recruitment approaches such as: planning for day-of loss of some recruited participants by recruiting enough participants to support a certain portion of 'no-shows,' and providing appropriate incentives and implementing convenience strategies such as co-locating focus groups where participants are coming for other needed services. Clinical partners will lead the recruitment efforts for each of the focus groups they are hosting so that recruiters are knowledgeable about possible participants and participants are familiar with staff conducting outreach, which will likely support more robust recruitment. Focus groups will be conducted at locations and times that are most convenient for the majority of participants such as at the clinic where they regularly come for services.

Focus group participants will each be provided with a $50 cash or cash equivalent incentive such as a gift card or money order pending the policies and processes of each organization and needs of the community. This will serve as an incentive for participants to partake in focus group activities and will help offset any cost to the participants for their participation, such as travel costs and time.

4. Tests of Procedures

Each moderator guide has been developed and reviewed by key experts in the field, including those with extensive experience conducting focus groups with these groups of stakeholder. A comprehension/reading level that does not exceed a fourth grade level has been applied to the moderator guides in order to support broad understanding among participants of discussion topics and questions. No formal pretesting was conducted.

5. Statistical Consultants

AHRQ has engaged The Lewin Group and their ACTION Team to support the design and implementation of focus groups, and analyses of the findings. The Lewin ACTION Team includes members with expertise in sampling and analysis, listed below, who were consulted in the design of data collection methods. The project and data collections do not, however, require detailed statistical sampling approaches.

- Anjali Jain, Managing Consultant, The Lewin Group, Principle Investigator
- Maria Britto, Cincinnati Children's Hospital Medical Center, Project Director