Recruitment in the Cooperative Study of Sickle Cell Disease (CSSCD)

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ABSTRACT: The Cooperative Study of Sickle Cell Disease (CSSCD) is a multiinstitutional investigation of the natural history of clinical course of sickle cell disease from birth through adulthood. The study is not a trial; rather, it involves data collection at 23 institutions in a uniform, standardized fashion on 3800 patients. Recruitment aspects that were addressed include issues related to recruitment of different age groups, ranging from newborns to pregnant women to patients over 50 years of age; the need to include mildly affected patients to ensure that the study would not reflect only a severe hospital-based population; recruitment from rural populations; and the need to screen and enter a newborn population at birth. The recruitment goal of entering 3200 patients, including 2100 patients with SS hemoglobinopathy, over a 24-month period was accomplished after 27 months.

KEY WORDS: sickle cell disease, patient recruitment, hereditary disease

INTRODUCTION

Sickle cell disease is a hereditary disorder of the hemoglobin molecule that leads to sickle-shaped red blood cells. It is the most common inherited single gene defect and affects mainly the black population in this country, but it is a significant worldwide problem involving many different races and nationalities.

Even though sickle cell disease has been known for many years and its manifestations have been described, the natural history or clinical course from birth to death has been poorly understood. This is largely because of the variable degree of severity, the variability of the many manifestations, and the complexity of the interaction of the disease process with other health-related events. Therefore, information obtained before 1977, upon initiation of the study, had been largely anecdotal and retrospective in nature and had...
involved small numbers of patients. Consequently, there remain many unanswered clinical questions about this illness. In 1977, the Sickle Cell Disease Branch, Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), initiated the Cooperative Study of Sickle Cell Disease (CSSCD) to evaluate the questions.

METHODS

The investigation involves 23 clinics across the country with over 60 investigators and a statistical coordinating center. The clinics represent a broad distribution throughout the country and are all university based. Most are urban clinics, and three clinics are providing data from rural populations. The clinics follow a varied number of patients, ranging from 60 to over 200 patients at some clinics.

Organizationally, the study has been administered by the Sickle Cell Disease Branch, DBDR, NHLBI, NIH. The cooperative group, headed by Dr. Wendell Rosse and Dr. Jeanne Smith, was organized into committees, including a recruitment and retention committee. A policy board, a group of external advisors not participating in the study with expertise in hematology, epidemiology, and biostatistics, has reviewed and made recommendations concerning all aspects of the study.

The overall objective, to investigate the clinical course of sickle cell disease from birth to death, encompasses specific objectives related to different age groups (newborns, adolescents, adults), psychosocial aspects, and major complications (such as surgery, pregnancy, and acute chest problems).

RECRUITMENT GOALS

The following goals were established during the initial year of planning by the clinic directors, statistical coordinating center, Sickle Cell Disease Branch, and policy board:

Entry of only patients with the major phenotypes of sickle cell disease (SS, SC, and Sβ+α Thalassemia).

Inclusion of mild patients.

Acquisition of a total sample of 3200 patients, with a SS sample of 2100 with 350 in each age/sex category.

Inclusion of patients from rural areas.

Entry of all special interest patients, i.e., newborns and pregnant women with disease.

The rationale for adopting the above objectives and the strategy to meet them are discussed below.

Major Phenotypes

It was recognized that the numbers of less prevalent phenotypes (e.g., SD, SE) would not be adequate for evaluation.
Inclusion of Mild Patients

For the investigators to describe accurately the clinical course reflecting the entire spectrum of severity in this illness, it was considered crucial for the study not to be limited to hospital-based patients, thereby reflecting findings on only the sickest patients. To ensure inclusion of mild patients, the following strategies were implemented:

All 23 clinics supplied a coded listing of all patients seen by them in the preceding 2 years, even if a patient had been seen only once during the 2-year period. This was to promote inclusion of patients seen infrequently and therefore with less severe clinical illness.

This roster of patients was then randomized by the statistical coordinating center to delineate the patient order for entry. This approach was designed to avoid entry of patients as they appeared for care or entry of the most ill patients early. The early recruitment of mildly ill patients was considered essential so that their contribution to the patient-years of follow-up would be similar to those of the sicker patients.

All programs were encouraged to recruit patients in the community who were not being followed by their particular hospital-based programs. This recruitment effort sought referrals from local physicians and health departments.

Sample Size

Among the major study objectives, the objective to obtain data related to selected major complications played an important role in determining the needed sample site. The literature varied widely on the incidence rates for specific complications, ranging from 2% to 50% because these estimates were based on studies involving small numbers of patients. Assuming an average follow-up of 4 years, an annual attrition rate of 6%, and a precision needed to estimate annual incidence rates as low as 2%–3%, it was recognized that only those patients with sickle cell anemia (SS phenotype) would provide adequate numbers to permit meaningful statistical inferences to be drawn. Patients with SC or Sβ thalassemia phenotypes would not provide adequate numbers. Therefore, data pertaining to the latter phenotypes would be purely descriptive in nature.

Recruitment in Rural Areas

Inclusion or exclusion of patients from rural populations, seen infrequently because of unreasonable distances for patients to travel to clinics, was a major study question. It was decided that patients living 75–100 miles away from the clinic would be seen for routine evaluations only once a year, whereas patients living closer would be seen routinely (twice a year and also when hospitalized for major illness). Therefore, rural patients were recruited and entered with their level of participation determined by the distance from the clinics. In addition, some clinics established satellite centers 100 miles away from the hospital, and the study team traveled to the population.
Special Interest Patients

These included patient categories in which special effort to enter all patients (not a sample) was emphasized because of the importance of the information for certain groups, for example, newborns and pregnant women. The newborn population was the only group to be entered with a matched AA control.

Patients were recruited from the following sources:

1. Existing patients being followed at the clinic.
2. Screening programs (this applied mainly to the newborn population).
3. Local physicians in the community.

The specific recruitment goals, established upon initiation of recruitment, included the following: a total sample of 3200 patients; a SS sample of 2100 with 350 in each age/sex category; a 2-year entry period, with each center entering 100 patients per year or 25 per quarter; diagnosis and entry of all newborns, with 2 controls if possible, at a rate of 100 per year; and a 70% entry rate of patients from the randomized roster list. All goals were established prior to recruitment by center directors, statistical coordinating center personnel, and the external policy board.

A log of contacts was sent to the statistical coordinating center monthly by each center to expedite monitoring of the entry process. A recruitment committee monitored the entry process and study progress and evaluated each clinic’s performance relative to recruitment goals every 3 months.

RESULTS

After 1 year of planning, there was a 5-month interim period to hire and train personnel, initiate recruitment procedures, and establish newborn screening programs prior to the initiation of entry. The recruitment coordinators, and in some clinics the nurses, were responsible for contacting, logging in, and tracking patients for entry and served as recruitment coordinators. However, anyone on the management team, for example, the laboratory technicians, could try to recruit a patient/family. The social worker was an important part of the recruitment effort related to tracking down and finding patients not seen for some time.

Recruitment and entry began in March 1979 and was scheduled to terminate 2 years hence. After 1 year of entry, 1,984 of the expected 3,200 (61% of the goal) had been realized (Table 1). However, 2 months from the anticipated date of termination of entry, 3200 (93% of the goal) had been reached, plus 140 newborns with 70 control babies. Most important, the total goal for SS patients (2100 SS) was not met, with only 1724 SS patients entered, and the goal of 350 patients in the age/sex categories was not met, especially in the male adolescent and adult groups. Therefore, the executive committee and policy board recommended extending the entry period an additional 4 months to permit (1) additional time for some clinics to enter the contracted number of patients (at that point, three clinics had not reached 90% of their expected recruitment goal), (2) an increase in SS patients, especially in the critical age/sex categories, and (3) an opportunity to offset a possible attrition rate in excess of 10%.

The final enrollment effort, after an additional 3 months, shows an overall
Table 1 Rate of Entry in Study

<table>
<thead>
<tr>
<th>Month</th>
<th>Number Entered</th>
<th>Percent</th>
<th>Cumulative Number Entered</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (3/79)</td>
<td>204</td>
<td>6.3</td>
<td>204</td>
<td>6.3</td>
</tr>
<tr>
<td>2</td>
<td>203</td>
<td>6.6</td>
<td>407</td>
<td>12.6</td>
</tr>
<tr>
<td>3</td>
<td>197</td>
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<td>18.6</td>
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<tr>
<td>4</td>
<td>189</td>
<td>5.8</td>
<td>793</td>
<td>24.5</td>
</tr>
<tr>
<td>5</td>
<td>154</td>
<td>4.8</td>
<td>947</td>
<td>29.2</td>
</tr>
<tr>
<td>6</td>
<td>186</td>
<td>5.7</td>
<td>1133</td>
<td>35.0</td>
</tr>
<tr>
<td>7</td>
<td>138</td>
<td>4.3</td>
<td>1271</td>
<td>39.2</td>
</tr>
<tr>
<td>8</td>
<td>140</td>
<td>4.3</td>
<td>1411</td>
<td>43.5</td>
</tr>
<tr>
<td>9</td>
<td>147</td>
<td>4.5</td>
<td>1558</td>
<td>48.1</td>
</tr>
<tr>
<td>10</td>
<td>98</td>
<td>3.0</td>
<td>1656</td>
<td>51.1</td>
</tr>
<tr>
<td>11</td>
<td>176</td>
<td>5.4</td>
<td>1832</td>
<td>56.5</td>
</tr>
<tr>
<td>12 (2/80)</td>
<td>152</td>
<td>4.7</td>
<td>1984</td>
<td>61.2</td>
</tr>
<tr>
<td>13</td>
<td>127</td>
<td>3.9</td>
<td>2111</td>
<td>65.1</td>
</tr>
<tr>
<td>14</td>
<td>155</td>
<td>4.8</td>
<td>2266</td>
<td>69.9</td>
</tr>
<tr>
<td>15</td>
<td>138</td>
<td>4.3</td>
<td>2404</td>
<td>74.2</td>
</tr>
<tr>
<td>16</td>
<td>109</td>
<td>3.4</td>
<td>2513</td>
<td>77.5</td>
</tr>
<tr>
<td>17</td>
<td>95</td>
<td>2.9</td>
<td>2608</td>
<td>80.5</td>
</tr>
<tr>
<td>18</td>
<td>101</td>
<td>3.1</td>
<td>2709</td>
<td>83.6</td>
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<td>19</td>
<td>85</td>
<td>2.6</td>
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<td>86.2</td>
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<tr>
<td>21</td>
<td>64</td>
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<td>2943</td>
<td>90.8</td>
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<tr>
<td>22</td>
<td>69</td>
<td>2.1</td>
<td>3012</td>
<td>92.9</td>
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<tr>
<td>23</td>
<td>53</td>
<td>1.6</td>
<td>3065</td>
<td>94.6</td>
</tr>
<tr>
<td>24 (2/81)</td>
<td>41</td>
<td>1.3</td>
<td>3106</td>
<td>95.8</td>
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<tr>
<td>Completion target date</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>55</td>
<td>1.7</td>
<td>3161</td>
<td>97.5</td>
</tr>
<tr>
<td>26</td>
<td>56</td>
<td>1.7</td>
<td>3217</td>
<td>99.3</td>
</tr>
<tr>
<td>27 (5/81)</td>
<td>24</td>
<td>0.7</td>
<td>3241</td>
<td>100.0</td>
</tr>
</tbody>
</table>

entry of 3241 patients (101% of the goal), with 2243 (70%) entries from the roster and 998 (30%) new patients (Table 2). This number of roster entries represents 56% of the roster patients available and 70% of the CSSCD patient population from which study data presently are being collected. New patients were obtained mainly from referrals from physicians or other health care sources. There were no screening programs mounted to find patients for entry other than the newborn population. The number of new versus roster patients

Table 2 Patient Entry in Relation to Goal and Source

<table>
<thead>
<tr>
<th>Patients Contracted For</th>
<th>Roster Patients Available</th>
<th>Roster Patients Contacted</th>
<th>Patients Entered</th>
<th>Percent of Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 3200 SS 2100</td>
<td>4028 2816</td>
<td>3138 1657</td>
<td>2243 1657</td>
<td>3241 2166</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2243 993</td>
<td>3241 (101%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2243 509</td>
<td>2166 (103%)</td>
</tr>
</tbody>
</table>
Table 3 Patient Population by Phenotype

<table>
<thead>
<tr>
<th>Hemoglobin Phenotype</th>
<th>Number</th>
<th>Percent</th>
<th>Cumulative Number</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>2166</td>
<td>66.8</td>
<td>2166</td>
<td>66.8</td>
</tr>
<tr>
<td>SC</td>
<td>632</td>
<td>19.5</td>
<td>2798</td>
<td>86.3</td>
</tr>
<tr>
<td>S8*</td>
<td>166</td>
<td>5.1</td>
<td>2964</td>
<td>91.5</td>
</tr>
<tr>
<td>S8°</td>
<td>175</td>
<td>5.4</td>
<td>3139</td>
<td>96.9</td>
</tr>
<tr>
<td>Transfused</td>
<td>102</td>
<td>3.1</td>
<td>3241</td>
<td>100.0</td>
</tr>
</tbody>
</table>

*At end of recruitment.

varied widely among clinics, from one clinic with only 1% of the total population recruited being new patients to three clinics where 50% of the patients entered were new patients.

A total of 2166 patients with SS were entered (103% of the goal). The additional 3 months of recruitment allowed entry of an additional 442 SS patients and realization of our overall recruitment goal for patients with SS hemoglobinopathies. The 1657 roster SS patients represent 77% of the total SS population being followed. The goal of 350 SS patients per age/sex category was not reached in the females younger than 10 years of age or in the adult and adolescent male groups. However, the additional time did increase adolescent and adult male categories by 89 and 100 patients, respectively, and at least 93% of the goal was attained in each cell.

Thirty percent of the roster patients (895) to be entered did not enter. Most were lost (30%), 21% refused to participate, 5% died, 22% had moved, and 15% had transferred and were available to the study through another program. The overall CSSCD patient population is depicted in Table 3.

Since 1981, 657 newborns had entered, with 109 control babies. The total CSSCD population is presently over 4000. Of the newborns found to have sickle cell disease from cord blood screening programs, 70% entered the study. However, this entry rate varied widely across clinics, from a high of 100% to a low of 25%.

**DISCUSSION**

The overall recruitment goals, including a total sample size of 3200 patients that included 2100 patients with SS disease, were successfully accomplished. These goals were achieved over a 27-month period rather than the anticipated 24-month period. However, the additional 3 months did not significantly impede the study's progress or increase its cost. The cost relates mainly to personnel. With personnel in place, additional patients had a negligible impact on cost.

It is important to point out that the recruitment did not suffer from an initial lag time, as is frequently the case in clinical trials. In fact, initially the entry rate exceeded the goal of approximately 185 patients per month study-wide. For the first 6 months, the monthly rate was 190 patients per month, and after that period of time, 35% of the total goal had been realized. After 12 months of entry, 61% of the patients had been entered, with the only decrease in entry rate during the month of December (Table 1). However,
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entry began to decrease after 19 months of recruitment and entry of 86% of the patient goal. This slowdown was due to exhausting roster lists in a few clinics but also to clinics ceasing entry once their contracted number of patients to be entered was reached. For example, if a clinic contracted to enter 100 patients, with the study recruitment requirement of entry of 25 patients per quarter, they would discontinue entry after 12 months.

This recruitment history is probably due to a number of factors: all clinics had a 5-month interim period to establish and initiate the recruitment process; most patients were recruited from a roster of patients who were seen within the previous year (80%); and patients had a close, positive working relationship with the principal investigators, nurses, and social workers and later with the recruitment coordinators. In addition, most of the staff members involved in recruitment were black. This increased the level of trust and communication about study needs and objectives and probably played an important role in recruitment success.

Another factor contributing to the success of the overall recruitment process was an active recruitment committee, with an involved chairperson who closely monitored clinic performance and, where problems arose, notified the particular clinics personally in conjunction with the project officer.

Performance varied widely across clinics and seemed to be related more to the interest and involvement of the clinic director and the motivation he or she provided to the key staff members than to the other factors (e.g., patient availability, institutional support).

Another aspect of the successful overall result, which may possibly account for the addition of new patients (30%) without major recruitment efforts, is the long-standing relationship many clinics have had with their local black communities relative to sickle cell disease. Many of the clinics had a history of working with active community sickle cell groups who provided community education, raised funds for patient transportation, and established sickle cell camps. Special CSSCD pamphlets, which explained the need for the study, objectives, and basic design, served an important role in disseminating information throughout the community.

The recruitment goals not fully realized include:

The failure to enroll 350 SS adolescent and adult males and females younger than 10 years of age.

The entry of only 70% of the newborn population identified with disease and without two matched controls.

The inability to admit more patients that had not been seen in the preceding year to increase the inclusion of possible mild patients.

In evaluating these aspects more closely, it can be postulated that the inability to recruit and enter the projected sample of SS adolescent and adult men (334 and 331, respectively) was related to decreased patterns of health care utilization by these two important subgroups in general. The fact that only 324 females under 10 years of age were recruited and entered was surprising and unexplainable. However, it is clear that the shortfall in these groups will not affect the ability to draw statistical inferences about the groups, because the retention rate has been better than anticipated (3% attrition rate annually instead of an expected 6%).
The 70% entry rate of all newborns diagnosed has not affected the projected goal of entering 100 babies per year. The inability to recruit newborns experienced by some clinics was due to the fact that most of the families were enrolled in Health Maintenance Organizations (HMOs) and other health care plans. The total health care of these families (well-baby and sick care) was provided by HMO-type services. Many of these families were unwilling to curtail their ongoing connection for one new family member for study purposes.

The issue of recruiting mildly affected patients presented the most difficult and challenging aspects of the entire process. Because a major objective of the study is to develop a standard Classification of Severity to apply to all patients, there was no way to determine at recruitment which patients were mildly or moderately affected clinically by their disease. Therefore, it was assumed that patients not seen in over a year ("inactive") and not lost or receiving care elsewhere might be more well than patients seen more often. Of the 4000 roster patients available at the clinics, 20% had not been seen in the preceding year. However, of the final roster entries, only 10% were considered inactive, with only 30% of all inactive roster patients being entered.

The reasons for nonentry of the inactive patients compared with "active" patients were not significantly different. The proportion of inactive and active patients who had moved was 13% and 10%, respectively. Twenty percent of inactive and 13% of active patients could not be contacted. An equal percentage of active and inactive patients refused to participate.

At this point, it is impossible to know the success or failure of the recruitment of mild patients because this assessment must await development of the Classification of Severity and its application to the patient population.

In summary, the recruitment effect for the CSSCD was successful as it relates to the total patient population, the SS population, and the age/sex categories. The success can be attributed to recruitment from an "in-place" system, i.e., physicians, nurses, social workers, and data/recruitment coordinators—the majority of whom were black—and a chronically ill patient population, in which, in most instances, long-standing positive working relationships with health care providers had already been established.

ACKNOWLEDGMENTS
This study was sponsored by the Sickle Cell Disease Branch, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland.

APPENDIX: Cooperative Study Group

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Recruitment in the Sickle Cell Disease Study

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