The Benefit of Being There: Overcoming Recruitment Obstacles in the Sickle Cell Community

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INTRODUCTION

The sickle cell disease (SCD) community is a notoriously hard-to-engage population for clinical trials recruitment. Four clinical trials are open to accrual at Virginia Commonwealth University (VCU) focused on the treatment of SCD in adult populations. Principal Investigator Wally Smith, MD works with one Clinical Research Coordinator (CRC) to recruit for and administer these studies. Here, we address best practices for clinical research coordinators to develop relationships with this community that help overcome barriers to recruitment and lead to successful sickle cell disease clinical trials.

BACKGROUND

At Virginia Commonwealth University, many sickle cell disease patients come from a culture that is distrustful of the medical community. They live with difficult socioeconomic circumstances and hold personal beliefs about their own disease that may prevent them from pursuing new opportunities for treatment. For example, patients may believe that the burden of their health is theirs alone, or that there are no treatments that will make them feel better.

The Centers for Disease Control and Prevention estimate that approximately 100,000 Americans are affected by sickle cell disease (SCD), including about 1 out of every 365 Black or African-American births.1 In a 2008 Workshop on Sickle Cell Disease, the NIH identified key principles to guide the infrastructure of SCD clinical research, which included the importance of community engagement and active involvement of patients and families. The following challenges to enrolling patients were highlighted:

- Poor access to care for many patients
- Poor reimbursement for care delivered, reducing institutional and investigator resources invested in SCD research
- Relative lack of potential profitability for industry
- Few studies which are community-based
- Competing studies for subjects willing and available to participate.2

Our best practices are designed to ensure that those patients who are accessing care have every opportunity to participate in the research studies that are available.

METHODS

To engage a population that is frequently unfamiliar with clinical trials, we use a method of recruitment that is closely related to volunteer recruitment methods for many non-profit organizations. In this model, we focus on being there and building relationships with patients who may be good candidates for participation. The following best practices make up the recruitment and retention cycle.

- Go out for outreach: Attending community events where SCD patients may be provided a new opportunity for potential participants to see research up-close and personally.
- Health fairs, support group meetings, disease-related non-profit events (such as fundraising walks), and other places where information can be shared are excellent venues for handing out printed materials and speaking one-on-one with key stakeholders in the community about your research.
- Reach in for outreach: The traditional approach of combining your institution’s electronic medical record and physician referral are key to finding patients who meet your screening criteria and are good candidates for your study.

RESULTS

Following this method of recruitment, VCU consistently meets or exceeds enrollment goals in SCD clinical trials. Additionally, patients are retained through completion of the protocol. An example of the success of these recruitment and retention best practices is below:

- Number & % of Randomized Patients Completing Study at Investigator Site

<table>
<thead>
<tr>
<th>Investigator Site</th>
<th>Number of Patients</th>
<th>% Completing Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>50</td>
<td>80%</td>
</tr>
<tr>
<td>Site 2</td>
<td>60</td>
<td>90%</td>
</tr>
<tr>
<td>Site 3</td>
<td>70</td>
<td>95%</td>
</tr>
<tr>
<td>Site 4</td>
<td>80</td>
<td>100%</td>
</tr>
</tbody>
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CONCLUSIONS

While recruitment methods cannot solve socioeconomic conditions, or suddenly change long-held beliefs about the management of a chronic illness, there is a distinct benefit achieved by a Clinical Research Coordinator (CRC) being present and focused on building relationships. Trust is established when an individual consistently sees and experiences a commitment to his or her well-being and best interests.

Recruitment and retention must be recognized as a cycle if common barriers to clinical trials recruitment will be overcome, particularly in patient populations that lack trust in the medical field.

RECOMMENDATIONS

1. Each time around the cycle, a CRC has multiple opportunities to recruit participants. As more members of the recruitment pool are reached in the cycle, trust is built in the community. Individuals who may not have been willing to commit at first contact may be more willing to do so.

2. We have found that good candidates for clinical trials are more likely to commit and participate in a study if they feel valued, heard, and respected. Building relationships by engaging the community is an essential tenet of successful recruitment and retention.

REFERENCES


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