Implementing Patient-Centric Principles in Asthma Research

Shann Williams
Project Management Operational Service Leader, Rho

The term patient centricity is fraught with uncertainty for many. This term carries the nuances of widely varying practical application methods as well as theoretical disagreements from stakeholders in our industry. For example, an article in Applied Clinical Trials entitled ***FDA and Industry Share Perspectives on Patient Centricity*** contrasted the biopharmaceutical industry and the FDA's perspectives on patient centricity and concluded that industry thinks patient centricity is patient engagement, whereas the FDA is focused primarily on developing clinically meaningful outcomes to patients.

Although it is understandable that we would be intimidated by the lack of regulatory guidance and the uncertainties of taking on risks in any relatively new area, I would argue that this isn't rocket science. Some of the same practices we have known about for years that make for successful studies can be implemented to demystify patient centricity and provide a starting place. Here, we'll share simple, actionable, "bite-sized" strategies we've employed on asthma studies to provide a more patient centric approach.

Two high-level patient-centric concepts that we've learned from years of clinical and community-based asthma research can have positive impacts on studies are: **easing patient burden** and **effective communications.** These strategies fall into the category of "study volunteer ease" which was found to have the biggest bang for a relatively small investment by this **DIA/Tufts study**.

EASING PATIENT BURDEN

High participant retention is important for any clinical trial. It is critical to our ability to reach power for study analysis and is an indicator of overall study success. Patients choose to participate in studies because the benefit of their participation outweighs their perceived risk, burden, and general inconvenience. Some patients are being altruistic while others are hoping their participation will improve their health. We can help to change the perception of clinical trials by making them less burdensome for patients overall.

The Urban Environment and Childhood Asthma (URECA) study is an observational birth cohort study currently in its 13th year. It was funded out of the National Institutes of Allergy and Infectious Disease. URECA currently has 448 total patients enrolled. In its first two years it had 89% retention rate and 448 of the 609 original patients are still enrolled (74% retention) 13 years into the study. That high retention is attributable to several patient-focused practices described in detail below.

These were the 8 patient-focused practices employed in the URECA study and discussed in detail in our publication in ***Clinical Trials from 2010:***

Call hours

- Any reminder phone calls, follow-up questionnaires or recruitment and screening calls are often conducted after regular business hours when patients are more likely to be available.

Employ culturally competent staff

- The sites employ culturally competent staff that speak the patient's native language, understand the nuisances of that specific population, and identify with challenges and considerations within that specific demographic and geographic location.

- **Flexible visit scheduling**
  - Many of our sites and clinics are open on Saturdays or have extended hours to allow patients to avoid missing work and school.
- **Provide reimbursements for transportation and parking (no brainer!)**
- **Host retention events**
  - This is an example of something that worked for this specific population that may not work for others and points back to really knowing your population via hiring competent staff. The study involves mothers and their young children, and these events brought a sense of community. Patients got to know other mothers and children that were in the same study and were able to create relationships and deepen relationships with study staff.
- **Offering home visits**
  - The success of this study hinged on our ability to meet the needs of this population. Young mothers with asthma who have babies with respiratory infections do not want to brave the winter in Boston and call a taxi to take them across town so that they can have a nasal lavage performed. There are risks that come with doing home visits, and an option like this has additional implications that must be considered carefully.
- **Cell phone or texting reimbursements**
  - This is especially important for those families who buy minutes.
- **Distributing quarterly newsletters**
  - This is an easy way to make families aware of study status. The one from a winter month offered an update on the study retention rates and included indoor activities – making snowman cookies, connect-the-dots snowman for the children, and tips for staying safe in cold weather. These are more than just visit reminders or asthma educational materials, they are geared toward ensuring the patients feel engaged in the study.

EFFECTIVE COMMUNICATION

Community-based research success hinges on community engagement. Building Bridges was a school- and community-based asthma study. The goal was to disseminate a nation-wide program to "build the bridge" between the school nurses who see students with asthma frequently and their care providers who see them less often. Our hope was that this would provide greater asthma control and improve academic performance by reducing school absenteeism due to asthma.

Denver and Hartford school districts participated in the study. The study team conducted focus groups with school nurses to help design the program and the entire first year was considered a pilot before expanding to other schools.

Following the first year pilot, we were able to revise questionnaires and streamline the approach to ease the burden on the nurses, parents, students, and school administrations to improve our ability to achieve program results. We received invaluable information from the nurses during this pilot period regarding student/parent preferences and the feasibility of the program. For example, the number of school nurses assigned to various schools was a serious consideration. Some districts had a single nurse covering multiple schools while others had assistants that could help distribute medications and print letters to send to the asthma care providers. The key to success here was our ability to tailor our approach to the community and schools while keeping the core components of the program consistent across the districts.

The information we collected during the Bridges pilot phase gave us invaluable insight into the research experience from the eyes of the nurses, patients, and their families. This principle applies to engagement of patients for all clinical research studies and is in line with what the DIA/Tufts study outlined regarding "study volunteer feedback" and engaging patients during protocol design.

These practices take careful pre-planning, but by incorporating patient-centric principles based on the time, schedule, and budget for each study, we can move in the direction of putting our patients first.

***Shann Williams** has over 10 years of experience managing clinical trials. She is the Director of Operations of the Statistical and Clinical Coordinating Center for the division-wide Consolidated Coordinating Center sponsored by the National Institute of Allergy and Infectious Disease (NIAID). In addition, Shann serves as Rho's Project Management Operational Service Leader, an internal expert sharing project management best practices, processes and training.*