Patients Involved – Ethnography and advocacy in sickle cell disease

Introduction

A case report on trained medical anthropologists shadowing people with sickle cell disease(SCD), to gain new insights into the world of what it's like to live with the disease and identify new approaches to recruitment.



Where in the process? – Phase II

When does it happen? – Phase II

Description of the case

Clinical trials in people living with sickle cell disease are generally slow to enrol, enrol fewer than expected participants, and many studies are terminated due to slow enrollment.* As a Phase II trial was ongoing and a Phase III was planned the clinical team knew they needed a new approach to recruitment to advance the program for a new potential medicine. The anchor to that new approach was to gain new insights into the world of what it's like to live with sickle cell disease, to have painful crises, and what they might consider if they were to think about joining a clinical trial.

Trained medical anthropologists were matched with 25 people with sickle cell disease by race, age and gender. They spent almost every waking moment shadowing their assigned patient, from breakfast to bedtime for at least two days. They learned how these patients viewed themselves, how they made decisions about their healthcare, and what they thought of healthcare practitioners. The ethnographer's videotapes and notes were coded and used to identify common themes that may be helpful in recruitment and other aspects of planning for Phase III.

In addition, the study team engaged sickle cell disease advocates for feedback.

*https://ash.confex.com/ash/2013/webprogram/Paper65249.html

Type(s) of patient (advocates) involved

Patients with personal disease experience.

External consultancy firm.

Pfizer clinical team.

Patient advocates.

Benefits of patient involvement

The Pfizer team learned that clinical trial education and the beginning of the informed consent process should be in advance of when a person is having a painful crisis with recruitment in venues other than emergency room settings. We understood more about the language patients used to describe their pain, about the fatigue patients experienced and attempted to design the trial to be more convenient for participants. This patient community trusted each other more than other resources and social media (from people with SCD) methods of learning about clinical trials. As spirituality was important to this group

consideration was given to including inspirational quotes in recruitment materials.

Challenges and barriers

The nature of ethnography research is resource intensive and time consuming to sort through the identified themes and apply them to planning.

Some insights gained cannot be integrated in a manner that is compliant with regulations or codes of practice. For example the suggestion that spirituality lends itself to messages of ‘hope’ for example from Phase II work would not be an appropriate representation of potential risks, benefits and uncertainties of participation in a clinical trial. Feedback to advocates was provided as to why it would not be possible to integrate all of their insights.

Learnings

As we gain additional experience with various types of patient engagement at key points in the lifecycle we may be able to better match circumstances that warrant more resource intensive engagement such as ethnography. We might also consider this type of engagement before phase II and even when we don’t anticipate as much of a challenge with enrolment. The insights gained may improve the participant experience as well as potentially having an effect on improving recruitment or retention.

A3-ethnography-in-sickle-disease-V1.0

Attachments

- Patients Involved Case Report – Ethnography and advocacy in sickle cell disease

Size: 860,332 bytes, Format: .pdf

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