Patient Pioneers: The Patient- and Site-centricity Movement

Could patients participate safely in a clinical trial and hardly ever visit the study site in person? Surely this is achievable with modern technology and the support of dedicated research nurses whose passion is putting patients first. If that can be accomplished, then why stop there? New tech and skilled photographers can perhaps take clinical imaging and videography to the patient's home too. Reducing the burden on both patients and their investigative sites can enable hospitals to enrol more quickly and participate in a greater number of studies, giving even more patients access to potentially life changing new drugs.

The patient-centricity movement has been inspired by the empowerment of patients and patient advocacy groups through the internet, social media and new technology. This has caused a paradigm shift in the clinical research industry, with protocol developers now viewing mobile nursing as an almost essential ingredient to the success of their trial.

Research is seeing an objective shift, making participation in a clinical study easier for patients by replacing site visits with appointments at home, school or work that, where appropriate, fit around the patient – relieving some of the burden on work-life and family. This demonstrates a duty of care to patients while at the same time providing sites with extra resources, freeing up their hospital time to recruit more patients, often allowing them to meet enrolment targets faster. The benefits to a sponsor and CRO partners are many; primarily, however, the early completion of a trial can mean longer patent protection for the drug and of course earlier access to much-needed medicines for patients.

Let it be clear, clinical research still requires skilled site staff and the specialist equipment needed for assessment in many trials. An effective partnership between site personnel, third party research nursing companies, the pharmaceutical companies themselves and patients is critical for the success of a truly patient centric approach.

Patient advocacy groups, along with social media, are also driving this movement, allowing both the patient and their families to take more control by providing additional information and support which would not have previously been available. This development has made patients, families and research question and challenge why we conduct clinical trials as we do… with the old adage "we always have" no longer an appropriate answer.

The Solution?

The solution seems simple: specialist GCP (Good Clinical Practice) trained research nurses delivering where appropriate, and the protocol allows, visits away from the research site.

Vital signs, blood draws, IMP administration, urine sampling and ECGs can all be performed in a safe, convenient location for the patient when delivered by a suitably qualified research nurse, while visits which require specialist equipment remain at the clinical site, for example MRI scans. The visits which could be appropriate for this service can be identified at the protocol development stage as part of the proposed schedule of events.

One example of this is the administration of a subcutaneous infusion given to patients in their homes by utilising research nurses who were contracted to visit patients twice daily, in the morning and evening. The logistics of this can be challenging but achievable with a sponsor who is determined to show compassion to their patients and appreciates the sacrifices involved in participation.

Imagine a family with two children suffering from a rare disease travelling from their home in Reykjavik, Iceland to a site in another country every two weeks. This example seems extreme but is not an uncommon situation for parents of children with orphan diseases to encounter. It's an impossible decision: put your child and family through the stress of travelling regularly to receive treatment or do nothing, receive no additional treatment. This was mitigated by finding, recruiting and training a local research nurse, eliminating a significant number of round trips by visiting the children in their own home and enabling parents to continue working and children to attend school. For a sponsor, this can save a huge amount of money by avoiding having to pay for regular, often business class airfares for the study duration. For the family, it avoided the burden of participation becoming overwhelming which avoided the children ultimately dropping out of the trial.

Another example of the service playing it's part is in the distressing condition Epidermolysis Bullosa (EB), whose sufferers are mainly children living with a rare disease that means they are highly susceptible to contracting infection in their lesions. The nature of the disease makes it extremely difficult for EB sufferers to travel; even a trip to a nearby site may require specialist transport, chaperones, and much logistical planning.

Research nurses visiting patients in their home reduced stress and kept the children as safe and pain-free as possible. Nurses trained in wound care expertly soaked off and re-dressed lesions which form on patients' paper-thin skin, with experience in paediatric trials and the skilled sensitivity required to manage such fragile participants. Furthermore, one of the endpoints in the study was image-based and the nurses were able to use specialist calibrated cameras to monitor the wounds and further prevent the need for site visits. Clinical photographers performed ongoing quality control, advising nurses if images need to be retaken and permitting the relevant data to be collected without having to repeat visits.

This innovative approach enabled the sponsor to minimise patient travel, while maximising the time which research nurses have with patients, capturing key data and benefiting all stakeholders. Sites received CRF data directly from the nurse, as well as access to high-resolution images per subject, while families experienced as little impact as possible on their daily lives. The condition means they already have much to deal with and we believe this approach benefited all involved.

These examples highlight how taking care of patient needs boosts recruitment and supports retention, while the integrity of robust high-quality data increases the likelihood of a successful study and shortens time to market.

Still not convinced? Take it from the patients themselves. The comments below were from patients and their families participating in a multi-centre global Duchenne Muscular Dystrophy study. All are speaking about how research nurses aided their ability to contribute to this study.

- "The fact that we do not have to travel to site every time we do analytical work is already very comfortable and good for the patient."
- "Our son was more relaxed having bloods taken at home; he found it a lot easier only having one nurse and not lots of people in the room, with time to make sure he was ok and relaxed. I found it a lot less stressful as we would need to travel a great distance to hospital and have to pull over to put "magic cream" on his arms. It's more of a relaxed experience with yourself."
- "The home delivery service was excellent, impeccable both for the punctuality and for the professionalism and availability. The nurse also proved very understanding with the problems of the child who was happy about this feeling reassured by this attitude. The service was very efficient as was the nurse we met. She was very timely and always behaved well with my son. In practice, the service was perfect."
- "My opinion about the nursing service was that it was all perfect. The nurse with her work and with the family, we are pleased and wish this service success in future."
- "My experience with our nurse who took care of the home samples for the trial was certainly positive. She is a person who makes herself loved by parents and especially by the child who willingly accepted samples that are notoriously unpleasant at the age of nine. The nurses' joy, patience and willingness to play and involve the whole family was very good and we are happy that among many doctors, nurses and therapists, there was also our nurse we saw regularly."

This service has impressed families and sponsors alike. In one example, a sponsor was struggling with children dropping out of a rare disease study. The protocol required children to attend weekly hospital visits. This can lead to a major loss of time at school, loss of earnings for their parents due to lost time from work, and general inconvenience.

The sponsor adjusted the protocol to allow 75% of all visits to be conducted within the child's home, rather than them having to attend the hospital. Research nurses visited the children in their homes three out of every four weeks for a two-year treatment period. After the two years, not one child had dropped out of the study. Parents and their children were delighted with the rapport built up, and it meant the loss of school time, loss of earnings of parents, and general inconvenience was kept to a minimum.

There is also the rise of the virtual clinical trial, which technology has made much more achievable. 'Siteless', or centralised studies run the risk of becoming impersonal and detached, however: patients often decide to enrol on trials in order to have more access to healthcare professionals, not less. Patient materials, advertising campaigns, apps and other support mechanisms mean nothing if patients become disengaged or feel abandoned, and ultimately discontinue involvement. In a hybrid approach, research nurses can provide that highly valuable face-to-face engagement, building a rapport with their patients, helping to navigate them through the study, and increasing their likelihood of compliance.

Patient advocacy is becoming more than just a buzz word and it will drive the future of clinical research as patients and their families become more empowered with greater access to information and support.

It should be acknowledged that technology will play an increasingly important part of clinical care including research, but can we or should we ever replace the human touch? The introduction of specialist trained clinical research nurses enables the smoothest possible clinical trials experience for patients and families. This approach also gives the patients a single point of contact who they see regularly and build a relationship with, resulting in a more realistic view of the patient's views and needs, something technology alone could never deliver.

Thus, perhaps pioneering patients is about empowerment and ensuring we can offer a truly patient-centric solution, by offering seamless clinical research solutions involving sites, technology, nurses and – most importantly – the patients.

Helen Springford

Helen Springford was promoted to Chief Operating Officer at Illingworth Research Group in June 2019. She has over 25 years experience within the clinical trials arena. Having spent five years as a research nurse managing over 25 cardiology clinical trials in hospital and subsequent to that, seven years in clinical project management within both a CRO and big pharma setting, Helen truly appreciates the importance and difference a patient-centric approach can make.

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