Collaborating with Patients for Better Trial Design

PEER REVIEWED

88% of American patients would be willing to share their personal information online for the sake of improving care and treatment options.[1] Modern patients are taking control of their own healthcare, from sharing information with one another to approaching industry organisations with their concerns.

Thomas P Sellers, Senior Director of Patient Advocacy at The Takeda Oncology Company outlined the emergence of the modern patient-consumer, eager to learn about and contribute to the processes that affect their healthcare:

"In the past, industry viewed doctors as the customer and patients as the subjects, but that has begun to change with the emergence of patient thought leaders in the community who could talk about the science and about clinical trial designs."[2] Thomas P Sellers

As a result of readily available online healthcare information and united patient advocacy groups, patients are taking a more active role than ever in the care they receive, researching treatments and weighing up the pros and cons of trial participation for themselves. Support online and offline allows patients to reach out to one another, compare their experiences, and recommend or raise concerns about trials.

In order to appeal to this new wave of patient-consumers, clinical trial organisers are having to reconsider key components of trial design to reflect these concerns and ensure adequate enrolment. Rather than simply monitoring patients' potential barriers to participation, however, the time has come to go straight to the source and involve patients in trial design from the very beginning.

Why Should Patients be Incorporated?

In the age of information, patients are no longer satisfied with taking a back seat, demanding a more active role in not only their own healthcare decisions, but in the research process itself. Far from being a hindrance to the trial process, this active patient-partner role can provide a significant incentive for trial involvement. 56% of patients participating in a retinal health trial at the Sydney Eye Hospital claimed that they joined due to a wish to contribute to medical science, compared to just 10% who joined because they wanted free treatment.[3]

As major stakeholders in both the short- and long-term results of a study, patients are unlikely to join or remain involved in studies that they feel aren't working for them. However, the reasons patients give for non-participation often differ significantly from physician-perceived barriers. For example, oncologists considered fear of placebo to be a significant reason why patients might hesitate or refuse to join a trial, with 67% suggesting it as a major reason. However, in actuality, only 10% of patients surveyed agreed with this.[3] We can't afford to make assumptions when it comes to the needs and concerns of patients. Rather than wasting time and money on trial designs based purely on physicians' suppositions, we need to put patients at the centre of clinical trials.

While patient support often focuses on practical ways to make the trial experience easier and more engaging, for patients the heart of the matter remains emotional. From logistical issues, such as transport and accommodation, to building relationships with physicians, we are dealing directly with the concerns of critically ill people, their families, and their carers.

Whereas the goal of putting life-enhancing drugs on the market is common to all trial stakeholders, the potential barriers to patient involvement are far more personal and varied. Some patients may worry about spending long periods of time away from their children, while others may be more concerned about the accumulating costs of regular hospital visits during their time away from work. Each individual case stands to offer a unique perspective of the burdens associated with trial participation, and an opportunity to improve trial design.

Where Are We Missing the Mark?

Integrating patient perspective into regulatory decision-making has become a key point for FDA development, with the organisation's Patient Representative Program4 seeking input on drugs and devices as well as wider regulations. However, expanding these practices across private sector companies relies on a more general shift in the dialogue between patients and researchers.

A survey conducted by the Clinical Trials Transformation Initiative and the Drug Information Association found that only about 45% of large pharmaceutical companies actively engage with patient groups, with 41% claiming that they had no immediate plans to do so. Furthermore, many respondents that did reference patient engagement did so late in the process, often only during Phase III trials.[5]

This highlights how, despite incorporating patient-centric measures, researchers tend to heed the patient voice too late in the process, resulting in less-than-ideal solutions at a significant cost in both time and money. By neglecting the practical and emotional concerns of the patient populations at an early stage, sites and CROs are spending time and money developing recruitment plans and trial protocols that are irrelevant or retrograde to the needs of the patients themselves.

The first step in accelerating enrolment and retention should be open, active listening. Clinical trial organisers need to understand the language patients use to discuss their own illnesses and experiences and incorporate this into their own messaging, creating an equal and accessible dialogue devoid of medical jargon.

How Can Patients be Incorporated?

Modern patients expect choice and control in all aspects of their treatment and trial experience, and an initial request for informed consent is no longer enough. Instead, trial participation needs to be an ongoing conversation, starting from the ground up.

Rather than simply offering patients materials and resources to guide them through the trial process, we should allow them input in creating those resources, giving them wider opportunities to ask questions, suggest changes, and define their own experiences.

Offering patients opportunities to join or form advisory boards, give structured feedback, and take a key role in furthering medical research, could improve both enrolment and retention rates, changing the overarching rhetoric around clinical trials into a more active and appealing concept.

Advisory Boards and Focus Groups

Whether focused around in-person meetings or online discussions, advisory boards and focus groups can facilitate a two-way conversation. Firstly, they serve to educate patients more fully about the risks and benefits of trial participation, allowing patients to actively debate and discuss these rather than simply reading resources. This goes a long way to gaining patient trust, ensuring they have answers to all their questions before the trial begins.

At the same time, this involvement stands to inform clinical trial organisers of potential issues and improvements at every level of trial design, including finding an appropriate trial venue, transport, accommodation, food, drug delivery and other logistical issues.

While healthcare staff follow protocols to keep the patient's best interests at heart, the patients themselves have wider considerations still – their families and caregivers. By listening to patients' perspectives on the wider implications of trial participation, we can engage with the wider community of people invested in combatting illness, and ensure that the trial experience is supportive and empowering to all.

When engaging patients at this level, it's important to keep in touch with your legal and compliance departments, maintaining transparency about hard regulations and ensuring you don't mistakenly offer patients something you can't legally or logistically deliver. It is vital that patients see their suggestions being duly considered and actioned, otherwise they will consider their participation in trial design to be a mere token gesture, and not worthy of their time.

Consider maintaining a central online hub, via which patients can check the status of their feedback and the progress of any patient-focused projects they're involved with. This will not only reassure patients that their points are being taken seriously, but also allow patients, caregivers, physicians and trial organisers to stay on the same page across the trial experience.

The Role of Technology

The easy accessibility of online patient support groups is giving patients a new voice when it comes to the trial changes they want to see. A questionnaire of 528 online patient support group members found that respondents felt significantly 'better informed' and experienced 'enhanced social wellbeing' as a result of such groups.[7] Combined with the accurate and real-time insight patients are given into their own conditions and treatments via big data, health wearables and designated trial apps, these online communities allow patients to put forward better-informed ideas than ever about their own trial experiences.

It falls to clinical trial organisers to take advantage of these platforms, or to create bespoke trial-specific patient communication hubs, where feedback can be offered and responded to in real time across the trial period.

Services such as **md**group's **patient**primary app, allow for patient feedback pertaining to the wider trial experience. As well as allowing patients to access important trial information, make appointments and book transport and accommodation, the app offers a space for patients to review the services and make special requests, ensuring that their changing needs are taken into account.[7]

A bespoke patient advisory app could go one step further, allowing patients to make qualitative notes about their experience alongside clearly-presented quantitative information taken from wearable devices. This will give both patients and physicians a fuller picture of the patient's experience. The information could

be uploaded to a portal, from which researchers could compare feedback from all patients across the trial, and base objectives on this.

Furthermore, giving patients ready app-based access to information about the trial, specific data on their condition, and a dictionary to help them decipher medical jargon will empower them to understand and speak out about their trial experience, feeling like active partners in the research, rather than helpless guinea pigs.

This could be combined with space for a trial-specific support group chat, accessible via the app. This way, patients can compare notes, raise queries, and represent themselves throughout the trial, emboldened by conversations with fellow patients.

Social Monitoring

Data mining gives another interesting option for discovering and responding to patient opinions – particularly those that may not be shared in a formal setting. Companies such as Treato[9] algorithmically monitor public conversations on Facebook, Twitter and patient forums, capturing real-time commentary and analysing it for particular patient language. The trends captured give healthcare staff and patients alike a global overview of the big conversations in relation to specific conditions. Clinical trial organisers could use this information to monitor public opinions of trials and treatments, anticipating patients' expectations in order to exceed them.

Connectivity and Communication

In order for researchers and physicians to communicate with patients and translate their requirements into the trial process, efforts must also be made to ease administrative burdens, freeing time, resources and expertise to be spent on improving the patient experience.

Here, too, technology is opening more options than ever before. With the global wireless health market projected to grow from $39 billion in 2015 to $110 billion by 2020,[10] connected hospitals and trial environments will soon rely on automation for routine processes such as retrieving patient files, inputting and analysing data, and filling prescriptions, allowing staff to invest more in forming relationships with patients.

These advances could benefit clinical research in more ways than simply boosting retention rates. By being seen as an active and personable presence throughout the trial experience, staff can improve the level of open and empowered feedback they receive, ensuring more accurate qualitative data and allowing for further patient input into future trial design.

Trial Technology Challenges

Before launching patients into a world of apps and online forums, researchers should consider the fact that many patients are still uncomfortable with the use of certain technology, for both cultural and practical reasons. Older patients may struggle to keep up with digital processes, while those with demobilising conditions may struggle to scroll through their phones.

It's important to approach patient feedback in a flexible patient-centric manner, giving every trial participant an equal chance to offer their thoughts and feedback, and adapting processes on a case-by-case basis.

For example, a workshop introducing trial apps to patients who are unfamiliar with mobile technology could make them feel more confident and involved in the process, while incorporating functionalities for the physically, visually and hearing impaired into an app could go a long way to make collaborative trial design accessible to all.

The First Steps

While it will take time to change the paradigms around clinical trials universally, we can start by reaching out to patients and offering them a safe, supportive space to make their voices heard, and to find out how *they* want to be involved in the rest of the trial design process.

Kick-start the trial enrolment process with a meeting for all potential stakeholders, including healthcare staff, researchers, patients, their carers, and representatives from patient support and advocacy groups. Involve patients who can't attend in person by live-streaming the meeting online.

Make sure that you come to the meeting with some specific ideas of what patient advisors can help to address. Getting the ball rolling with a few practical questions can get patients comfortable discussing a wider range of ideas in the long term. An unstructured and uncentred meeting, on the other hand, could put patients off future involvement. Leave time for patients and staff to get to know one another, both online and in person, ensuring a comfortable starting point for future conversations.

Bear in mind that not all patients will have the time, energy or inclination to take on the full responsibilities of advisory board members, but their opinions could still be instrumental to creating patient-centric processes. It's therefore important to express that suggestions made at any point will be welcomed and taken seriously.

True patient collaboration is not a set endpoint but a constant discussion, requiring refinement for individual differences and changing patient needs. While finding the balance takes dedication, the reward is multifold: a patient-centric trial will not only cut the time and cost taken to bring a drug to the market, but also create an accessible dialogue around disease, treatment and clinical research that will change the face of clinical trials.

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