Caregivers in Oncology: How to Address the Needs of These Hidden Heroes

There's an important person out there influencing your next oncology trial patient. We don't often talk about this person within clinical research, much less plan for them. Yet, they will have an unprecedented impact on your patient's understanding of the trial, their ability to make site visits, and their adherence to medications and protocol.

This person is the patient's caregiver.

For those who may not know, The American Cancer Society defines a caregiver as *"...The person who most often helps the person with cancer and is not paid to do so... Caregivers may be partners, family members, or close friends. Most often, they're not trained for the caregiver job. Many times, they're the lifeline of the person with cancer."*

Caregiver Burdens

The phrase "they're the lifeline of the person with cancer" is telling. When it comes to oncology trials, caregivers have historically shared much of the patient burden while also facing their own unique issues. In fact, caregivers often face the exact same burdens as patients, such as taking time off work, providing or finding transportation to patients, finding or providing childcare, ensuring medication adherence, and ensuring the patient progresses through the trial as needed.

They may also take on basic duties that support the patient outside of the trial. These can range from household chores (cooking, cleaning, etc.), to monitoring general health and providing emotional and financial support. In addition, caregivers often find themselves providing their own level of healthcare to patients, helping with symptom management, treatment monitoring, and more.

However, that's not all. Caregivers are in a unique position with oncology patients, who may be suffering from side-effects from cancer treatment. Patients on chemotherapy often suffer from excessive fatigue, neuropathy, and "chemo brain" (difficulty in thinking or recalling information). Each of these conditions can create additional burdens for caregivers, depending on their severity, or can make an already difficult situation more dire. For instance, a patient suffering from chemo brain and excessive fatigue may rely more on their caregiver than usual for basic needs such as cooking and cleaning, in addition to trial needs such as medication adherence and remembering site visits.

As a result of all this, caregivers often seek as much information about oncology, cancer treatments, and clinical trials as patients do. Thus, it's important that clinical trials treat oncology patients as a unit, recognising the legitimate needs of both the patient and their caregiver(s). Put simply, caregivers are just as essential to an oncology trial as the patient themselves and can be one of the reasons some patients end their participation in the trials.

Clinical Research vs. Standard of Care

The first place that patient and caregiver needs can be addressed is in explaining the differences between a clinical trial and standard of care. It's important that clinicians ensure that both the patient and their caregiver(s) understand that the primary intent of clinical trials is to answer questions about the treatment itself, rather than treat the patient themselves.

Patients and their caregivers may also be unfamiliar with their trial drug, whether or not it's blinded, or how to get information surrounding the drug. It's essential that clinicians ensure patients understand how the trial, its protocol, and the therapy will work. Sponsors, contract research organisations (CROs), and research facilities can help ease clinician's duties in these regards by providing them with pre-made materials about the trial, with answers to common questions that patients or their caregivers may have.

Here, clinicians must be careful. Many oncology patients may have existing care plans to address common oncological co-morbidities that require regular or emergency visits to healthcare facilities outside of clinical research. Thus, any changes to the trial may be hard on patients and their caregivers, especially if it causes the trial to compete against their existing care plan.

It's also paramount that patients and their caregivers understand the nuances and levels of consent. While some standard treatment options typically require consent, most patients and their caregivers will be unfamiliar with the level of consent required for a clinical trial, such as re-consenting for protocol changes, consenting for biosamples, or trial-specific procedures. This is especially significant, as the larger the perceived burden is on the

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patient and their caregiver, the more likely they may be to drop out.

Another key conversation topic is the financial requirements of the trial. Those coming from the oncology standard of care world may understand that insurance covers their regular care, but may not understand that the clinical trial sponsor covers the medication, biopsies, lab treatment, etc. As mentioned before, the higher a burden that a patient and caregiver feel, the more likely they may be to drop from the trial. Therefore, it's important to ensure they understand that these items are taken care of and won't provide any additional financial burden.

Opportunities to Address Caregiver Specific Needs

As mentioned previously, a caregiver can be as essential to the trial as the patient themselves. Thus, providing them with specific information geared towards their experience will help not only the caregiver, but the patient and the trial as a whole.

At the least, caregivers should receive the exact same trial information as the patient. Research from Dewalt (Dewalt, D.A. *et al*., 2010) shows that patients are likely to forget 40% to 80% of the medical information they receive. Of what is retained, only half is correct. Thus, the information given to patients and caregivers around the treatment, visit schedules, adherence, diaries, or other requirements should be uniform. This is to ensure that the caregiver can act as a backup to the patients' knowledgebase if need be. This is especially true in patients who do receive chemotherapy or other impairing treatments as part of their standard of care, who likely need the extra support.

In most cases, clinicians should provide caregivers with specific information that pertains to their unique needs and burdens. Clinicians should seek to provide additional information to caregivers that shows how to best care for their loved one, within the best of their ability. This means basic instructions on how to increase comfort when a patient is feeling unwell, how to monitor symptoms, and when to seek medical help.

Caregivers must also be armed with information about how to best care for themselves during this difficult time -OR- Caregivers offer a unique perspective on the patients' condition

As caregivers are most often assigned with logistical tasks, it's also important to provide them with emergency contact numbers, a primary point of contact for any non-emergency questions, take home instructions for any devices, reporting, adherence, or other tasks.

Caregivers must also be armed with information about how to best care for themselves during this difficult time. It is common for caregivers to devote more time to their patient, ensuring they have everything they need as they help them through this difficult time. However, this can often lead to diminished self-care. Here, it's quintessential to let caregivers know that this is common, and to provide them with support services such as health navigator, support groups, or other local services.

Within the last decade, several trials have made an effort to consult with clinicians and their patients prior to developing a trial's protocol. They've done so in order to provide a trial protocol that would be best for patients, sites, and investigators all at once. In these instances, trial sponsors should also seek to consult with patients' caregivers, who will best understand the impacts to their own lives and ability to care for their loved one.

Surveys are another quick and easy way to see the impact that your trial has on your patients' caregivers. Caregivers have a unique perspective on the patients' condition and often provide useful information that patients are unwilling to provide or cannot see on their own. They're also a great way to understand, quantify, and document the amount of extra burden that is placed not only on the patient, but their entire familial unit.

Lastly, consider offering caregivers the same benefits that patients receive. For instance, if you reimburse patients for adherence to medication, visits, or for other reasons, consider offering the same incentives to caregivers. Or, consider offering caregivers the option to rely on an alternate means of transportation for a few site visits.

Changing the Conversation

When it comes to oncology clinical trials, the industry must remember that our patients are often not tackling trials alone.

In fact, there's an important person out there with direct influence on your next oncology trial patient. We don't often talk about this person – but it's time we do.

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