Patient-Reported Side Effects: A Crucial Part of Cancer Clinical Trials

By Julie Grisham, **Tuesday, February 26, 2019**

Clinical trials nurse Asia McCoy, shown here speaking with a patient, helps oversee studies at MSK related to bladder cancer.

Summary

> Patients' reports on their symptoms and experiences are considered the gold standard for documenting side effects in clinical research.

Memorial Sloan Kettering researchers oversee hundreds of **clinical trials** every year. Some of the most exciting and potentially revolutionary studies look at brand-new drugs that are being given to people with cancer for the very first time.

Clinical trials investigate both the safety and efficacy of new treatments. One component of safety relates to side effects that impact the quality of life of the person getting the treatment. Symptom-based side effects — like fatigue, insomnia, and pain — often can't be measured with a scan or a blood test yet are still significant.

Patient-reported outcomes are unfiltered reports directly from patients. They reflect the symptoms and experiences of people enrolled in clinical trials, and are considered the gold standard for documenting these side effects. Increasingly, the experiences of people in trials are helping shape how a new treatment is used and even whether it ultimately gets approved by the US Food and Drug Administration.

"People who participate in clinical trials are truly our partners in cancer research," says **Thomas Atkinson**, of MSK's **Patient-Reported Outcomes, Community-Engagement, and Language Core**. "It's our duty to allow them to provide input into clinical decision-making processes."

> "It's no longer considered acceptable for a clinician to assess how a patient is feeling without including input from the patient."

Thomas Atkinson
behavioral scientist

Collecting data on patient-reported side effects is a key part of clinical trials, explains clinical trials nurse Asia McCoy, who helps oversee the studies at MSK related to **bladder cancer**. "We stress to patients who are participating in clinical trials that they need to contact us if they're experiencing any new symptoms, even if they seem insignificant or unrelated," she says.

An Increased Focus on Patient-Reported Symptoms

Dr. Atkinson was part of a team funded by the National Cancer Institute (NCI) that developed a new system to make it easier for patients to report their treatment-related symptoms during clinical trials. In 2014, the team released an electronic platform called the **Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)**. It collects information about these symptomatic experiences. PRO-CTCAE is now used in the majority of NCI-funded trials.

"There's been a shift toward capturing information about side effects directly from patients," he explains. "It's no longer considered acceptable for a clinician to assess how a patient is feeling without including input from the patient."

Dr. Atkinson says the increased emphasis on **survivorship** is a big reason for this change. The primary focus of cancer treatment was once treating the disease almost at any cost, he notes. But as people are living longer with cancer and many are being cured of their disease, the short- and long-term side effects of therapy have become ever more important.

With Side Effects, Expect the Unexpected

With the boom in the development of cancer therapies, including newer treatments like immunotherapy and targeted therapy, the number of clinical trials conducted every year has grown. Every clinical trial must be approved and monitored by a hospital's Institutional Review Board. This team of experts is responsible for protecting the rights and welfare of trial participants.

Until a new drug is given to a patient for the first time, however, researchers can't always anticipate every side effect. Some symptoms may not be predictable even when researchers know which kinds of cells and tissues will be affected by the drug. Other side effects are not easy to measure in animal studies.

Clinical trials nurse Lauren Kaplanis helps manage many of the trials conducted by MSK's Early Drug Development Service.

"The first time I meet with a patient, I review all of the possible side effects that

we already know about," says Lauren Kaplanis, a clinical trials nurse who helps manage many of the trials conducted by MSK's **Early Drug Development Service**. "When it's a new drug, we're honest about the fact that we don't always know what all the side effects will be."

"Data about symptoms is important information for us to have," Ms. McCoy adds. "It can propel a drug into the next stages of development, or it can shut down a protocol."

An Emphasis on Open Communication in Cancer Trials

Dr. Atkinson, Ms. McCoy, and Ms. Kaplanis all worry that people enrolled in trials may be afraid to report side effects.

"They're concerned they may have to make an extra trip to come see us," Ms. McCoy says. "Or they think we'll view them as complaining too much."

Fear of being removed from a study may also be a factor, especially if the patient considers it their last chance for successful treatment.

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Asia McCoy
clinical trials nurse

"It's human nature to worry that if you're constantly reporting things like severe pain or nausea, you may get taken off a trial," Dr. Atkinson says. "But trial participants need to understand that they have to report these things. If the drug eventually gets FDA approved, the doctors who are prescribing it need to know which side effects may occur, so they can help future patients."

If a patient is experiencing a lot of symptoms when receiving a new drug, they may be able to continue receiving it, at a lower dose, for example, or they may take a temporary break, Ms. Kaplanis explains. "We want people to know about these

opportunities for treatment, and we stress the idea of having an open dialogue," she says. "We're all on the same team."

Comments

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Vivek Joshi

May 4, 2019 • 9:48 AM
Hello doctor,

My mother is suffering from liver cirrosys(liver cancer).
I am from india. We are taking treatment here but when we started treatment she was 60kg and now after 6 months she is 48kg. Doctor is telling she is deteriorating. Is there a complete cure in your hospital,if so can I know approximate cost and time.

God bless you

Memorial Sloan Kettering

May 5, 2019 • 2:20 PM
Dear Vivek, we're very sorry to hear about your mother's diagnosis. If you would like to consult with someone at MSK you can contact our **International Center** at **international@mskcc.org**. Thank you for your comment and best wishes to both of you.

PREVIOUS
In the News

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