

Should Informing Patients About Clinical Trials Become Standard of Care?

*A Health Policy Roundtable
with Diverse Stakeholders*



Coalition for
Clinical Trials
Awareness

www.CCTAwareness.org

Imagine if discussing clinical trials opportunities were a standard part of patient care – a routine and potentially life-changing conversation for physicians and their patients with cancer, Parkinson’s disease, arthritis, asthma and many other conditions.

To explore this possibility, the Coalition for Clinical Trials Awareness talked with a diverse group of stakeholders:



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This document highlights their insights on both the potential advantages and challenges of a health care system in which every patient would be offered information about joining a clinical trial.

SECTION 1: BARRIERS

Current Challenges in Clinical Trials



DC: It's very difficult to fill studies that are ongoing at our nation's academic medical centers.



RP: It has become more difficult to recruit patients, and also the sites are not as spread out throughout the country.



ES: One of the things we're acutely aware of is financial toxicity. Patients may have regional access to a clinical trial and not have the means to travel to a site that is an hour and a half away. What we found in [the *CancerCare*] study was that for people not on Medicare, the average out-of-pocket expense per month was \$1,112 while in treatment.



MR: [For cancer], precision medicine trials are very, very hard because they need smaller [but highly specific] patient populations. And the challenge with the Cancer Moonshot that you've heard a lot about—trying to move 10 years of research in 5 years—well that's not going to happen if we don't have trials running, and trials filling.



ES: For people to take the best care of themselves, and get the best care, they really need to be a full partner in making decisions and understanding treatment options. Patients, if they don't know enough about trials, are not presented with trial options...then they are making decisions based on incomplete information.

Keeping Physicians Current



DC: How does a community physician or a primary care physician remain abreast of what's going on in clinical trials? It's impossible.

For example, I'm a neurologist, and I know specifically which trials are going on in Parkinson's disease at my academic research center. I couldn't even begin to talk about what's going on in other disease states such as cancer or heart disease. And

then could I find them if needed? Could I find exactly what trials are going on quickly and easily in, say, diabetes or liver disease?

What if I'm in front of a patient, and a family member says, 'Oh, can you tell me about that?' I would struggle to help get them quickly to the right resource, even within my own academic medical center.

Financial Disincentives



DC: Representatives from oncology groups pointed out to me that the treatment of cancer in some practices can be very lucrative. So the idea of a community oncologist saying, “We can offer you the standard of care treatment here in our office or you can go across town to the academic medical center and participate in a clinical trial”...there’s actually a financial disincentive for the community practice in some cases, and the amount can be very large.



ES: I think that’s very real. And that’s even true in academic centers. [I have a friend] whose only hope is a clinical trial, and yet his physician, who’s treating him...is being very reticent regarding what trials may be available.

Some of this is financial [dis]incentive....

SECTION 2: SOLUTIONS

Creating Tools to Direct and Inform



RP: Everybody will say: ClinicalTrials.gov. But that’s not meant to be a portal for patients or physicians to find clinical trials. The intent of that portal was just to identify studies that industry was participating in for the case of publication or for regulatory approval....

So we need to create something from scratch... a ClinicalTrials.gov 2.0 that includes a lot of materials that physicians can easily navigate and patients can easily navigate...and somehow have a portal that attaches everything to one another where the patient can go and say, “I have diabetes at this age, at this gender. This is the number of years, multiple medicines I’m on...” and “Boom!” out pops the clinical trials that are available within their geographic area.



ES: The whole gamut of communication channels really needs to be used in applying these tools so that people can understand them, and digest them, and determine whether [clinical trials] are right. [We need to consider] what role anxiety and distress plays in [patients’] ability to comprehend information, and to assess options, and to consider issues around access.



MR: There’s nobody in a clinical office who is designated to be the educator. As a health care system, it would be great to invest in somebody who can be the expert at reaching patients and be the expert at talking about these things so that it’s not all on the physician in the 15 minutes they’re allotted with the patient.

Talking to Patients about Clinical Trials



RP: There needs to be much more of an explanation from physicians about, “What does a trial mean?” and “What is the standard of care?” and “Where do you fit into that standard of care?” It will involve physicians doing much more [participation] in this explanation, and a lot more time on their part. And I believe that the specialists can do it. I’m not certain if the primary care, family physicians can really do that....



MR: Patients and physicians need to meet halfway. Patients need to be aware that this isn’t something scary and it’s an option to them, another thing to consider as they’re shopping around for what’s best for them. [In the physician’s office] we have to make sure there is time to bring it



up....

DC: There is no cookie cutter, one-size-fits-all answer... I do believe that discussing clinical trials should be the standard of care, but depending on what the condition is, it may be completely inappropriate to bring it up at the time of diagnosis.

Also, it may be appropriate for another health care provider to introduce the idea of learning more about clinical trials; it doesn’t have to be the physician. Could it be someone on the care team for the patient that introduces the notion of a clinical trial? I believe so. It needs to be tailored to the patient, but it must happen.

How Government and Industry Can Help



RP: We need a campaign. We have a roadmap for the campaign to educate, but at the back end, we also need to have a campaign about developing an infrastructure for people to be able to find where those clinical trials are.



DC: What we’re proposing at the Coalition for Clinical Trials Awareness is a national campaign to elevate the public’s awareness of the benefits of clinical trials to society.

One of the solutions is to reach out directly to the patients, to the community...such that if they became ill, or they have a friend, a loved one who’s ill that it comes to mind: ‘Hey, we need to look into the possibility, or the option of clinical trials.’

What’s the end result if we were successful in doing that? We would increase the speed at which medical innovation occurs, not only for America, but for the world.

Every new treatment we have available today had to first go through a clinical trial. Yet, clinical trials today are not meeting their enrollment goals. Some sites fail to enroll even one patient.

Elevating the public’s awareness about clinical trials will change that paradigm... It’s ambitious, but it will work, and it will have a significant impact on the health care of our nation.

LEARN MORE



Coalition for Clinical Trials Awareness

www.CCTAwareness.org

ABOUT CCTA

The Coalition for Clinical Trials Awareness is a nonprofit group of health care providers, patient advocates, medical researchers and industry and government stakeholders working together to increase public awareness about the importance of clinical trials participation.

To learn more, visit www.CCTAwareness.org.