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| Close-up image showing the leaf-sides of two oversized books side-by-side on a bookshelf, with additional books in soft focus background |
| Referring Providers Outreach Guide  How to “normalize” clinical trials in your community and encourage provider referrals |
| |  |  |  | | --- | --- | --- | | Boone, Leslie R | 3/1/19 |  | |

*This document was adapted and revised from the Education Network to Advance Clinical Trials (ENACCT) for the Recruitment Innovation Center (RIC) of the Trial Innovation Network. The Trial Innovation Network is supported by the National Center for Advancing Translational Sciences, National Institutes of Health, under award numbers U24TR001608, U24TR001597, U24TR001609, and U24TR001579.*

**Working with Community Providers**

**REFLECTION CHECKLIST**

Share this with your colleagues to see what your research department thinks about these issues.

|  |  |  |  |
| --- | --- | --- | --- |
| **Question** | **Very** | **OK** | **Not Very** |
| 1. How consistent are our referrals from outside providers? |  |  |  |
| 1. How well do we communicate with outside providers about particular studies? With community groups? |  |  |  |
| 1. How well do we communicate with our referring providers about clinical trials as a quality treatment option? |  |  |  |
| 1. How well do we communicate with our community about clinical trials as a quality treatment option? |  |  |  |
| 1. How well clinical trials are integrated in outreach and community relations of our larger organization? |  |  |  |
| 1. How well can our medical, clinical or administrative staff appropriately provide positive messages about clinical trials? |  |  |  |

If you answered, “OK” or “not very well” to more than 3 of these questions, your site may need to implement changes in this area. Take action with the tips from this guide.

COMMON concerns of referring providers (and how to handle them)

Because research shows that most participants will join a trial if recommended by their health provider or someone they trust, it is critical that research teams reach out to community health care providers (e.g., doctors, physicians’ assistants, nurses, and nurse practitioners).

**It is preferable to consider these activities as on ongoing effort to enhance access to clinical trials, rather than as an approach to enhance recruitment to a particular trial.**

Here are 15 common concerns community health care providers/referring clinicians may have about referring their patients to a clinical trial, as well as suggestions for how to respond to these concerns. **Be sure to address all concerns in a frank, open, and honest manner.**

|  |  |
| --- | --- |
| COMMON CONCERN | Potential Response (need to be customized for your trials) |
| 1. I don’t think it’s my role to discuss clinical trials with my patients | Most patients would consider a clinical trial if their doctors recommended they do so.31 One study showed that recommendation by their physician was the primary factor influencing patients’ decisions to enroll in a trial 32,33  Because of the often long-term relationships PCPs have with their patients, the message about clinical trial participation might be more readily accepted and heard by patients if their primary care physician introduces the subject38  PCPs are often in the best position to find the opportune moment—before making a referral to bring up the subject of clinical trials with their patients. Despite their influence, very primary care physicians routinely discuss clinical trials with their patients. 40 |
| 1. I’m not a researcher, so what’s my role in a clinical trial? | During referral, the referring clinician can help:   * Assess broad feasibility of the patient enrolling into a clinical trial * Discuss the possibility of a trial participation * Establish initial contact with the clinical research team * Schedule appointment and share appropriate clinical data with the research team   If the person ends up being accepted into a trial, the referring clinician:   * Continues to be involved in clinical care of the patient * Communicates with the research team regularly regarding patient’s condition and any significant changes * Provides emotional support to the patient   Helps answer questions the patient may have |
| 1. I think it would be imprudent for me to refer to a trial – or any research you are doing-- when I am not sure what is clinically appropriate. | Not knowing what is clinically appropriate is the precise reason for recommending a clinical trial. In fact, the ethics of clinical research require equipoise—a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial. If the best clinical intervention were known, there would be no need for the trial. |
| 1. My patients are already doing very well on the standard regimen I am already providing/the specialist is already providing. | You clearly take outstanding care of your patients. We want to find ways to help providers like yourself play a role in research we are conducting in our community that can have a significant impact on future care we all provide.  It’s great that the treatment you are providing is working well for so many of your patients.  (Possible additions include the following):   * This trial is testing a new approach that will complement the existing treatment * This trial is evaluating new approaches that your patients don’t have access to outside a trial. * Many patients on standard treatment experience (side effects, other difficulties). Might they be interested in exploring this opportunity? * Many providers want to be sure they are offering all options to their patients. Might you be interested in helping inform them of this opportunity? |
| 1. My patients wouldn’t be willing to travel to xxx to be evaluated for trial participation | While it’s true that many patients may not be willing to travel, or have difficulties travelling…   * Research shows that many people are never asked to participate in clinical trials, even though they may have been willing. * Research has also show that people from racial and ethnic minority groups, as well as older people are less likely to be asked to participate, even though they appeared to be eligible. * We believe it’s important to help your patients understand all their options, including the option to participate in clinical trials.   (Possible responses include the following):   * We have taxi vouchers for people who are interested in taking part * Many of the (screening) tests required for the trial can be completed at your site * Your records can actually help us determine if patients are eligible for trial participation |
| 1. My patients aren’t interested in clinical research | * Research shows that many people are never asked to participate in clinical trials, even though they may have been willing. * Research has also show that people from racial and ethnic minority groups, as well as older people are less likely to be asked to participate, even though they appeared to be eligible. * We believe it’s important to help your patients understand all their options, including the option to participate in clinical trials. |
| 1. Most of my patients are not eligible for clinical trials | Patient eligibility criteria for trials is highly variable, and trials open and close all the time. We think its more helpful for us to do the screening for a trial to help reduce burden for your staff. Once you know a patient might be interested in trials we have available, we suggest that you make the initial referral to our site.  *Be sure to outline your reliable referral systems to expedite trial screening access for patients. Describe exactly how you will make it as easy as possible for the physician to refer and address these specific concerns* |
| 1. My patients are uninsured and already have problems paying for treatment, let alone participating in a trial | Of course, financial issues are a serious concern.  Participating in a clinical trial does not guarantee free medical treatment or care and there may be limitations to what costs are covered by the study sponsor. Federal law requires most health insurance plans to cover routine patient care costs in clinical trials under certain conditions.  At our site, when people don’t have health insurance, we…  ***Be sure you can explain how your site will address this barrier.*** |
| 1. Why should I refer my patients? I know my patients wouldn’t be interested in participating … | * Research shows that many people are never asked to participate in clinical trials, even though they may have been willing. * Research has also show that people from racial and ethnic minority groups, as well as older people are less likely to be asked to participate, even though they appeared to be eligible. * We believe it’s important to help your patients understand all their options, including the option to participate in clinical trials.   At the very least, we hope you would be willing to   * encourage your patients to ask about clinical trials when you make referrals to specialists * help your patients understand how they can benefit from clinical trial participation |
| 1. It’s too much work to get the referral to [your site] I’ve sent patients to [your site] before and…  * I never hear about what happens with my patients on the study * It’s too hard to deal with all the paperwork | *Be sure to outline your reliable referral systems to expedite trial screening access for patients. Describe exactly how you will make it as easy as possible for the physician to refer and address these specific concerns.*   * *Provide easy access to the basic criteria for inclusion in the study and by making the act of referring simple.* * *Distribute a pocket card and fax referral form when speaking to potential referring providers.* |
| 1. I’ve sent patients to [your site] before and they aren’t treated well there; they prefer to stay here in the community | What’s In it For Me?   * Be sure you can define areas of mutual benefit * Outline potential benefits to his/her patients * Recognition as role model for other community providers * Participation in a learning health system as partners with researchers   Making Seamless Referrals   * Do you have a toll-free “one-stop” phone number/email/website that makes it easier to transfer records? * Do you have a toll-free “one-stop” phone number/email/website that makes it easier for patient contact ?   Keeping open communication   * Discuss how your site publishes reports, a newsletter, or letters outlining research activities and send out regularly * Discuss how your site will keep the referring providers informed about their patients’ participation in the trial |
| 1. How do I know my patients will be treated well if they are subjects in a study at your site? I’m skeptical about how people are taken care of in these trials… | *Describe exactly how your site* *has made changes in patient centered care, and how that is part of how clinical trials work at your site.* For example:  Explain the ways in which your site provides high quality, person-centered care. For example  Culturally sensitive care   * Training doctors and staff * Provider diversity * Translation of Materials * Interpreter Availability   Patient support services   * Patient navigation, social work, etc. * Patient Satisfaction Ratings: * Discuss your sites’ data around trials and patient satisfaction with experience * HCAHPS measures around communication with doctors, communication with nurses, staff responsiveness * Other quality indicators   Although people fear that trial participants are treated like guinea pigs, reports from actual trial participants disagree. In 2015, a survey of trial participants found that that an overwhelming majority said their overall experience was positive. Ninety-four percent said they would do it again and 92% said it met or exceeded their own expectations [[1]](#endnote-1)  We like to call people who decide to take part in clinical trials “participants,” not “subjects” and strict guidelines are in place to ensure how these volunteers are treated. Each participant:   * Has the right to withdraw from a trial at any time for any reason * Goes through the informed consent process. Through the informed consent process, people have the right to:   + Learn about all their options care   + Learn all that is involved in the trial, including details about the approach, tests, and possible risks and benefits   + Discuss the trial with the principal investigator (PI) and other members of the research team   + Both hear and read the information in language they can understand |
| 1. What are the risks and benefits of this study? | Every clinical trial has both benefits and risks. *(Be sure you can articulate these for your study!)*  In general. possible benefits include the following:   * Participants have access to promising new treatments and approaches that are often not available outside the clinical trial setting * The treatment being studied may be more effective than the current standard treatment * Participants receive regular and careful medical attention from a research team that includes doctors and other health professionals * Participants may be the first to benefit from the new treatment under study   + Results from the study may help others in the future   Risk is dependent on the type and phase of trial. Possible risks may include:   * + New drugs or procedures under study are not always better than the [standard treatment](http://www.cancer.gov/dictionary/db_alpha.aspx?expand=s#standard therapy) to which they are being compared   + New treatments may have side effects or risks that doctors do not expect or that are worse than those resulting from standard care   + Participants in [randomized](http://www.cancer.gov/dictionary/db_alpha.aspx?expand=r#randomized clinical trial) trials will not be able to choose which treatment they receive   + Health insurance and managed care providers may not cover all clinical trials costs   + Participants may be required to make more visits to the doctor than they would if they were not in the clinical trial |
| 1. I’ll never see my patient again if I refer to this trial. | Please be assured that any person you refer will remain a patient in your practice and you will continue to provide their clinical care. We will provide only the care necessary to conduct the trial in accordance with the study protocol and to ensure their safety.  We will refer the patient back to you as their primary care provider for any clinical issues.  We will keep you informed (every 3 months, every six months) about the study and your patients’ participation in the study |
| 1. How can I bring up the issue of participating in clinical trials with my patients who I am sending to a specialist for care? | At the very least, we think it is critical to mention clinical trials as a viable option for care and to encourage your patients to inquire about clinical trials. Here is one approach for care that requires specialist referral.  *“We’ve just found something that concerns me, so I am referring you to a specialist. When he/she discusses treatment options, you may want to talk to him or her about clinical trials, because a trial may be appropriate for you.”*  Other options when providing referrals to specialists who are conducting clinical trials:   * First, discuss what your patient should expect from diagnostic workup procedures in general. * Next, discuss what to expect from treatment options in general. * Then, mention clinical trials as an option through which to receive treatment.   Sample Script:  “I’m going to refer you to a specialist, who can talk about your treatment options in more detail. Ask him/her about clinical trials, because it’s a quality treatment option for many patients.” *[[2]](#endnote-2)* |
| 1. **Community health care providers may also have specific questions about trials in general, or a clinical trial that your research team will need to address.** | |
| * What is my role in referring patients to this trial? * How will I be kept appraised of my patients’ progress? * What information do I have to provide during referral? //What records will you need from my office? * What is the process I should use to inform my patients of the option of taking part in this trial? * How are you going to facilitate the referrals that I make? * Is this trial randomized? * What is the research question you hope to address, and why is it important to providers like me and my patients? | *Be sure to outline your reliable referral systems to expedite trial screening access for patients. Describe exactly how you will make it as easy as possible for the physician to refer and address these specific concerns.*  **It is important that your institution have specific policies to keep referring providers informed about their patients post referral. This is an important part of relationship-building. Make sure you address these concerns with referring physicians.** |

Referring Provider OUTREACH

Asking for COMMITMENT

Once a provider agrees, “Yes, I will let my patients know about the study…” It’s important to get a specific commitment for action. We list specific **ASKS for action below; it is critical to provide them with the need resources, and provide follow up within one week.**

**Dr. Smith, are you willing to…**

1. **Distribute “palm cards” in your office?**
   * *Ask: where? At Check out? In Waiting Room?*
   * *Offer to send materials to office manager for distribution*
2. **Search records for patients with diagnoses to distribute materials to my patients who may be eligible?**
   * *Offer to provide envelopes and palm cards to the office manager.*
3. **Hang up posters inside the exam room?** 
   * *Ask: where else? At Check out? In Waiting Room?*
   * *Offer to send posters/flyers to office manager for posting*

* **Talk to patients about the study?**
* *Suggestion: provide a “one stop shop” phone number for interested patients to call about their interest and facilitate getting their records sent to our clinic.*
* *Provide talking points about the study*
* **Invite me to do a “grand rounds” at the local medical society/nursing society?**
* *Suggestion: Offer to bring lunch, talk about my research, and discuss the importance of this trial*
* **Allow me to do a “lunch and learn” at your practice for your entire staff?**
  + *Suggestion: Offer to bring lunch and talk about this research study*

Referring Provider OUTREACH

Best Practices Tip Sheet (Relationship Building)

| Principle | Apply it by |
| --- | --- |
| Identify appropriate providers or practices who already treat or diagnose people for the condition/illness on which you are focusing | Finding appropriate providers that tend to serve people who you are interested in recruiting, such as…   * Providers treating illness/conditions of interest, such as those working in   + Gynecology   + Geriatrics   + Pediatrics   + Endocrinology * Providers treating >50% minority patients * Providers with outwardly strong commitment to treating LGBT patients * Providers treating patients with low incomes * Providers in rural areas   Sites serving people in   * Safety net hospitals * Community Health Centers * VA clinics or hospitals |
| Identify provider societies or associations (regional or state) with which you can target efforts | * American Indian Physicians (AAIP) * Association of Black Cardiologists (ABC) * National Council of Asian Pacific Islander Physicians (NCAPIP) * National Hispanic Medical Association (NHMA) and * National Medical Association (NMA) * National Black Nurses Association * National Association of Hispanic Nurses * Gay and lesbian medical association directory http://www.glma.org |
| Instead of promoting specific trials, build collaborative relationships and outline general areas of research conducted at the site | * Emphasize the fact that your institution provides high quality options for care for their patients, including clinical trials (in these areas) …   *In general, it is not a good idea to undertake any “Dear Colleague” like efforts for any specific treatment trial.* |
| * Providing educational opportunities to inform providers about the importance and availability of quality care and options offered through CCTs[[3]](#endnote-3),[[4]](#endnote-4),[[5]](#endnote-5) [[6]](#endnote-6) [[7]](#endnote-7),[[8]](#endnote-8),[[9]](#endnote-9) * Offering detailing/ “lunch and learns”/grand rounds for referring physicians [[10]](#endnote-10),[[11]](#endnote-11) * Keep to a brief 20-30 minute presentation * Address whole staff, not just physician * Developing reliable referral systems for clinicians who diagnose (the conditions you are studying) to expedite site access for patients * Developing business agreements with local practices to allow research team to pre-screen patients * Hiring navigators or translators to work at referring sites * Developing a clear policy to maintain communication with the referring providers to keep them informed about their patients * Publishing reports, a newsletter, or letters outlining research activities to keep providers informed |

Referring Provider OUTREACH

Best Practices Tip Sheet[[12]](#endnote-12) (Specific Trials)

| Principle | Apply it by |
| --- | --- |
| Start out with referring providers where relationships are already established | * Find out where others in your site have found traction with providers, and start there * See if these providers can help you identify other likely referrers |
| Make it as easy as possible for the provider to refer | * Provide easy access to the basic criteria for inclusion in the study and by making the act of referring simple. * Distribute a pocket card and fax referral form when speaking to potential referring providers. |
| Outline what their role could be around referral | During referral, the referring clinician can help:   * Assess broad feasibility of the patient enrolling into a clinical trial * Discuss the possibility of a trial \*\* * Establish initial contact with the clinical research team (this is preferable to direct communication by the potential participant as he or she may not have sufficient information on their medical conditions and prior treatment to determine eligibility) * Schedule appointment and share appropriate clinical data with the research team   If the person ends up being accepted into a trial, the referring clinician:   * Continues to be involved in clinical care of the patient * Communicates with the research team regularly regarding patient’s condition and any significant changes * Provides emotional support to the patient * Helps answer questions the patient may have |
| Assure them that your goal is solely to enroll the patient in research | “Please be assured that any person you refer will remain a patient in your practice and you will continue to provide their clinical care. We will provide only the care necessary to conduct the trial in accordance with the study protocol and to ensure their safety. We will refer the patient back to you as their primary care provider for any clinical issues.” |
| Provide an easy “script” for them to consider for referral[[13]](#endnote-13) | \*\*\*Three action steps when providing referrals to specialists who are also conducting clinical trials:   * First, discuss what your patient should expect from diagnostic workup procedures in general. * Next, discuss what to expect from treatment options in general. * Then, mention clinical trials as an option through which to receive treatment.   Sample Script:  “I’m going to refer you to a specialist, who can talk about your treatment options in more detail. Ask him/her about clinical trials, because it’s a quality treatment option for many patients.” |
| Provide follow up | State your plans to provide test results and findings about the patient back to the referring practitioner. Your site should provide **adequate information regarding:**   * Prescribed treatment * Expected side effects * Suggested management of any adverse events * Progress the patient is making * Adverse or unexpected situations regarding their patient   For community physicians, knowing that someone if going to spend time conducting extensive tests and assessments on their patients and provide that information back to them is often a major selling point for referring a patient.  Follow this up by **actually doing this** after each study visit. |
| Thank them | Once you get a physician who refers to you, the ball is in your court to get them to refer again. Send a thank you note to the referring practitioner. Offer them something valuable in return: Share test results, hold quarterly conference calls updating them on the trial and your center’s activities, invite them to MD events, offer to acknowledge them in the study first publication, etc. |
| Provide supplemental material | Expand the scope of information you provide when reaching out to your colleagues by including more than info about your study.  Provide information about seminars, grand rounds, patient symposia and/or support group information. Even if a provider doesn’t directly refer patients to your study, they may give their patients the info for your classes/groups (where you can then tell them about your study) |

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12. Michael J Fox Foundation Best Practices Manual https://www.michaeljfox.org/files/MJFF\_Recruitment\_Best\_Practices\_manual.pdf [↑](#endnote-ref-12)
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