

INNOVATION-TASK FIT

META-MEMO

CCOPs do not have the ability/authority to alter the characteristics of cooperative group trials in order to improve the fit with the CCOPs structures, processes, capabilities, resources. They have no control over trial eligibility criteria, protocol-required tests or treatments, data reporting requirements, and so forth. I think they can make very minor changes to the consent forms to fit local conditions, but that's about it.

What CCOPs can do, however, is decide not to open trials that do not fit local conditions. If the trial seems to labor- or time-intensive, the CCOP doesn't open it. If it requires resources that the CCOP doesn't have (e.g., pathology studies), the CCOP doesn't open it. If the medical oncologists don't like the chemotherapy regimen in an RTOG trial, the CCOP doesn't open it. So, they can improve innovation-task fit through the decision open or not open studies.

CCOPs can't really adapt the innovation to fit the organization (except through the menu of open studies), but they can adapt the organization to fit the innovation. The major innovation-task fit issue that CCOPs face is how to integrate clinical research into the workflow and workload of community oncology practice.

For some cancer control studies, CCOPs take the physician out of the equation all together. They can rely on clinic staff to help identify potential study participants, or they can assign (or dedicate) research staff members to focus on identifying, informing, and consenting study participants. CCOP Administrators like these kinds of cancer control studies.

For treatment studies (and some cancer control studies), the CCOP can't do an end-run around the treating physician. At a minimum, the treating physician has to decide whether or not a patient is eligible for a trial and should be approached. Most often, the treating physician is the one who introduces the idea of the clinical trial to the patient that he or she has deemed eligible.

The two biggest challenges that CCOPs face in putting patients on study is to (a) cue the physician that a patient might be potentially eligible for a study, and (b) minimize the time burden on the physician. The cuing problem comes up because physicians are busy. Some physicians have the clinical trials "mindset." They're constantly asking themselves (and/or staff members) if this particular patient is eligible for a clinical trial. Most physicians, however, don't have the clinical trials "mindset." They need help identifying potentially eligible patients and help remembering to offer the trial to those patients that are eligible. CCOPs typically cue physicians by screening patient charts (especially new patients) and alerting the treating physician that a patient might be eligible for a specific clinical trial. The mechanics of the cuing strategy vary from CCOP to CCOP, but the general outline is the same.

Cuing physicians is easier to do when research staff members have access to the lists of new patients to be seen and access to relatively complete patient charts for these patients. When physicians work off-site (e.g., outlying clinics, off-campus private practice), research staff

members can't always screen patient charts. Electronic medical records could help, but as we learned from Heartland, EMRs are useful only if the information needed to determine eligibility is in the chart. When charts are incomplete, the value of screening them ahead of time is limited. When research staff members can't screen charts, they are totally dependent on the physicians to identify potentially eligible participants for open clinical trials. This puts a heavy burden on the memory of busy clinicians. The prompting / cuing can take the form of stickers on charts, emails, text messages, and face-to-face communication. It varies from place to place and, sometimes, physician to physician.

The best way to alleviate the time burden for physicians is to delegate to the research staff the tasks of educating and consenting the patient. This is easier to accomplish when the research staff members are co-located with the treating physician. It gets much harder to do when the treating physicians are located elsewhere. Beaumont has research staff members drive to off-campus physicians' offices when a patient looks eligible. SRVCC and Heartland are experimenting with having research staff members "ride the circuit" with the physicians when they travel to the outlying clinics. It's not clear whether this strategy will increase accrual or not, but it will take some of the burden off the physicians.