INNOVATION-TASK FIT
ABCDE CCOP

DEFINITION***: Innovation-Task Fit*** refers to the extent to which the innovation is compatible with task demands, work processes, and organizational capabilities.

COMMENT: Implementation typically involves a process of mutually adapting the innovation and the organization to achieve a reasonable degree of operational, cultural, and strategic fit. CCOPs can use a wide array of implementation policies and practices to adapt the organization to the innovation. However, CCOPs have less ability to alter the attributes of the innovations (clinical trials) to fit the organization's task performance capabilities (e.g., patient populations served, workflow, and specimen storage facilities). This is because the cooperative groups, not the CCOPs, determine clinical trials' design characteristics (e.g., patient eligibility restrictions and data collection requirements). Even if a CCOP organization builds a strong implementation climate, implementation effectiveness (accrual) will suffer if clinical trials' design characteristics not fit the CCOP organization's task performance capabilities.

SUMMARY: We have 25 instances of this code across 8 interview participants and the grant renewal. The comments we coded as INNOVATION-TASK FIT fall into two categories: (1) general issues pertaining to the fit of cancer clinical research in community-based physician practice, and (2) specific issues about the feasibility of particular types of clinical trials.

A key issue facing all CCOPs is that of conducting clinical research in busy community practice settings. For CCOP physicians, clinical research is an extra activity, an activity that gets added to their patient care responsibilities. Not only do CCOP physicians have to find the time to do this extra activity, but they also have to find ways to integrate clinical research into their patient care activities. Clinical research and patient care are interdependent tasks.

Not surprisingly, we heard from ABCDE physicians that it takes time to do clinical research [25:8][26:30][26:31][26:42][30:11][30:14][31:34]. This time includes: time to read, think about, and decide to open/use the protocol; time to discuss the study with the patient to encourage them to participate; and time to follow the protocol (e.g., make dose modifications, set up technical aspects of care).

Although time is an issue for all physicians, it seems to be less of a barrier for XYZ physicians (and the pediatric oncologist) because the research staff screen their charts, assist with study enrollment, and support care delivery per-protocol [25:53][26:31]. The fact that these research staff are not only available, but immediately accessible (co-located) takes much of the burden off the medical oncologists. Apparently, they are there too to help the medical oncologists even when they have patients on study in remote locations, although they don't screen charts out there [26:39].

The radiation oncologists seemed to complain more about the time as a barrier to accrual. I gathered from the IVF memo that the CCOP is now providing more research staff support to the radiation oncologists as an IPP to boost their accrual (and prevent the loss of the RTOG affiliation). It will be interesting to see if this IPP works.

We did hear that ABCDE is not really organized in a way to support the few surgeons who have expressed interest in participating in CCOP studies [25:43][29:75]. SRVCC research staff members do not screen their charts [25:43]. This means the surgeon has to remember the trial

and offer it to the patient. Also, research staff find it challenging to support off-campus surgical practices [25:43][29:75]; it's hard for them to drive over there.

Another INNOVATION-TASK FIT issue facing CCOPs generally is getting the physicians to remember to mention (and recommend) to patients that they consider participating in a clinical trial [25:58]. As we learned in our earlier work, oncologists are focused on treatment. That's what they are thinking about. Work flow is organized around treatment. It's not easy for physicians to remember that a particular patient might be eligible for a particular trial. It's also not easy for physicians to remember to talk about that trial when they've got the patient in the exam room.

ABCD handles this issue (for the medical oncologists, at least) by screening new patient charts. This seems to work pretty well. However, ABCDE does not have a system in place to screen the charts of recurrent patients [25:54]. This leads to an under-accrual of these kinds of patients. One interview participant noted that many of the hematology trials currently available are for recurrent disease [25:69]. The absence of a screening mechanism might account for low accrual to these kinds of trials (and, by implication, low accrual by those physicians who see mostly these kinds of patients). Apparently, they are working on an IPP to fix this problem [25:54].

Interestingly, one of the most "successful" RTOG trials that ABCDE has done is RTOG 0122*, A Trial of Two Different Nutritional Supplements for Patients with Cachexia of Malignancy* [6:21]. The grant renewal notes that the nurses identified possible candidates and assisted the investigators and CRAs with accrual [6:24]. This might be a case where the trial was successful by taking the physician out of the equation all together (IPP).

Two broader issues affect INNOVATION-TASK FIT. The first concerns **patient acceptance of clinical trials.** Interview participants report that patients are sometimes leery of clinical trials in general and find the idea of randomization confusing or undesirable [23:47][23:63][31:37]. This can be a problem for prevention trials [25:58]. The radiation oncologists suggested that patients have a strong preference for the kind of treatment they want, which is why they have not had much luck enrolling women on the partial breast irradiation trial [31:37].

We also heard a little bit about **trial-population fit**. Trial eligibility criteria and protocol demands also have to fit the patient population and the local patterns of care [27:42][29:26].

With respect to the trial attributes that affect accrual (a gauge of innovation-task fit), we heard the following:

- No problems with pathology and tissue banking studies [29:56].