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# **CODING MANUAL**

## **IMPLEMENTING SYSTEMIC INTERVENTIONS TO CLOSE THE DISCOVERY-DELIVERY GAP (RO1-CA124402)**

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## Instructions

### Background

Coding involves breaking interview transcripts into discrete “text units” and interpreting their meaning vis-à-vis deductively or inductively derived constructs. “Text units” are simply chunks of text that seem to have meaning or coherence. With ATLAS.ti, you can make text units any size we want: a word, a phrase, a line, a sentence, a paragraph, or an entire document. In general, though, larger text units are more interpretable than smaller text units. One-line text units, for example, often lack enough of the conversational context to render their meaning unambiguous. In this project, we will set the default text unit size as a paragraph. The transcription service will format the interviews accordingly.

Text units that illustrate or inform a theoretical construct are tagged or labeled with a “code” that represents that construct. Codes are simply labels (representing constructs) that have defined parameters indicating when and when not to apply them.

To ensure consistency in coding, the investigators conducting this study have developed a coding manual that defines each code conceptually, outlines the decision rules for when to apply the code and when not to apply it, provides examples of appropriate and inappropriate uses of the code, and tracks any revisions that you make to the code’s definition or decision rules as the analysis proceeds.

To create the code book (which you have in your hand), we have used the study’s conceptual framework to generate a “starting list” of codes, which we plan to supplement with new codes as coding and analysis proceeds.

This code book is a “living document.” As we apply the codes to the interview transcripts, questions will arise about the meanings of the codes, the differences between codes, and the decision rules about when to apply codes. These questions will prompt discussion which, in turn, will prompt revisions and refinements of the code book. Definitions will get sharpened, new codes will get added, decision rules will be modified, and examples will get changed.

### Directions for Coding

We will instruct you in the mechanics of using ATLAS.ti to attach codes and memos to text units.

Take an “inclusive” approach to coding. If you have any doubt about applying a code, your bias should be in favor of applying the code. If the data for the code are oblique—for example, if the meaning of a given text unit depends on a text unit elsewhere in the interview—then you should attach a memo to the given text unit with a note to the investigator about the decision to apply the code. The memo should reference the other text unit in terms of its ATLAS.ti location number (i.e., document and line number).

You should also attach memos to text units where you considered applying a code, but chose not to do so. Explain which code you chose not to apply and why you chose not to apply it.

As indicated in the decision rules below, code both positive and negative instances of a code. For example, use **implementation climate** to code both positive and negative statements about climate.

In the first cycle of coding, we will be coding at a broad or general level. In later cycles we will code at a more refined or micro level. For example, we will begin by coding for **implementation policies and practices**. Later, we will code for specific types of policies and practices (e.g., staffing changes, information systems).

If you feel that a new code is needed (i.e., an “emergent” code), please create the new code, code the text units in question, and alert the investigator.

General coding rule: code text units indicating “don’t know” responses as well as negative responses. (3/5/08)

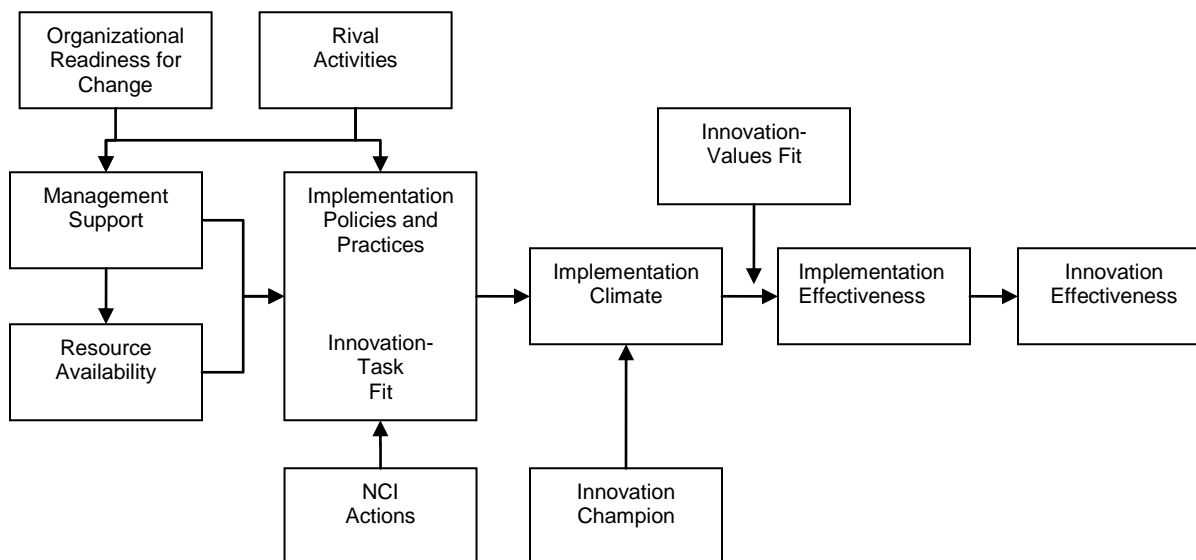
## CONCEPTUAL MODEL

We view community-based provider participation in research (CBPPR) as a complex innovation and draw upon innovation and organization theory to guide our study. A complex innovation is a new idea, practice, program, or technology whose implementation requires collective action and whose use entails collective behavior change on the part of organizational members [1-4]. Implementation refers to the transition period, following a decision to adopt a new technology or practice, during which intended users actually put the new idea, practice, program, or technology into use [3, 5].

To guide the study, we have adapted an organizational model of innovation implementation that we have developed and refined in prior work (see Figure). Briefly, the model posits that the effective implementation of the innovation (e.g., consistent, high-quality CBPPR) is a function of the management support and resources available for the CCOP organization; the quality of the implementation policies and practices that the CCOP puts into place, the adaptations that the CCOP organization makes to the innovation itself (how it adapts CBPPR to its local context), the climate for implementation that results from these policies, practices, and adaptations; and the extent to which intended implementers of the innovation (e.g., physicians, research nurses, and CRAs) perceive that CBPPR fosters the fulfillment of their values (e.g., professional autonomy, delivering state-of-the-art care, etc.). The organizational benefits of an innovation (e.g., improved care, marketing value of NCI affiliation) depend on effective implementation (consistent, high-quality CBPPR). Rival activities can compete for management attention and support, as well as undermine efforts to implement CBPPR. NCI/Group actions can help or hinder the CCOP organization's efforts to implement CBPPR. The presence (or absence) of an innovation champion can positively (or negatively) affect the climate for implementation (e.g., implementers' sense that CBPPR is rewarded, supported, and expected).

The constructs depicted in the Figure—and other constructs that represent alternative explanations for implementation effectiveness—are defined and discussed in more detail in the pages that follow.

**Figure. Conceptual Model of the Determinants of Effective Innovation Implementation in Organizations**



## ORGANIZATIONAL READINESS FOR CHANGE

**Organizational Readiness for Change** (ORC) refers to the extent to which targeted organizational members (especially the implementers and intended users) are psychologically and behaviorally prepared to make the changes in organizational policies and practices that are necessary to put the innovation into practice and to support innovation use [1].

ORC is a two-dimensional construct reflecting organizational members' collective commitment and collective efficacy to implement an organizational change. Change commitment refers to organizational members' shared resolve to pursue courses of action that will lead to successful change implementation. We emphasize shared resolve because implementing complex innovations involves collective action by many people, each of whom contributes something to the implementation effort. Change efficacy refers to organizational members' shared beliefs in their conjoint capabilities to organize and execute the courses of action required to implement change successfully [2]. These shared beliefs result from organizational members' exposure to external and internal stimuli, including past performance in implementing change [3, 4].

### Comment:

Implementing complex innovations usually entails making a host of inter-related changes in organizational structures and activities. Organizational readiness to make changes such as these is reflected in the level of change commitment and change efficacy. We posit that organizations that exhibit high readiness are more likely than those that exhibit low readiness for change to initiate the changes in organizational structures, policies, and practices that are necessary to support innovation use, and to do so more effectively.

### Use When:

- This code applies only to the “pre-implementation phase”—that is, the period before the organization implements the CCOP. Once implementation begins, this code is no longer pertinent.
- Interview participants comment on the level of commitment that specific groups (e.g., nurses, managers, or physicians) or organizational members as a whole (i.e., “everyone”) had during the pre-implementation phase for implementing the CCOP. Use the code regardless of whether the level of commitment was high or low, or whether the commitment was widely shared or limited to certain groups. Look for words like “motivated,” “supported” “excited,” “reluctant,” “skeptical,” “open,” etc.
- Interview participants comment on the level of confidence that specific groups (e.g., nurses, managers, or physicians) or organizational members as a whole (i.e., everyone) had during the pre-implementation phase that they could successfully become a CCOP—that they could mobilize the resources, take the actions necessary, and make adjustments along the way. Look for words like “can,” “could,” “confident,” “sure,” and “certain” (as well as their antonyms).

### Do Not Use:

- Interview participants comment on how things went (are going) after the pre-implementation phase. Consider using codes like **management support** or **implementation climate**.
- Interview participants mention outcome expectancies: what might or might not occur if they successfully perform the action. *Efficacy* focuses on the question: Can I (or we) do this? *Outcome expectancy* focuses on the question: If I (or we) do this, what will happen?
- Interview participants talk only about their own personal commitment or sense of efficacy about their role in the implementation process. If they do not reference collective (i.e., group or organizational) commitment or efficacy, then code the statements as **personal readiness for change**.

- Interview participants make general statements about having an innovative or change-oriented culture. ORC is change-specific. An organization can have high ORC for certain types of change, and at the same time low ORC for other types of change. Code general statements like this as **innovation-values fit**. We consider such statements as indicators of innovation fit with organizational values.

#### Examples of Correct Use:

- “People here were excited to become a CCOP.” (Code **ORC** because the statement refers to collective commitment/motivation to engage in the courses of action necessary to achieve desired goal.)
- “The oncologists were very interested in becoming a CCOP, but the hospital people were not.” (Code **ORC** because the statement suggests a lack of shared commitment to becoming a CCOP.)
- “We were concerned about whether we could enroll 50 patients a year.” (Code **ORC** because the statement refers to confidence in performing actions necessary to achieve desired goal.)

#### Examples of Incorrect Use:

- “I really wanted to see it happen.” (Do not code **ORC** unless this sense of commitment was shared by a specific group or organizational members as a whole. Code this as **personal readiness**.)
- “Our practice has always been innovative. We’re always looking for new ideas.” (Do not code **ORC** because this statement is general, not change-specific. Code **innovation-values fit**.)
- “We didn’t think the reimbursement from NCI would cover the true costs of the program.” (Do not code **ORC** because this statement does not refer to action capabilities. Code **NCI actions**.)

## MANAGEMENT SUPPORT

**Management support** refers to managers' shared resolve to pursue courses of action that promote the successful implementation of the innovation.

### Comment:

Management support shapes the organizational context of implementation by providing resources to support implementation (allocating), clarifying and shaping the meaning of the innovation (communicating), and providing legitimacy to the innovation (championing)[5]. Management support is often critical because implementation is resource intensive. Financial, material, and human resources are more likely to be forthcoming if management supports the implementation effort. In addition, managers' symbolic actions also contribute to successful implementation by signaling management's commitment to the innovation and by convincing implementers and users to expend the effort required to put the innovation into practice [6, 7]. Finally, managers' support is often critical for overcoming resistance and resolving intra-organizational disputes concerning changes in resource allocations, organizational routines, and lines of authority.

Note: management includes Chief Medical Officer. (3/5/08)

### Use When:

- Interview participants refer specifically to support for the CCOP among hospital (or cancer service line) leaders.
- Interview participants mention management's provision or non-provision of financial, material, or human resources to support implementation
- Interview participants mention management's verbal expressions of support (or lack of expressions of support) for the innovation, including statements about the innovation's importance to the organization.
- Interview participants mention management's efforts to overcome resistance or otherwise alter the intra-organizational political situation regarding the innovation.
- This code may overlap with **IPP** if the interview participant mentions management support in connection with deployment (or lack of deployment) of an implementation policy or practice.
- This code may also overlap with ORC when interview participants comment on management support during the pre-implementation phase.

### Do Not Use:

- Interview participants comment on the CCOP PI or CCOP Administrators' commitment to the CCOP. In this project, these organizational roles are not defined as "management."

### Examples of Correct Use:

- We've had tremendous support from the hospital. The CEO values what we're doing." (Code **management support**.)
- "We got along great with the VP for Research, but then they put us under the cancer service line. We've had some real problems with her." [Code **management support**.]
- "The hospital gives us a half-time billing specialist." [Code **management support**.]



Examples of Incorrect Use:

- “The CCOP PI is really gung-ho.” [Do not code **management support**. The CCOP PI is not considered management.]
- We requested and received an extra half-time research nurse through our CCOP grant. She will focus exclusively on symptom management trials. [Code **IPP**, not **management support**, since this resource allocation comes from NCI, not from management.]

## IMPLEMENTATION POLICIES AND PRACTICES

**Implementation Policies and Practices** (IPPs) refer to the plans, practices, structures, and strategies that an organization employs to put the innovation into place to support innovation use [8]

### Comment:

IPPs are the means by which an organization assimilates an innovation in order to achieve an acceptable level of operational, cultural, and strategic fit. The assimilation process, as others have noted, entails a mutual adaptation of the innovation and the organization [9, 10]. Some IPPs are temporary measures that intentionally or naturally disappear when the organization reaches desired levels of innovation use. Others remain in place long after the implementation phase in order to support and reinforce continued innovation use.

Organizations can make use of a rich inventory of IPPs including training and technical support, rewards or incentives, persuasive communications, end-user participation in decision-making, workflow or workload changes, alterations in staffing levels or mix, new reporting relationships, and/or documentation, monitoring or enforcement policies/procedures [8]. In general, the more IPPs, the better; yet, some high-quality IPPs may compensate for the absence or low quality of other policies and practices. Also, organizations can achieve the same level of implementation with differing mixes of policies and practices [8].

Note: the code can be used in pre-implementation phase to capture policies and practices *specifically* implemented in anticipation of the CCOP. (3/5/08)

### Use When:

- Interview participants mention specific policies or practices intended to support the implementation of the CCOP.
  - New decision-making policies or practices (e.g., new committees, roles, or authority)
  - Training and education (e.g., clinical trials in general, new cancer research findings, etc.)
  - Rewards or incentives (e.g., recognition, praise, monetary and non-monetary reward)
  - Persuasive communication (e.g., CCOP PI exhorts colleagues in staff meetings)
  - Workflow or workload changes (e.g., symptom management checklists)
  - New reporting relationships (e.g., CRAs report to CCOP Administrator)
  - Changes in staffing levels or mix (e.g., hiring CRAs, redistributing work roles)
  - New documentation, monitoring, or enforcement procedures (e.g., tracking systems)
  - Criteria used to evaluate whether or not to open a trial (3/26/08)
- Use the code regardless of whether the described policy or practice was actually used or merely considered but postponed or rejected.
- Interview participants mention that a specific policy or practice is missing or needed.
- Interview participants mention either focusing on certain kinds of trials or otherwise adapting trial attributes (e.g., advocating for changes in the trial's eligibility criteria).

### Do Not Use:

- Interview participants mention policies or practices that originate outside the CCOP (e.g., from NCI). Code these policies and practices as **NCI actions**.

- Interview participants mention a change in policy or practice that had an unintended effect on CCOP implementation and performance. These changes are important, but they are not IPPs. Consider the possibility of coding these **Implementation Climate**.

Examples of Correct Use:

- “We hired a great CCOP administrator.” (Code **IPP**.)
- “We really need a better way to track which physicians are putting patients on studies, and then feed that information back to the physicians.” (Code **IPP**.)

Examples of Incorrect Use:

- “The hospital CEO left. The new CEO doesn’t support CCOP.” (Code **management support**, not **IPP**.)
- “We’ve got too much to do to put patients on studies. I mean, it’s just not worth it.” (Code **implementation climate**, not **IPP**...unless they talk about specific incentives or disincentives.)

## IMPLEMENTATION CLIMATE

**Implementation Climate** refers to organizational members' shared perceptions of implementation policies and practices in terms of their meaning and significance for innovation use [8]. (James & Jones, 1974; James & Snells, 1981)

### Comment:

Implementation climate is a gestalt based on organizational members' shared information about, discussions of, and experiences with the organization's implementation policies and practices (IPPs) [8]. Through their actions, interactions, and discussions, organizational members make sense of the organization's IPPs. The meaning and significance that they ascribe to these IPPs enable them to interpret current events, predict possible outcomes, and gauge the appropriateness of their own subsequent actions (Jones and James, 1979). Of particular interest here is whether organizational members (especially the implementers and intended users) get the sense from the organization's IPPs that innovation use is expected, supported, and rewarded.

Climate is based on sense-making (interpretations). Norms might inform or shape organizational members' interpretations, but norms are not synonymous with climate (or interpretations). For example, a strong norm to distrust management might prompt intended users to interpret in a negative light various changes in work roles intended to support innovation use ("They're trying to take control of our work or pay us less").

Organizations can create a strong implementation climate by making use of IPPs that enhance organizational members' means, motives, and opportunities for innovation use. Like organizational readiness for change, implementation climate is innovation-specific. This specificity differentiates implementation climate from more general constructs like organizational climate or organizational culture. An organization may exhibit a positive climate in the workplace or a culture that values novelty and change, yet still exhibit a poor implementation climate for a specific innovation.

### Use When:

- Interview participants comment on the extent to which a particular IPP supports (or does not support) innovation use (i.e., engaging in those activities necessary to generate accrual). Support could take the form of enhancing knowledge and skills (means), encouraging effort (motives), or creating opportunities or removing barriers for innovation use (opportunities). Use of the **implementation climate** code will often, but not always, overlap with the use of the **IPP** code.
- Interview participants mention that engaging in CCOP-related activities is something that is expected, supported, and rewarded—even if they do not link this perception to a particular IPP. We would prefer that interview participants tie these perceptions to specific IPPs, but we don't want to neglect to code "floating" perceptions (i.e., those not tied to specific IPPs).
- Interview participants comment on the extent to which specific groups (e.g., nurses, managers, or physicians) or organizational members as a whole (i.e., "everyone") share the perception that a particular IPP supports (or does not support) innovation use. Such perceptions might be widely shared, somewhat shared, or not shared at all.

### Do Not Use:

- Interview participants talk only about their personal perceptions of IPPs and do not comment at all on whether those perceptions are shared by specific groups or organizational members as a whole. Use the **psychological climate** code instead.

- Interview participants mention internal motivating factors as opposed to external motivating factors. Use the **innovation-values fit** code instead. Implementation climate is about people’s perceptions of their work environment—especially those aspects of their work environment pertaining to the innovation.
- Interview participants focus on management’s support or lack of support for the CCOP. Use the **management support** code instead.

Examples of Correct Use:

- “I don’t think the oncologists think about it much. It’s not that they don’t want to put patients on studies. They just don’t think about it when they’re seeing patients.” (Code **implementation climate**. If they didn’t think about it because they didn’t care, then that might be **innovation-value fit**. But, in this example, they do care; they just have trouble remembering at the time of service delivery. This suggests that some critical IPPs are missing.)
- “The nurses know what they are supposed to do...how many patients they have to recruit.” (Code **implementation climate**. The nurses know what is expected of them. A better answer would indicate that they know what to do because they have clear accrual targets and routinely receive performance information.)

Examples of Incorrect Use:

- “The hospital CEO left. The new CEO doesn’t support CCOP.” (Code **management support**, not **implementation climate**.)
- “We keep track of nurses’ accrual activity and we take that into account in annual performance reviews.” (Code **IPP**, not **implementation climate**. There is no mention of what the nurses think in terms of whether innovation use is rewarded, supported, or expected.)

## IMPLEMENTATION EFFECTIVENESS

**Implementation effectiveness** refers to the consistency, quality, and appropriateness of innovation use within an organization [8, 11, 12].

Comment: Implementation effectiveness is an organization-level construct [8]. Generally speaking, the stronger an organization's implementation climate, the greater the likelihood that targeted employees as a group will exhibit consistent, high-quality, appropriate innovation use.

### Use When:

- Interview participants comment on:
  - CCOP accrual performance (collective, not individual, performance)
  - Number of physicians putting patients on studies
  - Research nurse productivity (not individual nurses, but nurses as a group)
  - Yield or efficiency of various patient identification, recruitment, and accrual strategies
  - ~~Number of studies open for enrollment (3/26/08)~~
  - Number of studies with actual accrual
- Use to code both positive and negative statements about CCOP performance.
- Use to code information on audits included in progress reports (3/5/08).

### Do Not Use:

- Interview participants comment on individual nurse or physician performance, not organizational (collective) performance.
- Interview participants mention individual or organizational benefits of the CCOP. Use the code **innovation effectiveness** instead.

### Examples of Correct Use:

- "We put on more patients than NCI expected. Our treatment accrual was great." (Code **implementation effectiveness**.)
- "We've opened a lot of studies, but most of our accrual comes from this one trial." (Code **implementation effectiveness**.)
- "Dr. \_\_\_\_ is our star. He puts on more patients than anyone." (Code **implementation effectiveness**. Although this comment focuses on one physician's accrual performance, it signals that he or she is contributing *disproportionately* to collective accrual performance. Because collective performance is implicitly referenced in the quote, code it **implementation effectiveness**.)

### Examples of Incorrect Use:

- "We just can't seem to put patients on the selenium and lung cancer trial." (This comment is about a specific trial, not about implementation effectiveness—i.e., consistency, quality, and appropriateness of innovation use within an organization.)
- "I haven't put that many patients on this year." (This is about personal, not collective performance.)

## INNOVATION-VALUES FIT

**Innovational-Values Fit** refers to the extent to which targeted employees perceive that innovation use will foster the fulfillment of their values [8, 11, 13, 14]. Values are concepts or beliefs that (a) pertain to desirable end-states or behaviors, (b) transcend specific situations, and (c) guide the selection and evaluation of behavior and events [15].

### Comment:

While individual differences exist in values, we are more interested in values that are either shared by all organizational members (organizational values) or by groups of organizational members (group values). When an organization adopts an innovation, targeted organizational members form judgments about the extent to which an innovation is congruent with their values. A good fit exists when targeted organizational members regard the innovation as congruent with their high-intensity values. A poor fit exists when targeted organizational members view the innovation as incongruent with their high-intensity values. A neutral fit exists when targeted organizational members see the innovation as either moderately congruent with their high-intensity values or moderately incongruent with their low-intensity values.

### Use When:

- Interview participants comment on the fit (or lack of fit) that specific groups (e.g., nurses, managers, or physicians) or organizational members collectively perceive between the CCOP and the values that they hold. For example, being a CCOP might or might not be compatible with the following values:
  - Autonomy/flexibility/discretion/control over one's work processes
  - Innovation/novelty/state-of-the-art/experimental/leader in the field of oncology
  - Evidence-based/scientific
  - Community-oriented/community benefit
- Interview participants mention the importance that specific groups or organizational members as a whole ascribe to the abovementioned values. Whereas the first decision rule emphasizes fit, this decision rule emphasizes intensity, or the amount of feeling attached to a particular value.
- Note: Previously we had used this code with regard to necessary job skills/qualities for positions (for example, 9:67). On 8/21/08 we decided to create a new code for these types of questions/responses. Previously coded IVF text units were re-coded as Personal Qualities.

### Do Not Use:

- Interview participants talk about personal values-fit rather than group or organizational values-fit. That is, they talk about themselves as individuals and do not reference groups within the CCOP or the organization as a whole.
- Interview participants talk about operational fit (e.g., fit with workflow). Code these statements as **innovation-task fit**.
- Interview participants talk about the fit of the CCOP vis-à-vis the organization's mission. Do not code these statements as **innovation-values fit** unless you get the sense that certain groups or organizational members as a whole believe in the mission (i.e., hold those values dearly).
- Interview participants comment on the benefits or outcomes that result from being a CCOP. Consider coding these statements as **innovation effectiveness**. People can value the benefits or outcomes that result from the innovation (e.g., greater resources) but not necessarily value the innovation itself. There are many ways to gain resources, for example.

#### Examples of Correct Use:

- “Our practice is committed to advancing the science. We might not design the trials, but we want **to stay at the forefront** of the science.” (Code **innovation-values fit**.)
- “Our hospital is very community oriented. We are here for the community. Being a CCOP increases access to state-of-the-art care in our community.” (Code **innovation-values fit** and **innovation effectiveness**.)
- “The nurses strongly believe that we should be doing more in terms of helping patients manage their symptoms. The symptom management trials have really raised the physicians’ awareness of patients’ quality of life.” (Code **innovation-values fit** and **innovation effectiveness**.)
- “Hospital management sees clinical research as a drain, a cost.” (Code **innovation-values fit**.)

#### Examples of Incorrect Use:

- “The CCOP PI really feels this is important. He’s totally committed.” (This statement is more about individual values-fit than it is about group or organizational values-fit)
- “The nurses feel like it’s important, you know. The CCOP PI is always stressing how important this is for the practice and the community.” (Code **IPP** and **implementation climate**, not **innovation-values fit**. The statement reflects the use of persuasive communication to create a positive climate for innovation use. The statement does not indicate whether innovation use—i.e., accrual—promotes the fulfillment of nurses’ values).
- “Being a CCOP increases awareness in the community of [the hospital’s] commitment to cancer, cancer research, and cancer care.” (Code **innovation effectiveness** because the statement refers to the benefits or outcomes of that result from innovation use, rather than the extent to which innovation use fosters the fulfillment of group or organizational values.



## RESOURCE AVAILABILITY

**Resource availability** refers to the accessibility of financial, material, or human assets that can be used to support initial and ongoing innovation use.

### Comment:

It takes resources to initiate and maintain implementation policies and practices. The most important resources that CCOPs need are (1) trials, (2) trial participants, and (3) money. These resources must not only be available, but accessible. That is, they must be readily available in order to support implementation. It refers to actual not hypothetical/abstract (3/5/08)

### Use When:

- Interview participants comment on:
  - The number and types of trials available to the CCOP from the research bases
  - Financial and non-financial assistance provided by the hospital(s) in the CCOP
  - The amount and accessibility of CCOP funding from NCI
  - Number of potential trial participants available (number of cases (incidence, volume)) (3/5/08)
- Use to code both positive and negative statements about resource availability

### Do Not Use:

- Interview participants mention staffing issues (e.g., inexperience, turnover, short-staffing). Use the **other barriers** code instead.
- Interview participants mention the general “support” provided by hospital (cancer service line) leaders. Code these statements as **management support** if no specific form of assistance is mentioned.

### Examples of Correct Use:

- “There aren’t that many cancer control studies available. It’s really been hard to get our cancer control credits.” (Code **resource availability**.)
- “The hospital gave us really nice space. We don’t have to cover that.” (Code **resource availability**.)
- “You have to find those patients. That is very time-consuming. We don’t get any money for recruitment.” (Code **resource availability** due to mention of no money for recruiting potential study participants.)

### Examples of Incorrect Use:

- “We lost one of our oncologists. He left the area.” (Code **????**, not **resource availability**)
- The hospital’s been very supportive. They really value what we’re doing here.” (Code **management support**, not **resource availability**.)

## RIVAL ACTIVITIES

**Rival activities** are events or actions that compete with the innovation for attention, resources, or both.

### Comment:

Rival activities can absorb resources that might otherwise be available for implementation policies and practices. They can command management attention, drawing off management support for innovation implementation. Finally, they can create for targeted organizational members doubt, confusion, or conflict over organizational priorities, thus resulting in weaker implementation climate. (Note: Includes in-house trials 3/6/08. Rival activities are more internal. 3/26/08)

### Use When:

- Interview participants comment doing industry-sponsored trials. Industry sponsored trials represent a potential rival for NCI-sponsored trials. Code statements that indicate either the presence or the absence of competition between “pharma” trials and NCI trials.
- Interview participants mention some organization-level, market-level, or sector-level event that draws away attention from CCOP implementation (e.g., patient safety incident or organizational merger.)

### Do Not Use:

- Interview participants mention focusing on one NCI-sponsored trial (e.g., SELECT) or one type of NCI-sponsored trials (e.g., treatment versus cancer control). Code these statements as **implementation policies and practices**.
- Interview participants mention some event or activity that they feel is important, but do not link that event to CCOP implementation or performance (i.e., accrual).

### Examples of Correct Use:

- “Doing industry trials actually helps our CCOP accrual. It gives us resources we would not otherwise have.” (Code **rival activities** and **resource availability**.)
- “She’s been doing more and more industry trials, and her accrual to NCI trials has dropped.” (Code **rival activities**.)
- “The two oncology groups in town merged last year and that hurt accrual.” (Code **rival activities**.)

### Examples of Incorrect Use:

- “We’ve been totally focused on the prevention trials. We really haven’t focused on the symptom management trials.” (Code **IPP**, not **rival activities**.)
- “Well Medicare cut reimbursement for chemotherapy, but that didn’t affect our accrual.” (This is an important event, but the comment does not suggest that it affected the CCOP. Code **other barriers** if they thought that the Medicare cuts affected CCOP accrual.)

## INNOVATION EFFECTIVENESS

**Innovation effectiveness** refers to the benefits an organization realizes from an innovation [8].

### Comment:

Innovation effectiveness is an organization-level construct, not an individual-level or group-level construct [8]. For CCOPs, these benefits could include better patient care, higher employee morale, lower physician/nurse turnover, higher physician/nurse retention, or enhanced public image. Implementation effectiveness is a prerequisite for innovation effectiveness. However, if the “program logic” of the innovation itself is faulty (e.g., if clinical trials participation does not really have quality-enhancing effects), or if during implementation the innovation has been adapted in ways that undercut its efficacy, no amount of consistent, high-quality, and appropriate use will generate the benefits anticipated by innovation adoption.

### Use When:

- Interview participant mention the presence or absence of measurable organizational benefits have resulted from physician participation clinical trials research. Possible organizational benefits include:
  - Better patient care
  - Higher employee morale
  - Lower physician/nurse turnover
  - Higher physician/nurse retention
  - Enhanced public image
  - Improved practice (or hospital) revenues
- Interview participants mention organizational benefits they perceive have or have not resulted from physician participation in clinical trials research. Note that this might overlap with **innovation values-fit**, especially if interview participants mention organization-level as opposed to group-level benefits.

### Do Not Use:

- Interview participants mention personal or individual benefits resulting from physician participation in clinical trials research.
- Interview participants mention achieving accrual goals or targets. Use the **implementation effectiveness** code instead.

### Examples of Correct Use:

- “I believe that patient care has gotten better as a result of CCOP participation.” (Code **innovation effectiveness**.)
- “We’ve been able to attract some top-flight oncologists because we have that connection with NCI.” (Code **innovation effectiveness**.)
- “It costs us money to do these trials. NCI doesn’t cover the full cost.” (Code **innovation effectiveness** and **NCI/Group actions**.)

### Examples of Incorrect Use:

- “I feel like my own practice has gotten better as a result of doing clinical trials.” (This statement refers to personally realized benefits rather than organizationally realized benefits.)
- “This is the third year in a row that we’ve met our accrual goals.” (Code **implementation effectiveness**, not **innovation effectiveness**.)

## INNOVATION-TASK FIT

**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.

### Use When:

- Interview participant make general comments about the ease or difficulty of doing trials.
- Interview participants identify specific trial attributes that make accrual difficult (or easy). Examples include study **eligibility criteria**, data collection forms, specimen storage requirements.
- Interview participants identify specific organizational features that make accrual easy (or difficult). Examples include workload, workflow, staffing levels, or staffing mix.
- Interview participants identify either specific or general observations about receptivity to clinical trials. (3/26/08)

### Do Not Use:

- Interview participants mention intrinsic motivating factors. Use the **innovation-values fit** code instead.
- Interview participants talk about whether putting patients on trial is rewarded, supported, or expected. Use the **implementation climate** code instead.
- Interview participants mention specific organizational changes that they implemented, but do not explicitly reference some challenge or obstacle that these changes were intended to address. We expect that CCOPs will use implementation policies and practices to increase innovation-task fit, but we do not want to infer innovation-task fit from comments that do not directly mention issues of fit.
- Interview participants talk about the number of **potential** participants. (3/5/08)

### Examples of Correct Use:

- "The physicians don't have the time to talk to patients about going on a trial." (Code **innovation-task fit** because this comment indicates a poor fit with workload or workflow.)
- "We weren't putting enough patients on symptom management trials because the physicians didn't know what symptoms the patients were experiencing. They were focused on treatment, not symptoms. So, we put a symptom management checklist in place and accrual jumped." (Code **innovation-task fit**, **IPP**, and **implementation effectiveness**.)

Examples of Incorrect Use:

- “The nurses don’t feel that it’s that important.” (Code **implementation climate**, not **innovation-task fit**.)
- “The physicians really believe in trials. They see it as a great way to improve patient care.” (Code **innovation-values fit**, not **innovation-task fit**.)

## INNOVATION CHAMPION

**Innovation champion** refers to a charismatic individual who throws his/her weight behind the innovation, thus, overcoming the indifference or resistance that a new idea often provokes in an organization.

### Comment:

- Can be a champion in pre-implementation phase (3/5/08)
- Can be someone who holds formal PI/Admin role (3/5/08)

### Use When:

- The champion's role is explicit. Interview participants identify someone who made a difference in implementation, particularly where they have made a personal investment in the innovation, e.g., putting personal prestige on the line.
- Champions are likely to be the CCOP PI, CCOP Administrator, some really influential physician, or some really influential research nurse. Use the code to capture descriptions of someone who goes "above and beyond" the call of duty on behalf of CCOP implementation.

### Do Not Use When:

- Interview participants refer to support for the CCOP among hospital (or cancer service line) leaders. Use the **management support** code instead. When their advocacy of CP/C research appears to be wholly related to their positional responsibilities."

### Examples of Correct Use:

- "Dr. \_\_\_\_ [the CCOP PI] is the key to the whole thing. If a physician is giving me static, I just call up Dr. \_\_\_\_ and he personally gets on the phone and talks to the physician. He's always there for us." (Code **innovation champion**.)
- "Dr. \_\_\_\_ [a urologist] somehow convinced all of the urologists in town to do the tests at no-charge to the patients. We didn't have money in the grant to pay him, but he got them all to agree to waive their fees." (Code **innovation champion**.)

### Examples of Incorrect Use:

- "The CEO has always been a big supporter of the CCOP." (Code **management support**, not **innovation champion**.)
- "The physicians really believe in trials. They see it as a great way to improve patient care." (Code **innovation-values fit**, not **innovation champion**.)

## NCI/GROUP ACTIONS

**NCI/Group actions** refer to the policies and practices that the NCI or cooperative groups put into place that affect CCOP implementation effectiveness.

Comment: CCOPs are embedded in a three-way partnership. The actions of the NCI and the cooperative groups can significantly affect CCOP implementation activities and accrual performance. This code is designed to capture these “external” influences.

### Use When:

- Interview participants mention an NCI policy or practice that positively or negatively affects CCOP implementation or accrual performance.
- Interview participants mention a cooperative group policy or practice that positively or negatively affects CCOP implementation or accrual performance.
- Interview participants mention an NCI or cooperative group policy or practice that is missing or needed that could affect CCOP implementation or accrual performance.

### Do Not Use:

- Interview participants mention actions taken on the part of hospital (cancer service line) management. Use the **management support** code instead.
- Interview participants mention policies or practices that the CCOP puts into place that affect CCOP implementation or accrual performance. Use the **IPP** code instead.

### Examples of Correct Use:

- “The NCI has got to raise the reimbursement rate for doing trials. We can’t keep subsidizing the trials.” (Code **NCI/Group actions**.)
- “Some of the groups now let us enter our data using the Internet. That’s taken a huge load off the nurses. It took a while to learn, though.” (Code **NCI/Group actions**.)

### Examples of Incorrect Use:

- “We really need a better way to track which physicians are putting patients on studies, and then feed that information back to the physicians.” (Code **IPP** not **NCI/Group actions**.)
- “The Cancer Service line director gave us an extra half-time nurse when we started putting a lot of patients on last year.” (Code **management support** not **NCI/Group actions**.)

## PERSONAL READINESS FOR CHANGE

**Personal Readiness for Change** refers to the extent to which an individual is psychologically and behaviorally prepared to make the changes in organizational policies and practices that are necessary to put the innovation into practice and to support innovation use [1].

Like ORC, personal readiness is a two-dimensional construct reflecting individuals' commitment and efficacy to implement an organizational change. Commitment refers to an individual's resolve to pursue courses of action that will lead to successful change implementation. Efficacy refers to an individual's confidence in his or her personal capabilities to organize and execute the courses of action required to implement change successfully.

### Comment:

Readiness for change is a multi-level construct. Organizational readiness for change (ORC) captures collective readiness at the group or organizational level. Personal readiness for change captures individuals' personal readiness.

**Personal readiness for change** is a "control" code. We are primarily interested in ORC, but we want to capture statement of personal readiness for change because this construct might represent a plausible alternative explanation for implementation effectiveness.

Note: In July, 2008 it was decided to take a looser interpretation of Personal Readiness for Change, allowing for it to identify an individual's readiness for change, but not necessarily the interview participant's own readiness for change.

### Use When:

- This code applies only to the "pre-implementation phase"—that is, the period before the organization implements the CCOP. Once implementation begins, this code is no longer pertinent.
- Interview participants comment on their own personal level of commitment during the pre-implementation phase. Use the code regardless of whether the level of commitment was high or low. Look for words like "motivated," "supported" "excited," "reluctant," "skeptical," "open," etc.
- Interview participants comment on their personal level of confidence during the pre-implementation phase that they could carry out those tasks necessary to successfully become a CCOP appropriate to their organizational role. Look for words like "can," "could," "confident," "sure," and "certain" (as well as their antonyms).

### Do Not Use:

- Interview participants comment on how things went (are going) after the pre-implementation phase. Consider using codes like **psychological climate**.
- Interview participants talk about collective commitment or collective capabilities. Use the **ORC** code instead.

### Examples of Correct Use:

- "I didn't think I could put that many patients on a study." (Code **personal readiness for change** if comment refers to beliefs held in the pre-implementation phase.)
- "I wanted to see this happen." (Code **personal readiness for change**, especially if interview participant gives no indication there were other organizational members who shared his or her commitment.)



Examples of Incorrect Use:

- “I wasn’t sure that we could meet those accrual targets.” (Code **ORC**, if statement refers to a belief held during the pre-implementation phase, because the interview participant refers to “we.”)
- “I don’t think it’s a priority.” (Code **psychological climate** because the interview participant does not indicate whether there are other organizational members who share this perception.)
- “Since we started using symptom checklists, I’ve put 10 women on that study.” (Code **implementation policies and practices**.)

## PSYCHOLOGICAL CLIMATE

**Psychological Climate**, as the term is used here, refers to individual organizational members own perceptions of implementation policies and practices in terms of their meaning and significance for innovation use [8]. (James & Jones, 1974; James & Snells, 1981)

### Comment:

Psychological climate refers to the perceptual and experiential components of a reciprocal interaction between the organizational environment and the employee (Michela, Lukaszewski, & Allegrante, 1995). It has been conceptualized as a construct “comprising an individual’s psychologically meaningful representations of proximal organizational structures, processes and events” and as “a means of explaining an individual’s motivational and affective reactions to change” (Parker et al., 2003, p. 390).

Climate is a multi-level construct. Psychological climate refers to individual perceptions of the way things are done around here. It concerns the perceptions of individual employees as to what is expected, rewarded, and supported in the organization. When individual employees share the same perception of the work environment, then an organizational climate is said to exist.

In this project, **psychological climate** is a “control variable.” The construct does not figure in our conceptual model. Our interest in coding for it is to exclude psychological climate as a plausible alternative explanation for implementation climate.

### Use When:

- Interview participants talk only about their personal perceptions of IPPs and do not comment at all on whether those perceptions are shared by specific groups or organizational members as a whole.

### Do Not Use:

- Interview participants comment on the extent to which specific groups (e.g., nurses, managers, or physicians) or organizational members as a whole (i.e., “everyone”) share the perception that a particular IPP supports (or does not support) innovation use. Such perceptions might be widely shared, somewhat shared, nor not shared at all.

### Examples of Correct Use:

- “Yes, I feel that I am expected to put patients on study. I know how many I’m supposed to recruit.” (Code **psychological climate** because there is no reference here to anyone other than the interview participant.)

### Examples of Incorrect Use:

- “The nurses know what they are supposed to do...how many patients they have to recruit.” (Code **implementation climate**, not **psychological climate** because there is a reference here to a specific group. The nurses know what is expected of them. A better answer would indicate that they know what to do because they have clear accrual targets and routinely receive performance information.)
- “I didn’t think I would have any problem putting patients on studies.” (Code **personal readiness for change** if the interview participant was commenting on the pre-implementation phase.)

## **OPPORTUNITIES & CHALLENGES (added 3/5/08)**

**DEFINITION:** Opportunities and challenges refer to issues that have affected or could affect CCOP implementation and accrual performance that do not fit the codes listed above.

**COMMENT:** This is a catch-all code to capture issues that don't fit neatly into the conceptual model we are using to guide the study. Opportunities and challenges could include, but are not limited to:

- Research staff, CCOP administrator, CCOP PI, or hospital management turnover
- Changes in patient populations served
- Healthcare payment challenges
- Regulatory challenges
- Competition from other physician groups, hospitals, cancer programs, or CCOPs
- Future plans for expansion of the CCOP

### **Examples include:**

Market competition (3/26/08)

Future activities (3/26/08) such as the affiliation of a new medical school (e.g. Oakland University Medical School 3/5/08)

Studies like P3 and P4 that are planned for, but are never opened. (8/21/08)

### **A decision was made on 8/28/08 to merge OTHER BARRIERS into Opportunities & Challenges**

**Other Barriers** refers to challenges or obstacles that affect CCOP implementation and accrual performance that do not fit the codes listed above.

### **Comment:**

Other Barriers is a "residual" code. Use it to capture challenges or obstacles that seem important but do not fit the more analytically useful codes above.

### **Use When:**

- Interview participants mention a challenge or obstacle, but no other code seems to apply.
- Examples could include staffing challenges (e.g., turnover, even if no effect is noted (3/5/08), patient population challenges (e.g., distrust), health care payment challenges (e.g., Medicare cuts), and regulatory challenges (e.g., adverse event reporting).

### **Do Not Use:**

- Another code applies.

### **Examples of Correct Use:**

- "We're getting killed trying to keep up with all the adverse event reporting requirements." (Code **other barriers**.)
- "We just lost a key physician. He moved out of state." (Code **other barriers**.)

Examples of Incorrect Use:

- “The nurses don’t feel that it’s that important [to put patients on studies]. There’s no one breathing down their necks to do it.” (Code **implementation climate**, not **other barriers**.)
- “It costs us money to do these trials. NCI doesn’t cover the full cost.” (Code **innovation effectiveness** and **NCI/Group actions**, not **other barriers**.)
- “We need better training.” (Code **IPP**, not **other barriers**.)

**PERSONAL QUALITIES (added 8/28/08)**

DEFINITION: Personal qualities refers to the knowledge, skills, and attitudes associated with the effective performance of the research staff member role (note 12/3/09 that this is applied just to a CRA type role).

**ORGANIZATIONAL STRUCTURE (created 3/5/2008)**

No definition, self explanatory.

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