

Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science

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I. Introduction

Examples abound in health services research, of interventions that fail to translate into meaningful patient care outcomes consistently across settings. In fact, some estimates indicate that two-thirds of organizations' efforts to implement change fail [1]. Barriers to implementation may arise at any level of healthcare delivery: the patient level, the provider team or group level, the organizational level, or the market/policy level [2]. Researchers must recognize the need to evaluate not only summative end-point health outcomes but also perform formative evaluations to assess the extent to which implementation processes are effective in a specific setting to maximize actual benefits from an intervention in that setting, prolong sustainability of the intervention in that setting, and promote wider dissemination of findings into clinical practice in other settings [3]. Health services researchers are increasingly recognizing the critical role of implementation science and research [4]. For example, the United States VHA established the Quality Enhancement Research Initiative (QUERI) in 1998 to “systematically [Implement]...clinical research findings and evidence-based recommendations into routine clinical practice” [5, 6] and The National Institute for Health Research Service Delivery and Organisation Program was established to “...promote the uptake and application of...evidence in policy and practice” in the United Kingdom. Many models and frameworks with differing terminologies and varying degrees of theoretical and empirical support have been described in the literature for use in various healthcare contexts and at different ecological levels (e.g., individual change efforts, organizational or team change) [7]. A comparison of all models and frameworks reveals much overlap, yet each is missing one or more key constructs included in other frameworks, in addition, associated terminology and definitions are not consistent. A comprehensive framework that identifies factors that influence effective implementation may facilitate needed research and its uptake into patient care. Our goal, therefore, is to establish a comprehensive typology called the Consolidated Framework for Implementation Research (CFIR) that comprises common constructs from implementation frameworks and models already in the literature. We describe a framework that embraces, not replaces, the significant and meaningful contribution of existing research in implementation science.

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The intended purpose of the CFIR is to support formative evaluations of interventions. The CFIR is not proposing specific or prescriptive models or theories for accomplishing implementation nor does it delineate interactions between constructs or between levels within constructs that may influence implementation. In essence, the CFIR is “meta-theoretical”—it includes constructs from a synthesis of existing theories, without depicting interrelationships or specific hypotheses. Many of the existing models focus on “what works” but more research is needed into what works where and why [8]. Research can be advanced by building a knowledge-base of findings across studies and settings. While specific theories or models may guide specific studies, the CFIR offers an overarching typology—a list of constructs to promote theory development and verification about what works where and why across studies and settings. Researchers can select constructs from the CFIR that are most relevant for their particular study and setting. The CFIR provides consistent terminology and constructs for conducting essential diagnostic assessments of the context within which implementation occurred or will occur. Not all constructs will be salient in all contexts. Users of the CFIR can appropriately limit their assessments to constructs that are salient for their particular study and context to avoid getting unnecessarily bogged down in analyses.

Developing a comprehensive framework is more challenging than simply combining constructs from all of the existing, relevant models and frameworks. We have carefully reviewed the terminology and constructs associated with published models and frameworks to offer a first draft of standardized terminology and taxonomy. Terminology for similar constructs differs across models and frameworks and different terms are used to describe the same construct, introducing difficulties for researchers to compare or combine findings across settings and studies. In the process of standardizing terminology, we have combined some constructs from published models and frameworks while separating and delineating others as we sought to develop definitions that can be readily understood and applied in actual implementation research studies.

In section II we describe foundational definitions and concepts and the models included in the CFIR. Section III provides an overview of the CFIR. Section IV describes a formative evaluation study that used the CFIR to identify barriers and facilitators for local uptake of a nationally

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disseminated program. Section V contains a detailed description of each of the constructs in the CFIR along with illustrative findings from the formative evaluation. We end with discussion of future directions for the CFIR.

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II. Foundations for the CFIR

Implementation is the constellation of processes intended to get an intervention into use within an organization [9]; it is the means by which an intervention is assimilated into an organization. The time period during which implementation occurs is the critical gateway between an organizational decision to adopt an intervention and the routine use of that intervention; the transition period during which targeted stakeholders become increasingly skillful, consistent, and committed in their use of an intervention [10].

Implementation researchers are interested in factors that influence implementation effectiveness, recognizing that many aspects of the local setting limit generalizability of findings across settings and studies. We collected theories, models, and frameworks (most, but not all, are labeled as models and we will, henceforth, refer to them collectively as models) that have been developed to facilitate or understand translation of research findings into practice, primarily within the healthcare sector. As recently as 2006, Estabrooks et al [11] asserted that the only model that came close to achieving status as an overarching model of knowledge-translation (aka implementation research) was Roger's diffusion of innovation theory [12]. We used Greenhalgh et al's "Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organization" [13] as a starting point which incorporates Roger's work as well as many other bodies of research. The task of identifying candidate models of implementation was daunting and is no doubt, incomplete. We used a snowball sampling approach to identify new articles through colleagues engaged in implementation research and models that cited Greenhalgh et al's synthesis and models or that have been used in multiple published studies in health services research (e.g., the PARIHS framework [14, 15]). We included models related to dissemination, innovation, organizational change, implementation, knowledge translation, and research uptake that have been published in peer reviewed journals (one exception to this is Fixsen et al's review published by the National Implementation Research Network because of its scope and depth [16]). We did not include practice models such as the Chronic Care Model (CCM) because this describes a care delivery

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system, not a model for change [17, 18]. The models we included in the CFIR may be used to guide implementation of interventions that target specific components of the CCM.

With few exceptions, we limited our review to models based on literature synthesis or very large numbers of cases. One exception to this criterion was Edmondson et al's implementation model which was unique in emphasizing the important role of reflection [19]. Our search for models and frameworks was not exhaustive but we did reach "theme saturation:" the last seven models we reviewed did not yield new constructs, though some descriptions were altered slightly with additional insights. We expect the CFIR to continue to evolve as researchers contribute to the knowledge-base.

In our review, we found that researchers use the terms "framework," "model," and "theory" interchangeably [11]. Kitson and colleagues recently sought to rectify this confusion in terminology by suggesting definitions for these terms [20]. Based on these definitions, we situate the CFIR as a framework and as such, it reflects a

"...professional consensus within a particular scientific community. It stands for the entire constellation of beliefs, values, and techniques shared by members of that community...[and] need not specify the direction of relationships or identify critical hypotheses."

It is important to take note of the last clause. The CFIR specifies a list of constructs within general domains that are believed to be antecedents or influencers (positive or negative, as specified) of effective implementation. However, the CFIR does not specify interrelationships between those constructs (within or between the major domains) nor does it specify hypotheses. The CFIR does provide a pragmatic organization of constructs upon which theories and models that do hypothesize specific mechanisms of change and how they interact can be developed and tested empirically. For example, Gustafson's Organizational Change Model (OCM) was developed as a subjective Bayesian model to estimate explanatory power of 18 different organizational features on implementation using data from 221 quality improvement projects [21]. The OCM constructs can all be mapped to constructs in the CFIR and findings about each

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construct can be added to the knowledge-base about that construct to promote synthesis with findings from other studies.

Table 1 shows the models we reviewed for inclusion into the CFIR. Greenhalgh et al's synthesis [13] was developed based on an exhaustive synthesis of a wide range of literatures including foundational work by Van de ven, Rogers, Damanpour, and Gustafson. This body of work is an important foundation for the CFIR though not explicitly listed in Table 1. The CFIR incorporates the most comprehensive set of constructs found in no other single published model. Constructs were selected for inclusion based on strength of conceptual or evidential support in the literature for influencing implementation, high consistency in definitions, alignment with our own experience, and potential for operationalization as measures. In a few cases, we introduce promising constructs that are relatively new to health services research as an invitation to explore their effects.

III. Overview of the CFIR

Context is increasingly recognized as an active interacting ingredient and not just as a backdrop in implementation [22, 23]. Implementation, by its very nature, is a social process that is intertwined with the context in which it takes place [24]. In fact, every model and framework we considered included some aspect of context. But what do we mean by context?

For implementation research, context is the set of circumstances or facts that surround a particular constellation of implementation efforts. Examples of facets of context include a provider's perception of the evidence supporting the use of the clinical reminder for obesity, local and central office policies about how to integrate that reminder into the local electronic medical record, the individuals involved and their organizational roles. In addition, the underlying theories used to develop the intervention itself and those used to guide implementation are also a part of the implementation context [25]. In this paper, we use the term "context" to connote this broad scope of circumstances and facts. We refer to setting as environmental characteristics surrounding implementation efforts. Most models in the literature use the term context

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interchangeably to refer to the broad context, as described above and also specifically referring to setting.

Figure 1 shows the CFIR's five major domains (the intervention, inner and outer setting, the individuals involved, and the process by which implementation is accomplished) that all interact in rich and complex ways to influence implementation effectiveness. Pettigrew and Whipp, more than 20 years ago, emphasized the essential interactive dimensions of content of intervention, context (inner and outer settings), and the process of implementation [26]. This basic structure is also partially echoed by the PARIHS framework which describes the three key domains of evidence, context, and facilitation [14, 15]. The CFIR has added a domain for the individuals involved to acknowledge their important role in implementation. Fixsen, et al emphasize the multi-level influences on implementation from external influencers to organizational and core implementation process components which include the central role of the individuals who coach and train prospective practitioners and the practitioners themselves [16].

The first major domain of the CFIR is related to characteristics of the intervention being implemented into a particular organization. Without adaptation, interventions usually come to a setting as a poor fit, resisted by individuals who will be affected by the intervention, and requiring participation in an active process to accomplish implementation. The left side of Figure 1 represents an intervention that has not been adapted for the setting – the puzzle metaphor implied by the limits of our 2-dimensional diagram is too simplistic. Imagining a cell and external organism that each must shift and reshape receptors to receive the intervention is a closer, though still incomplete, metaphor for the mutual shaping (co-evolution) that often occurs in both setting and intervention as implementation progresses [27]. Interventions can be conceptualized as having a “hard core” (the “irreducible” elements of the intervention itself) and “soft periphery” (adaptable elements, structures and systems related to the intervention and organization into which it is being implemented) [13, 16, 28].” For example, a clinical reminder to screen for obesity must include an alert that pops up on the computer screen at the appropriate time for the appropriate patient. This feature is part of the “hard core” of the intervention. Just as importantly, the intervention’s “soft periphery” allows it to be adapted to the setting without degrading integrity

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of that intervention. For example, depending on the work processes at individual clinics, the clinical reminder could pop up during the patient assessment by a nurse case manager or when the primary care provider evaluates the patient. Figure 1 delineates the intervention's hard core and soft periphery and shows visually, that components of the soft periphery can be adapted to a particular setting, and vice versa in a co-evolving/co-adaptive way [29-31], moving from the left (un-adapted intervention and setting) to the right side of the Figure (intervention and setting adapted to each other).

The next two domains in the CFIR are inner and outer setting. Most healthcare organizations are hierarchically organized and have interrelationships within and between institutions. Changes in the outer setting can influence implementation, often mediated through changes in the inner setting [32]. Generally, the outer setting includes the economic, political, and social context within which an organization resides and the inner setting includes features of structural, political, and cultural contexts through which implementations will proceed [33]. However, the line between inner and outer setting is not always clear (this is reflected by the overlapping shapes in Figure 1). The specific factors considered "in" or "out" will depend on the context of the implementation effort. For example, outlying clinics may be part of the outer setting in one study but part of the inner setting in another study.

The fourth major domain of the CFIR is the individuals involved with the intervention and/or implementation. Greenhalgh et al describe the significant but often unpredictable role of individuals:

People are not passive recipients of innovations. Rather...they seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, "work around" them, gain experience with them, modify them to fit particular tasks, and try to improve or redesign them – often through dialogue with other users. [13], p 598)

Many theories of individual change have been published [7] but little research has been done to gain understanding of the dynamic interplay between individuals and the organization within which they work and how that interplay influences individual or organizational behavior change.

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One recent synthesis of 76 studies using social cognitive theories of behavior change found that the Theory of Planned Behavior (TPB) model was the most often used model to explain intention and predict clinical behavior of health professionals. The TPB, overall, succeeded in explaining 31% of variance in behavior [34]. The authors offer one explanation for this low figure by suggesting that “special care” is needed to better define (and understand) *the context* of behavior performance. Frambach and Schillewaert’s multi-level framework is unique in explicitly acknowledging the multi-level nature of change by integrating individual behavior change within the context of organizational change [35]. Figure 1 shows individuals in the inner setting including targeted users and other potentially affected individuals. In addition, we depict individuals who actively promote the implementation process who may come from the inner or outer setting (e.g., local champions, external change agents).

The fifth major domain is implementation process. Successful implementation usually requires an active change process aimed to achieve individual and organizational level use of the intervention, as designed. The implementation process is depicted in Figure 1 as a series of sub-processes that do not necessarily occur sequentially. The multiple series of cycles and shadowed arrows represent the complexity of executing and evaluating implementation because there are often related processes happening simultaneously at multiple levels within the organization [33]. These sub-processes may be formally planned or spontaneous; conscious or sub-conscious; linear or non-linear.

In summary, the CFIR’s overarching structure supports explorations to essential questions encountered in a study or evaluation of implementation (formative evaluations) [3, 27]. Using the five major domains as an initial organizing structure (i.e., intervention, outer and inner setting, individuals involved, and process), we consolidate the plethora of constructs described in Greenhalgh, et al’s conceptual model and 18 additional models listed in Table 1. We combined some constructs within and across frameworks that have different labels but were redundant or difficult to distinguish from one another and parsed apart constructs that conflated concepts. In some cases, models acknowledge the importance of, for example, setting but do not explicate specific features (e.g., Fixsen’s implementation framework [16]). We provide detailed rationale for

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the constructs that constitute the CFIR in Appendix 1. The next section describes a formative evaluation study in which the CFIR was used to explore barriers and facilitators for uptake of a nationally disseminated program.

IV. An Example of CFIR Application

The CFIR was used in a mixed methods formative evaluation study that investigated barriers and facilitators to the uptake of the *MOVE!* weight management program in Veterans Health Administration (VHA) medical centers (VAMCs) [36]. This program was centrally promulgated to address the rising prevalence of obesity in veterans. Resources were made available on intra- and Internet (www.move.gov) sites that include policy documents, toolkits, and patient and teaching materials. No funds were provided to local VAMCs to implement the program. Key *MOVE!* stakeholders were interviewed at five geographically diverse VAMCs that were purposively selected: two sites had high uptake of *MOVE!* as reflected by a high number of *MOVE!* patient visits, two sites had no or very low numbers of patient visits, and one site was in transition; after failed efforts in the first year, they hired a new coordinator and implemented a pilot in one clinic and were about to expand the program to other clinics. Stakeholders were identified by first contacting the regional and facility *MOVE!* coordinators. Additional interviewees were identified at each site using a snowball sampling approach; asking each interviewee for names of people involved in *MOVE!* implementation at their facility. The 24 interviewees included all regional- and facility-level *MOVE!* coordinators and in addition, included physical therapists, dietitians, nurses, and physician champions. A semi-structured interview guide was developed to explore the influence of program (intervention) characteristics, setting (inner and outer), and the process used to implement the program at their facility. The interviews were transcribed verbatim and then read and coded by at least two analysts. A hybrid approach was used for coding: the CFIR was used deductively to code salient passages while, at the same time, searching for themes not addressed by CFIR constructs. A team consensus approach was used to determine final coding [37]. We found evidence of the role for most of the constructs in this particular study

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and intentionally kept our evaluation broad. Many studies, however, will need to select a limited number of constructs a priori, to avoid being bogged down.

The next section provides a description of how the CFIR constructs were applied in the analysis of the implementation of the MOVE! program, along with specific examples when applicable. For most constructs, we provide contrasting illustrations of their positive or negative effects (acting as barrier or facilitator) on implementation. However, we were not able to discern the differential effects of all constructs in this study because some constructs did not vary across settings. For example, the MOVE! program was developed by an entity outside the local hospital and so the influence of the program being internally or externally developed could not be discerned because everyone we talked to perceived the program as an externally developed program – and in fact, it was. For these constructs, a synthesis of findings from several studies that vary within and across constructs is needed.

V. Detailed Description of CFIR Constructs

Table 2 provides a short definition for each CFIR construct as a quick reference. Some constructs appear in many of the models and frameworks included in the CFIR (e.g., available resources appears in 10 of the 19 models) while others are more sparsely supported (e.g., cost of the intervention only appears in 5 of the 19 models). Appendix 1 provides a more detailed rationale for each construct. Appendix 2 provides a matrix showing the list of models and constructs included in each model.

Evaluation of most of the constructs relies on individual perceptions. For example, it is one thing for an outside expert panel to rate an intervention as having “gold standard” level of evidence supporting its use. Stakeholders in the receiving organization may have an entirely different perception of that same evidence. It is the latter perceptions, socially constructed in the local setting, which will affect implementation effectiveness. It is thus, important to design formative evaluations that carefully consider how to elicit, construct, and interpret findings to reflect the perceptions of the individuals and their organization, not just the perceptions or judgments of outside researchers or experts.

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1. Intervention Characteristics

A. Intervention Source: Perception of key stakeholders about whether the intervention is externally or internally developed [13, 38]. An intervention may be internally developed as a good idea, solution to a problem, or other grass-roots effort or developed by an external entity (e.g., vendor or research group). In the MOVE! study, the program was developed outside the receiving facility. However, one of the high uptake sites regarded MOVE! as an incremental change to their internally developed weight management program and was not regarded as much of an outside annoyance compared to the other sites.

B. Evidence Strength and Quality: Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes. Sources of evidence may include published literature, guidelines, anecdotal stories from colleagues, information from a competitor, patient experiences, results from a local pilot, and other sources [15, 39]. In the MOVE! study, a regional coordinator for one of the high uptake sites was able to procure dedicated personnel for the program because they perceived results from a national pilot feasibility study as sufficiently robust and positive. Conversely, one of the low uptake sites perceived this same evidence as inadequate: "...unfortunately, with the pilot study data not being very robust, we had a difficult time selling [our] chief of staff and chief of medicine on the efficacy of the pilot study."

C. Relative advantage: Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution [21]. In the MOVE! study one high uptake site saw the advantage that the MOVE! program had over their current weight management program: "...with the help of MOVE! information, MOVE! literature, MOVE! whatever...it boosted [our existing program] more and we were able to expand more..." Conversely, one low uptake site felt that a community program in their city was superior to MOVE! and they referred their patients there instead of implementing MOVE! at their hospital (other than doing an initial patient assessment).

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D. Adaptability: The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs. Adaptability relies on a definition of the "hard core" (the "irreducible" elements of the intervention itself) versus "soft periphery" (adaptable elements, structures and systems related to the intervention and organization into which it is being implemented) [13, 28] of the intervention, as described in the Overview above. A component analysis can be performed to identify the hard core versus soft periphery components [40] but often the distinction is one that can only be discerned through trial and error over time as the intervention is disseminated more widely and adapted for a variety of settings [27]. There is a natural tension between the need to achieve full and consistent implementation across multiple settings while providing the flexibility for local sites to adapt the intervention as needed [41]. In the MOVE! study, both of the high uptake sites regarded MOVE! as highly adaptable and were able to tailor a program for their facility. One of the low uptake sites, however, got hung up on one aspect of the program that they understood to be a rigid requirement: "...all of our patients would need to be referred for an EKG prior to starting the program. There were some barriers that we didn't understand..."

E. Trialability: The ability to test the intervention on a small scale in their own organization [13] and to be able to reverse course (undo implementation) if warranted [42]. The ability to trial is a key feature of the Plan-Do-Study-Act quality improvement cycle which allows users to find ways to increase coordination to manage interdependence [43]. Piloting allows individuals and groups to build experience and expertise, and time to reflect upon and test the intervention [14, 44] and usability testing (with staff and patients) promotes successful adaptation of the intervention [42]. In the MOVE! study, the transition site was the only one to trial MOVE! locally. This approach was regarded by the site coordinator as a key facilitator for implementation.

F. Complexity: Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement [7, 13, 21].

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Radical interventions require significant reorientation and non-routine processes that produce fundamental changes in the organization's activities and a clear departure from existing practices [13]. One way to determine complexity is by assessing “length” (the number of sequential sub-processes or steps for using or implementing an intervention) and “breadth” (number of choices presented at decision points) [45]. Complexity is also increased with higher numbers of potential target organizational units (teams, clinics, departments) or types of people (providers, patients, managers) targeted by the intervention [45] and the degree to which the intervention will alter central work processes [7]. In the MOVE! study, the two high uptake sites regarded MOVE! as relatively simple to implement because it was an incremental change to what they were already doing. In one low uptake site, MOVE! was very complex because of the groundwork that was required, involving multiple units who had little coordination.

G. Design Quality and Packaging: Excellence in how the intervention is bundled, presented, and assembled [46]. In the MOVE! study, VHA's National Center for Health Promotion and Disease Prevention (NCP) developed program materials to assist facilities in their implementation and delivery of the program. Thus, the “packaging” was the same for all facilities. Four of the five facilities in the study gave high marks for the quality and helpfulness of the materials and program start guides. Though all sites had access to the same materials and websites, one of the low uptake sites had a negative opinion about the packaging of the materials saying, “...the initial start up manual had very not positive pictures on it. Depressed looking, heavy sailors in stretched out white tee-shirts...” Many mentioned the poor quality of the pedometers that were available through the program and did not actively use the pedometers as an integral part of their program.

H. Cost: Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs. It is important to differentiate this construct from Available Resources (part of inner setting, below). In many contexts, costs are difficult to capture and available resources may have a more direct influence on implementation. In the

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MOVE! study, costs associated with the various implementations attempted by each site were not available.

II. Outer Setting

A. Patient needs & resources: The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and integral to the organization. Clearly, improving the health and well-being of patients is the mission of all healthcare entities and many calls have gone out for organizations to be more patient-centered [2, 32, 47]. Patient-centered organizations are more likely to implement change effectively [48]. The majority of interventions are designed to improve patient outcomes. Many models of research uptake or implementation acknowledge the importance of accounting for patient characteristics [14, 42, 44, 49] and that consideration of patients needs and resources must be integral to any implementation that seeks to directly or indirectly improve patient outcomes [2, 32]. The PRISM model delineates six elements that can help guide evaluation of the extent to which patients are at the center of organizational processes and decisions: patient choices are provided, patient barriers are addressed, transition between program elements is seamless, high satisfaction with service and access, complexity and costs are minimized, and patients receive feedback [42]. Patients typically reside outside a healthcare organization but are actually part of the inner setting in long-term care facilities. This is an example of the blurring between inner and outer setting. The pressures patients may bring to bear from the outer setting may heighten an organization's collective regard for patients' needs which may become ingrained in the culture or climate of the inner setting. For example, the increasing prevalence of multiple chronic and complex co-morbid conditions suffered by older patients (outer setting) may push an organization to implement a patient-centered care model with organizational goals that are more closely aligned to patient needs in their specialty clinics. This shift may result in changed attitudes of clinicians and staff (inner setting and individual characteristics) and monitoring and feedback to staff (part of the inner setting).

In the MOVE! study, the contrast in perception of patients and the extent to which patient preferences were considered was clear between low and high uptake sites. We heard many

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stories of patient successes and one team member at a high uptake site shared the story of a patient who recruited other patients for the program, "...[he] goes and talks to other patients in the waiting rooms saying what a great program it is, takes their names and...leaves it in my boxes...and we actually have a tremendously long waiting list..." In contrast, a team member at a low uptake site expressed frustration over the lack of patient interest, "...our system is geared to paying people to be disabled....I think the commitment of the patients has to be up there among the top three [difficulties]...because...we live in a society of quick fix and if the medicine won't do it; 'you don't expect me to starve for 10 weeks, do you?'" Though patients at both sites were veterans with similar demographic characteristics, perceptions of the interest and ability of patients' ability engage in MOVE! was vastly different; we don't know whether these perceptions were accurate but certainly the difference in these perceptions influenced how they interacted with their patients.

B. Cosmopolitanism: The degree to which an organization is externally networked with other external organizations. Organizations that support and promote external boundary-spanning roles of their staff are more likely to implement new practices quickly [13, 50-53]. The collective networks of relationships of individuals in an organization represent the social capital of the organization [54-57]. Social capital is one term used to describe the quality and the extent of those relationships and includes dimensions of shared vision and information sharing. One component of social capital is external bridging between people or groups outside the organization [13]. In the MOVE! study, we saw a clear example of the power of external connections in the transition site. This site had a failed implementation attempt the first year. A new coordinator was hired who spoke about the importance of her connections across VHA: "...from the get-go, I knew what was going on...I talked to different VAs that had done it different ways and I just kind of balanced out with our facility...and what had worked the best in other facilities to pick the way we implemented it."

C. Peer Pressure: Mimetic or competitive pressure to implement an intervention; typically

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because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge. “Peers” can refer to any outside entity which with the organization feels some degree of affinity or competition with at some level within their organization (e.g., competitors in the market, other hospitals in a network). The pressure to implement can be particularly strong for late-adopting organizations [58]. In the MOVE! study, we did not see evidence of peer pressure; most likely because MOVE! was already centrally mandated and this was the more salient construct.

D. External Policies & Incentives: A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting [27]. In the MOVE! study, VHA promulgated the program through a central directive and it was widely regarded as an unfunded mandate. This put pressure on all the sites to get MOVE! implemented. However, a coordinator affiliated with one of the low uptake sites said that priority would not be given to MOVE! as long as it was not tied to a performance measure from a VHA-wide incentive system targeted at medical center directors and providers, “...everything takes a backseat to performance measures. If something isn't a performance measure and figures into the performance appraisal for the [regional] director and that facility director, then it isn't given the same weight.” Indeed, VHA implemented MOVE! performance measures for 2009 to exert pressure for facilities to effectively implement MOVE!. These examples show how multiple external policies and incentives may work at odds with one another.

III. Inner Setting

Contributing to the complexity inherent in describing the many constructs related to the inner setting, are challenges inherent in conceptualizing the myriad levels in which these constructs influence and interact. Little systematic research has been done to understand how constructs apply to different levels within an organization; whether constructs apply equally to all levels; which constructs are most important at which level.

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A. Structural Characteristics: The social architecture that describes how large numbers of people are clustered into smaller groups and differentiated and how the independent actions of these differentiated groups are coordinated to produce a holistic product or service [59, 60]. This construct also includes characteristics of organizations such as age and size. These characteristics are by-and-large, quantitative measures and in most cases, measurement instruments and approaches have been developed for them. Damenpour conducted a meta-analysis of many structural determinants based on 23 studies conducted outside the healthcare sector [61]. Functional differentiation is the internal division of labor where coalitions of professionals are formed into differentiated units. The number of units or departments represents diversity of knowledge in an organization. The more stable teams are (members are able to remain with the team for an adequate period of time; low turnover), the more likely implementation will be successful [19]. Administrative intensity (the ratio of managers to total employees) is positively associated with innovation [61]. Centralization (the dispersion or concentration of decision-making autonomy) is negatively associated with innovation [61] but has also been found to be positive or negative, depending on the stage of intervention (initiative stage v. implementation stage) [62]. Size, age, maturity, and degree of specialization (the uniqueness of the niche or market for the organization's products or services) also influence implementation [13]. We did not assess structural characteristics in the MOVE! study.

B. Networks and Communications: The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization. Research in organizational change has moved beyond reductionist measures of organizational structure and increasingly embraces the complex role that networks and communications has on implementation of change interventions [63, 64]. Connections between individuals, units, services, hierarchies may be strong or weak, formal or informal, visible or invisible. Social capital describes the quality and the extent of relationships and includes dimensions of shared vision and information sharing. One component of social capital is the internal bonding of individuals within the same organization [13]. Complexity theory posits that relationships between individuals may

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be more important than individual attributes [65] and building these relationships can positively influence implementation [66].

Regardless of how an organization is structurally organized, the importance of communication across the organization is clear. Communication failures are involved with the majority of sentinel events in US hospitals [67]. High quality of formal communications contributes to effective implementation [68]. Making staff feel welcome (good assimilation); peer collaboration and deprivatization and review (in the context of feedback about work practices from peers), clear communication of mission and goals, cohesion between staff, informal communication quality, all contribute to effective implementation [68].

Networks and communications concepts are especially challenging to characterize in a way that is consistent and meaningful across disparate settings and studies because we do not yet understand the precise characteristics of networks and communications that are significant for measurement and study; nor is there a set of characteristics that apply across studies and settings. In the MOVE! study, an important feature of high uptake sites was the degree of “teamness” they created with members of the MOVE! multi-disciplinary team, “[team members are] very amicable; very, very good, pleasant, very professional. I mean there isn’t a week that doesn’t go by that ...we’re not communicating with each other and not really... having a good time too with the group sessions...we’re all there to make the patients really change the way they’re eating and their activity habits...” In contrast, the low uptake sites did not have effective communications or relationships in place for team members. Lack of communication spilled over onto patients who came to MOVE! orientation not understanding why they were there, nor what the program really was.

C. Culture: Norms, values, and basic assumptions of a given organization [69]. Most change efforts are targeted at visible, mostly objective, aspects of an organization that include work tasks, structures, and behaviors. One explanation for why so many of these initiatives fail, centers on the failure to change less tangible organizational assumptions, thinking, or culture [70]. In the MOVE! study, we did not focus on culture, but instead elicited information about more immediate

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factors related to implementation climate and readiness, described below.

Some researchers have a relatively narrow definition of culture while other researchers incorporate nearly every construct related to inner setting. Climate, likewise, suffers from inconsistent definition. Culture and climate can, at times, be interchangeable across studies, depending on the definition used [71]. A recent review found 54 different definitions for organizational climate [69] and likewise, many definitions exist for culture [71]. Culture is often viewed as relatively stable, socially constructed, and subconscious [71]. The CFIR embraces this latter view and differentiates climate, as the localized and more tangible manifestation of the largely intangible, overarching culture [69]. Climate is a phenomenon that can vary across e.g., teams or units, and is relatively less stable over time compared to culture. Appendix 1 provides more discussion and rationale for the constellation and grouping of sub-constructs for Implementation Climate and also for Readiness for Implementation.

D. Implementation Climate: The shared receptivity of involved individuals to an intervention [13] and the extent to which use of that intervention will be “rewarded, supported, and expected within their organization” [10](p 1060). Climate can be assessed through tangible and relatively accessible means such as policies, procedures, and reward systems [69]. Six sub-constructs contribute to a positive implementation climate for an intervention: tension for change, compatibility, relative priority, organizational incentives and rewards, goals and feedback, and learning climate.

D1. Tension for change: The degree to which stakeholders perceive the current situation as intolerable or needing change [13, 17, 18, 68]. In the MOVE! study, the transition site recognized the need for change after implementation efforts stagnated during the first year, “...all of the group was pretty excited ...because they had sat stagnant for a year...they had put up...posters [for] the MOVE! program and all that stuff and they didn’t have anything set up so people were consulting to the MOVE! program when there wasn’t even a program set up...”

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D2. Compatibility – The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems [10, 13]. The more individuals perceive alignment between the meaning they attach to the intervention and meaning communicated by upper management, the more effective implementation is likely to be. For example, providers may perceive an intervention as a threat to their autonomy while leadership is motivated by the promise of better patient outcomes. In the MOVE! study, providers at the high uptake site already referred patients to pre-existing weight management programs and they saw MOVE! fitting into that flow. These providers believed that weight loss achieved through MOVE! aligned with their goal to reduce high blood pressure in their patients. However, providers at one low uptake site appeared to see MOVE! as a distraction to their more immediate concerns to control blood pressure with medication.

D3. Relative priority: Individuals' shared perception of the importance of the implementation within the organization [10, 42, 46]. In the MOVE! study, staff at one high uptake site succeeded in linking MOVE! implementation with leaderships' desire to start a bariatric surgery program, "...we were approved to start a bariatric surgery program bam, right away... all our doctors and administrative people are enormously interested a bariatric surgery...and all resources and interests funneled into bariatric surgery...we did everything backwards...in hindsight, it probably was a good way to do that because our criteria for eligibility for people to have bariatric surgery is that they must be enrolled in MOVE! for one year." Conversely, MOVE! implementation suffered from lower relative priority at one low uptake site in the face of heightened pressure to reduce waiting times for primary care.

D4. Organizational Incentives & Rewards – Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect [46, 72]. In the MOVE! study, a physician at a low uptake site talked about lack of incentives as a barrier to implementation, "...we had no incentive...we didn't get our

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boxes checked for getting this program implemented...I didn't get a raise, I didn't get a bonus; nobody was patting me on the back..."

D5. Goals and Feedback: The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals [45, 68, 73-76]. The Chronic Care Model emphasizes the importance of relying on multiple methods of evaluation and feedback including clinical, performance, and economic evaluations and experience [17, 18]. In the MOVE! study, one high uptake site reported weight loss statistics regularly to the team and to leadership. The other high uptake site's team was motivated by anecdotal stories from successful patients. This information helped build support at both sites for the implementation. Neither of the two low uptake sites had a means by which to track or communicate goals or feedback. One staff member worked at home after-hours in an attempt to assemble summary indicators of progress.

D.6. Learning Climate: A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation (in general, not just in a single implementation) [10, 46, 77]. These interrelated practices and beliefs support and enable employee and organizational skill development, learning, and growth to maximize an organization's absorptive capacity for new knowledge and methods [13]. Quantitative measurement instruments are available for measuring an organization's "learning" capability [78, 79]. In the MOVE! study, at one high uptake site, the coordinator was able to share dreams with the chief of staff, for expanding the program which hints at a strong learning climate. In contrast, the coordinator at one low uptake site, talked about having to be careful about recruiting a physician to help champion the program to avoid "getting arrows in my back."

E. Readiness for Implementation: Tangible and immediate indicators of organizational commitment to its decision to implement an intervention, consisting of 3 sub-constructs.

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Implementation readiness is differentiated from implementation climate in the literature by its inclusion of specific tangible and immediate indicators of organizational commitment to its decision to implement an intervention.

E.1. Leadership Engagement: Commitment, involvement, and accountability of leaders and managers [46, 72, 76, 80, 81]. The term “leadership” can refer to leaders at any level of the organization including executive leaders, middle management, front-line supervisors, and team leaders, who have a direct or indirect influence on the implementation. One important dimension of organization commitment is managerial patience (taking a long-term view rather than short-term) to allow time for the often inevitable reduction in productivity until the intervention takes hold [46]. In the MOVE! study, leaders at the high uptake and transition sites showed clear commitment to implementation. At one high uptake site, a leader was able to convince an executive board to hire needed staff and was actively involved in hiring and mentoring the new program coordinator.

E.2. Available Resources: The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time [2, 16, 20, 22, 59, 60]. In the MOVE! study, all sites talked about constrained resources that inhibited their ability to implement the program. However, staff at the high uptake sites tended to see these constraints as challenges worth overcoming. In contrast, space, time, and financial constraints had a significant impact on the ability of the coordinator at one low uptake site to implement MOVE! by their initial targeted date.

E3. Access to information and knowledge: Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks [13, 46, 72, 82]. Information and knowledge includes all sources such as experts, other experienced staff, training, documentation, and computerized information systems. In the MOVE! study, all sites had access to intranet and internet (www.move.gov) sites from which they could download policy documents,

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implementation toolkits, and training information. In addition, NCP (the central office leading dissemination of MOVE!) set up regular conference calls and made themselves available for questions and problem-solving, “I think this is the only program that has a dedicated staff of experts that are there to help you when you need it. You can call them, you can email them; they’re there.” The high uptake sites had additional support from regional staff and supported each other locally, as well. Low uptake sites, however, did not have as much access to regional or local information and support to aid them; though access to knowledge and information through NCP was helpful.

IV. Characteristics of Individuals

Little research has been done to gain understanding of the dynamic interplay between individuals and the organization within which they work and how that interplay influences individual or organizational behavior change. Organizations are composed, ultimately, of individuals. However, the problem of the *level* of analysis is particularly clear when describing individual characteristics. Though the characteristics described here are necessarily measured at the individual level, these measures may be most appropriately aggregated to team or unit or service levels in analyses. The level at which to perform analysis is determined by the study and setting. For example, VanDeusen Lukas, et al measured knowledge and skills at an individual level but then aggregated this measure to the team level in their study of factors influencing implementation of an intervention in ambulatory care clinics [83]. Organizational change starts with individual behavior change and individual knowledge and beliefs toward changing their behavior and the level of self-efficacy to make the change have been widely studied and are the two most common individual measures in theoretical models for individual change [7, 34, 73, 84]. The CFIR includes these two constructs along with individual identification with their organizational and other personal attributes.

A. Knowledge and Beliefs About the Intervention: Individuals’ attitudes toward the intervention and familiarity with facts, truths, and principles related to the intervention. Skill in using the intervention is a primarily cognitive function that relies on adequate how-to knowledge and

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knowledge of underlying principles or rationale for adopting the intervention [12]. Enthusiastic use of an intervention requires a positive affective response to the intervention. Often, subjective opinions obtained from peers, based on personal experiences are more accessible and convincing and these opinions help to generate enthusiasm [12]. Of course, the converse is true as well, often creating a negative source of active or passive resistance. We did not formally assess knowledge and beliefs of individuals in the MOVE! study.

B. Self-efficacy: Individual belief in their own capabilities to execute courses of action to achieve implementation goals [85]. The level of confidence that an individual has to make a change. Self-efficacy is a significant component in most individual behavior change theories and models [73]. Individuals with high self-efficacy are more likely to make a decision to embrace the intervention and exhibit committed use even in the face of obstacles. We did not formally assess individual self-efficacy in the MOVE! study.

C. Individual Stage of Change: Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention [7, 46]. The specific stages used will depend on the underlying model being used in the study. Prochaska's trans-theoretical model characterizes these stages as pre-contemplation, contemplation, preparation, and action and maintenance [86]. Rogers' diffusion theory delineates 5 stages [12]. Grol et al describe a 5-stage model with 10 sub-stages based on their synthesis of the literature [7]. In the MOVE! study, we did not formally assess individual stage of change.

D. Individual Identification with Organization: A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization. These attributes may affect the willingness of staff to fully engage in implementation efforts or use the intervention [87-90]. These measures have been studied very little in healthcare but may be especially important when evaluating the influence of implementation leaders' (described under Process below) on implementation efforts. Organizational citizenship behavior characterizes how

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well organizational identity is taken on by individuals and whether, because they associate themselves with the organization, whether they are willing to put in extra effort, talk well of the organization and take risks in their organization [91, 92]. Organizational justice is an individual's perception of distributive and procedural fairness in the organization [87]. Emotional exhaustion is an on-going state of emotional and physical depletion or burnout [93] and may negatively influence implementation by stunting the ability and energy of an individual to help or initiate change [89, 90]. AHRQ recently published a guide to for determining whether a particular implementation will be successful and included questions about individual perceptions of whether they believe the organization could be doing a better job, belief about whether work is done efficiently, and whether there are inequities as potential barriers to implementation [94]. The Organizational Social Context (OSC) measure, developed by Glisson, et al, includes constructs related to psychological climate (perception of the psychological influence of work environment) and work attitudes (job satisfaction and organizational commitment) [95]. These factors are believed to influence implementation of interventions in mental health clinics. We did not assess these measures in the MOVE! study. However, in another mixed methods study of infection control practices at US hospitals [96, 97], we found differences in the willingness and ability of individuals to engage in implementing quality improvement efforts. Staff at one site who had mixed success implementing new practices were reluctant to take on extra work related to quality improvement efforts; "...everyone thinks when they label you as a champion... 'oh, more work, more problems'..." indicating emotional exhaustion or a lack of organizational commitment. In contrast, staff at another hospital that exhibited a high degree of success in implementing new infection control practices had this explanation when asked why, "Oh you're asking a career person here that thinks their company is the biggest and the best so I mean, I could go on and on." This enthusiasm was echoed by everyone we talked to at this hospital. Staff at this hospital were "assertive and aggressive" when taking on new implementation efforts. The difference in the nature of organizational commitment and the possible role of emotional exhaustion and its effects on implementation between these two hospitals was palpably clear.

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E. Other Personal Attributes: This is a broad construct to include other personal traits. Traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, innovativeness [35], tenure [35], and learning style, have not received adequate attention by implementation researchers [13].

V. Process

We describe 4 essential activities of implementation process that are common across organizational change models: 1) planning; 2) engaging; 3) executing; and 4) reflecting and evaluating. These activities may be accomplished formally or informally through, for example, grassroots change efforts. They can be accomplished in any order and are often done in a spiral, stop-and-start, or incremental approach to implementation [38]; e.g., using a Plan-Do-Study-Act approach to incremental testing [98]. Each activity can be revisited, expanded, refined, and re-evaluated throughout the course of implementation.

A. Planning: The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and quality of those schemes or methods. The fundamental objective of planning is to design a course of action to promote effective implementation by building local capacity for using the intervention, collectively and individually [27]. The specific steps in plans will be based on the underlying theories or models used to promote change at organization and individual levels [7, 49, 99]. For example, the Institute for Healthcare Improvement's (IHI) [98, 100], Grol et al [101], Brach et al [94], Glisson and Schoenwald [102], and Graham and Logan [49] (just to name a few) all describe comprehensive approaches to implementation based on theories of what works. These models were developed in different contexts and prescribe different sets of activities – though commonalities exist as well. Grol et al list 14 different bodies of theories for changing behaviors in social or organizational contexts [7] and Estabrooks et al list 18 different models of organizational innovation [11]. Thus, the particular content of plans will vary depending on the theory or model being used to guide implementation. Implementation plans can be assessed by the degree to which five considerations guide planning: 1) stakeholders' needs and perspectives are considered; 2)

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strategies are tailored for appropriate sub-groups (e.g., delineated by professional, demographic, cultural, organizational attributes); 3) appropriate style, imagery, metaphors, etc. are identified and used for delivering information and education; 4) appropriate communication channels are identified and used; 5) progress toward goals and milestones is tracked using rigorous monitoring and evaluation methods [12, 13]; and 6) strategies are used to simplify execution including plans for dry runs (simulations or practice sessions) to allow team members to learn how to use the intervention before going live [19], trials are done to allow users to test procedures, gain confidence, and build an environment of psychological safety [19], or an incremental approach is used where the intervention is broken down into manageable parts that can be adopted incrementally [61]. The plan can be formal or informal but should consider all salient contextual factors – both modifiable and non-modifiable factors. Work-arounds can be developed for non-modifiable factors and strategies can be designed to modify factors that can be modified (e.g., increase stakeholders' knowledge of the intervention).

Because the MOVE! study was retrospective, we did not evaluate the planning process at the study sites.

B. Engaging: Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities. Engaging members of teams tasked with implementing an intervention (or to be “first users”) is an often overlooked part of implementation [103]. It is vital that early members are carefully and thoughtfully selected or allowed to rise naturally [19, 103]; especially “implementation leaders.” If early users and leaders are homophilous (similar socioeconomic, professional, educational, and cultural backgrounds) with intended users, individuals will be more likely to adopt the intervention [13]. The influence of these leaders can be evaluated by assessing their presence or absence (e.g., does the implementation effort have a clear champion or not?), how they are brought on board (e.g., appointed, volunteered), their role in the organization (formal and/or informal roles), and their role in implementation. One means by which influence is transmitted is role modeling [104]. We have identified four types of

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implementation leaders. Terms and definitions of roles vary widely in the literature. The remainder of this section suggests standard definitions for each.

B1. Opinion leaders: Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention [12, 13]. There is general agreement that there are 2 different types of opinion leaders: 1) experts; and 2) peers. Expert opinion leaders exert influence through their authority and status [13]. Peer opinion leaders exert influence through their representativeness and credibility [13]. We did not evaluate opinion leaders in the MOVE! study.

B2. Formally appointed internal implementation leaders: Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role. These leaders may or many not have explicit time dedicated to the task. Implementation is “part of the job.” In the MOVE! study, the program coordinators all volunteered for the role, “The staff that’s gotten involved in the MOVE program was not appointed. We all had interest in this. We got involved...we got...administration to free this time up so that we can continue [what] became...a mandate.”

B3. Champions: “Individuals who dedicate themselves to supporting, marketing, and ‘driving through’ an [implementation]” [105](p. 182), overcoming indifference or resistance that the intervention may provoke in an organization. A defining characteristic of champions is their willingness to risk informal status and reputation because they believe so strongly in the intervention [106]. The main distinction of champion from opinion leader is that a champion *actively* associates themselves with support of the intervention during implementation. There is the old adage that an intervention “either finds a champion or dies” [107]. In the MOVE! study, the coordinator at the low uptake site exhibited characteristics of a champion, going beyond the call of duty, buying t-shirts and other supplies out-of-pocket until finally getting approval to purchase with hospital funds, organizing field trips for participants in MOVE!, and serving homemade meals at reunions to provide an encouraging venue for “graduates” and “alumni” to continue to lose weight.

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B4. External change agents: Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction. They usually have professional training in a technical field related to organizational change science or in the technology being introduced into the organization. This role includes outside researchers who may be implementing a multi-site intervention study and other formally appointed individuals from an external entity (related or unrelated to the organization); e.g, a facilitator from corporate or regional office; hired consultant.

C. Executing: Carrying out or accomplishing the implementation according to plan. Execution of an implementation plan may be organic with no obvious or formal planning which makes execution difficult to assess. Quality of execution may consist of the degree of fidelity of implementation to planned courses of action [40], intensity (quality and depth) of implementation [108], timeliness of task completion, and degree of engagement of key involved individuals (e.g., implementation leaders) in the implementation process. We did not evaluate execution in the MOVE! study.

D. Reflecting and Evaluating: Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience. It is important to differentiate this processual construct from the Goals and Feedback construct under Inner Setting, described above. The focus here is specifically related to implementation efforts. Evaluation includes traditional forms of feedback such as reports, graphs, and qualitative feedback and anecdotal stories of success [73]. Objectives should be specific, measurable, attainable, relevant, and timely (the SMART rubric) [94]. Less attention is paid, in the literature, to the need for and value of group and personal reflection. Time should be taken to reflect or debrief before, during, and after implementation to promote shared learning and improvements along the way [19]. In the MOVE! study, one of the high uptake sites made time to share success stories, discuss and solve problems, and dream about future enhancements by meeting together over lunch breaks and sometimes after-hours. Individuals at the low uptake

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sites did not have or make the time to evaluate or reflect on implementation progress.

VI. Discussion

The CFIR provides a pragmatic structure for identifying potential influences on implementation and organizing findings across settings and studies. Many researchers have published models for translating evidence into practice. We intend the CFIR to complement these models by providing an explicit, comprehensive, and unified list of potential antecedents to effective implementation. For example, the CFIR complements a recently published model by Pronovost and colleagues from the Johns Hopkins Quality and Safety Research Group for large-scale translation of scientific evidence into practice that encompasses four major steps [103]. The second step in this change model is to identify local barriers to implementation. The CFIR provides an explicit list of antecedents that may be considered in an implementation study. Another framework is increasingly being used to guide comprehensive evaluation of interventions in terms of Reach, Effectiveness, Adoption, Implementation, and Maintenance (sustainability) (RE-AIM) [109]. The CFIR opens the “black box” of the “I” (implementation) component to promote richer understanding of complex implementation contexts.

The constructs described in the CFIR represent a beginning foundation. Each implementation study will need to judge each construct for salience, carefully adapt and operationalize definitions (paying special attention to sometimes indistinct boundaries between constructs), discern the level(s) at which each should be evaluated and defined (e.g., individuals, teams, units, clinics, medical centers, regions), make decisions about how to measure and assess, and be aware of the time-points at which measurement and evaluation occurs while acknowledging the transient nature of the state of each of these contextual factors. Each decision and rationale should be documented along with findings related to each construct. For example, a study conducted by Van Deusen Lukas and colleagues found that “clinic team knowledge and skills” was associated with effective implementation [83]. They assessed team knowledge and skills by surveying individual staff members and then aggregating to the team level as one unit of analysis in predictive models. Their final model found significant contextual factors at the system

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(external policy and incentives), facility (management support), and team (knowledge and skills) levels. As findings accumulate into knowledge across settings and studies, implementation researchers will learn about what works where and why and thus be better equipped to predict implementation effectiveness across disparate interventions, settings, and implementations.

The CFIR can be used in structuring the implementation evaluation, whether it be formative/ process, or summative. Mendel et al's framework of dissemination describes three components of evaluation in an intervention study or program evaluation [27] (these are also described by Stetler et al [3]). Prior to implementation, capacity and needs assessments are done to identify potential barriers and facilitators to implement from the perspective of the individuals and organizations involved in the implementation. The CFIR provides a list of explicitly defined factors for which data could be collected. It is important, however, that the CFIR not be applied wholesale to every problem. The long list of constructs, each with their own level of "maturity" in definition and operability, can quickly mire evaluations. Rather, each construct should be evaluated strategically, in the context of the study or evaluation, to determine those that will be most fruitful to study [25]. Among them, information necessary to properly adapt the intervention to the setting should be elicited. For example, in a current implementation study, we are assessing the benefits of an intervention designed to improve blood pressure management for patients with diabetes. We found setting differences between sites before implementation which guided how we adapted the intervention and how we implemented that intervention at each site, including developing site-specific protocols so that the intervention pharmacists could get blood pressure cuffs to patients in a timely manner.

During implementation, baseline findings from pre-implementation assessments can be used, guided by the CFIR, to evaluate implementation progress and process. For example, in the implementation study related to improving blood pressure for diabetes patients, we discovered, midstream, that case managers at one site did not realize the intervention had started, so we facilitated communication between the case managers and the intervention pharmacist. The CFIR was used to guide our evaluation of implementation progress. Findings thus far, have allowed us

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to obtain real-time data to guide refinements and address issues before they threaten the intervention's viability.

The third type of evaluation described in Mendel et al's model is outcome and impact evaluation. Post-implementation, the CFIR can be used to guide exploration into the question of what factors influenced implementation and how implementation influenced performance of the intervention. This was the context for the MOVE! study. In addition, the CFIR can be used to assess changes in the setting as a result of implementing the intervention – the co-evolution that often occurs through effective implementation [31]. At all three evaluative stages, the CFIR provides a framework by which to better understand the dynamic, multi-level, transient nature of implementation in particular settings and to organize and communicate findings across settings.

Approaches for conducting formative evaluations vary widely and draw on multiple scientific disciplines. Implementation research has not matured to the point of specifying any 'best practice' and perhaps a standard practice is not an appropriate aspiration. Groh and colleagues describe an elaborate and comprehensive framework for designing, implementing, and evaluating change efforts in healthcare [101]. They and many others advocate mixed methods, drawing on qualitative and quantitative data sources, triangulation and reflexivity to build deeper understanding of complex implementation contexts [110, 111]. Longitudinal or ethnographic studies may be needed to deeply understand the dynamic and transient activities that underlie implementation process. The appropriate level at which to assess the constructs included in the CFIR must be carefully considered and will likely differ between implementation studies. The appropriateness of studying factors at the team, unit, service line, organization, or system level should be determined by the scope and nature of the particular intervention and implementation goals. Weiner and colleagues highlight the need to decide whether to aggregate appraisals of individual self-efficacy or whether to aggregate individuals' appraisals of their organization's collective self-efficacy to implement change [112].

At a macro level, the CFIR can be used to organize and promote synthesis of research findings across settings and studies [27] using consistent and coherent language and terminology

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which will further stimulate theory and model development. The CONSORT Trial Bank Project was developed to do this for clinical trials by capturing study design, execution details, and results from randomized clinical trials in a form that promotes synthesis of results from multiple studies [113, 114]. The recently published SQUIRE guidelines are designed to promote knowledge-building for implementation and quality improvement studies by standardizing how findings from quality improvement and implementation research studies are reported. The SQUIRE guidelines take into account two essential considerations missing from the CONSORT guidelines but essential for implementation studies: “reflexivity” and setting [24]. The guidelines suggest that authors specify, “...how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized [24](Table, p 671).” Pawson and Tilley describe a realist approach to synthesizing research findings across settings and studies by iterating between theories underlying actions and empirical data that support or appear to refute those theories to gain a deeper understanding of how mechanisms (intervention, process, and individuals involved) and context (inner and outer setting) work together to produce actual or hypothesized outcomes [25]. The CFIR can support realistic evaluation approaches to develop and revise middle-range theories based on findings from multiple settings and studies by providing common terminology, definitions, and an organizing framework [115].

The ultimate judgment of the CFIR’s utility and validity can only be discerned by coalescing answers to three questions over time [20]:

- 1) Is terminology and language coherent?
- 2) Does the CFIR promote comparison of results across settings and studies over time?
- 3) Does the CFIR stimulate new theoretical developments?

If answers to all three questions are yes, then we are on the right path.

Conclusion

The CFIR provides a pragmatic structure for identifying potential influences on implementation and organizing findings across settings and studies. It embraces, consolidates, standardizes, and unifies constructs shown to be associated with implementation from other

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published frameworks and models. The CFIR can be used to help guide formative evaluations of interventions in local settings and offers an organizational framework for synthesizing and building knowledge about what works where, across settings and studies. We propose the CFIR as a means by which to see far and as a road-map for the journey of accumulating an ever more rich understanding of the complexities of implementation and a more predictable means by which to ensure effective implementations.

NOT FOR CITATION

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

LJD and JCL conceived of the paper. LJD drafted the initial form and all revisions of this paper. All other authors (REK, DCA, SRK, JAA) made significant contributions to the conceptual framework and read and modified drafts. All authors read and approved the final manuscript.

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NOT FOR CITATION

Figure 1: Major Domains of the CFIR

(See Figure 1.ppt)

NOT FOR CITATION

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Table 1: Citation List of Models Analyzed for the CFIR

1	<p>Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organization</p> <ul style="list-style-type: none"> Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O: Diffusion of innovations in service organizations: systematic review and recommendations. <i>Milbank Q</i> 2004, 82:581-629.
2	<p>Conceptual Model for Implementation Effectiveness</p> <ul style="list-style-type: none"> Klein KJ, Sorra JS: The Challenge of Innovation Implementation. <i>The Academy of Management Review</i> 1996, 21:1055-1080. Klein KJ, Conn AB, Sorra JS: Implementing computerized technology: An organizational analysis. <i>J Appl Psychol</i> 2001, 86:811-824.
3	<p>Dimensions of Strategic Change</p> <ul style="list-style-type: none"> Pettigrew A, Whipp R: Managing change and corporate performance. In <i>European Industrial Restructuring in the 1990s</i>. Edited by Cool K, Neven DJ, Walter I. Washington Square, NY: New York University Press; 1992: 227-265
4	<p>Theory-based Taxonomy for Implementation</p> <ul style="list-style-type: none"> Leeman J, Baernholdt M, Sandelowski M: Developing a theory-based taxonomy of methods for implementing change in practice. <i>J Adv Nurs</i> 2007, 58:191-200.
5	<p>PARIHS Framework: Promoting Action on Research Implementation in Health Services</p> <ul style="list-style-type: none"> Kitson A: From research to practice: one organisational model for promoting research based practice. <i>Edtna Erca J</i> 1997, 23:39-45. Rycroft-Malone J, Harvey G, Kitson A, McCormack B, Seers K, Titchen A: Getting evidence into practice: ingredients for change. <i>Nurs Stand</i> 2002, 16:38-43.
6	<p>Ottawa Model of Research Use</p> <ul style="list-style-type: none"> Graham ID, Logan J: Innovations in knowledge transfer and continuity of care. <i>Can J Nurs Res</i> 2004, 36:89-103.
7	<p>Conceptual Framework for Transferring Research to Practice</p> <ul style="list-style-type: none"> Simpson DD: A conceptual framework for transferring research to practice. <i>J Subst Abuse Treat</i> 2002, 22:171-182. Simpson DD, Dansereau DF: Assessing Organizational Functioning as a Step Toward Innovation. <i>NIDA Science & Practice Perspectives</i> 2007, 3:20-28.
8	<p>Diagnostic/Needs Assessment</p> <ul style="list-style-type: none"> Kochevar LK, Yano EM: Understanding health care organization needs and context. Beyond performance gaps. <i>J Gen Intern Med</i> 2006, 21 Suppl 2:S25-29.
9	<p>Stetler Model of Research Utilization</p> <ul style="list-style-type: none"> Stetler CB: Updating the Stetler Model of research utilization to facilitate evidence-based practice. <i>Nurs Outlook</i> 2001, 49:272-279.
10	<p>Technology Implementation Process Model</p> <ul style="list-style-type: none"> Edmondson AC, Bohmer RM, Pisana GP: Disrupted routines: Team learning and new technology implementation in hospitals. <i>Adm Sci Q</i> 2001, 46:685-716.
11	<p>Replicating Effective Programs Framework</p> <ul style="list-style-type: none"> Kilbourne AM, Neumann MS, Pincus HA, Bauer MS, Stall R: Implementing evidence-based interventions in health care: Application of the replicating effective programs framework. <i>Implement Sci</i> 2007, 2:42.
12	<p>Organizational Transformation Model</p> <ul style="list-style-type: none"> VanDeusen Lukas CV, Holmes SK, Cohen AB, Restuccia J, Cramer IE, Shwartz M, Charns MP: Transformational change in health care systems: An organizational model. <i>Health Care Manage Rev</i> 2007, 32:309-320.

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13	<p>Implementation of Change: A Model</p> <ul style="list-style-type: none"> Grol RP, Bosch MC, Hulscher ME, Eccles MP, Wensing M: Planning and studying improvement in patient care: the use of theoretical perspectives. <i>Milbank Q</i> 2007, 85:93-138. Grol R, Wensing M, Eccles M: <i>Improving Patient Care: The Implementation of Change in Clinical Practice.</i> Edinburgh, Scotland: Elsevier; 2005.
14	<p>Framework of Dissemination in Health Services Intervention Research</p> <ul style="list-style-type: none"> Mendel P, Meredith LS, Schoenbaum M, Sherbourne CD, Wells KB: Interventions in organizational and community context: a framework for building evidence on dissemination and implementation in health services research. <i>Adm Policy Ment Health</i> 2008, 35:21-37.
15	<p>Conceptual Framework for Implementation of Defined Practices and Programs</p> <ul style="list-style-type: none"> Fixsen DL, Naoom, S. F., Blase, K. A., Friedman, R. M. & Wallace, F.: Implementation Research: A Synthesis of the Literature. (The National Implementation Research Network ed.: University of South Florida, Louis de la Parte Florida Mental Health Institute; 2005.
16	<p>Will it Work Here? A Decision-maker's Guide Adopting Innovations</p> <ul style="list-style-type: none"> Brach C, Lenfestey N, Roussel A, Amoozegar J, Sorensen A: <i>Will It Work Here? A Decisionmaker's Guide to Adopting Innovations.</i> Agency for Healthcare Research & Quality (AHRQ); 2008.
17	<p>Availability, Responsiveness and Continuity: An Organizational and Community Intervention Model</p> <ul style="list-style-type: none"> Glisson C, Schoenwald SK: The ARC organizational and community intervention strategy for implementing evidence-based children's mental health treatments. <i>Ment Health Serv Res</i> 2005, 7:243-259. Glisson C, Landsverk J, Schoenwald S, Kelleher K, Hoagwood KE, Mayberg S, Green P: Assessing the Organizational Social Context (OSC) of Mental Health Services: Implications for Research and Practice. <i>Adm Policy Ment Health</i> 2008, 35:98-113.
18	<p>A Practical, Robust Implementation and Sustainability Model (PRISM)</p> <ul style="list-style-type: none"> Feldstein AC, Glasgow RE: A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. <i>Jt Comm J Qual Patient Saf</i> 2008, 34:228-243.
19	<ul style="list-style-type: none"> Multi-level Conceptual Framework of Organizational Innovation Adoption Frambach RT, Schillewaert N: Organizational innovation adoption: a multi-level framework of determinants and opportunities for future research. <i>Journal of Business Research</i> 2001, 55:163-176.

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Table 2: CFIR Constructs and Short Descriptions

Code	Topic/Description	Short Description
I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in their own organization and to be able to reverse course (undo implementation) if warranted
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement
G	Design Quality and Packaging	Excellence in how the intervention is bundled, presented, and assembled
H	Cost	Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and integral to the organization.
B	Cosmopolitanism	The degree to which an organization is externally networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture that describes how large numbers of people are clustered into smaller groups and differentiated and how the independent actions of these differentiated groups are coordinated to produce a holistic product or service.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.

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2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
D	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers.
2	Available Resources	The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time.
3	Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.

IV. CHARACTERISTICS OF INDIVIDUALS

A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward the intervention and familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

V. PROCESS

A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention
2	Formally appointed internal implementation leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.

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3	Champions	“Individuals who dedicate themselves to supporting, marketing, and ‘driving through’ an [implementation]” [101](p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

NOT FOR CITATION

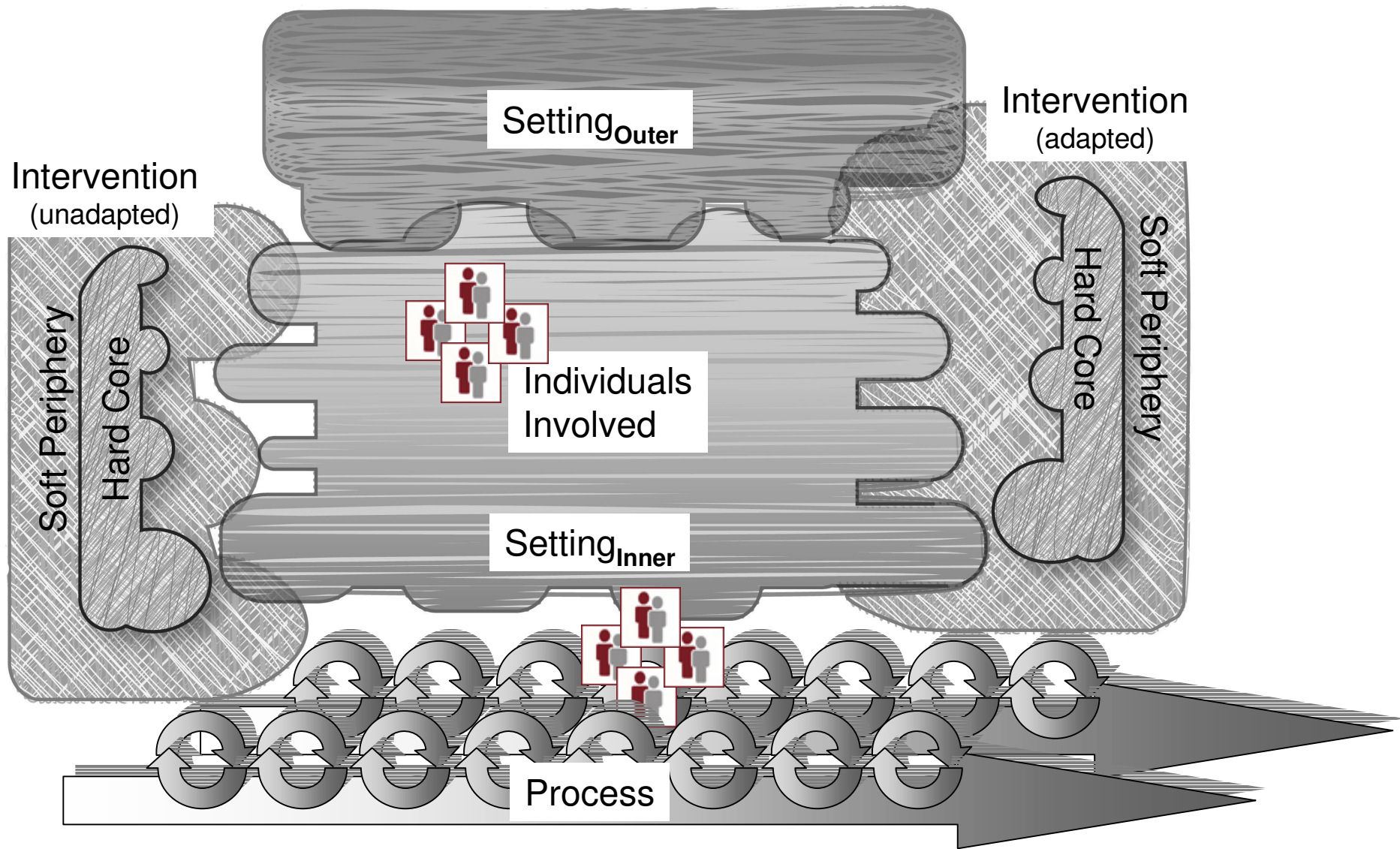


Figure 1

Additional files provided with this submission:

Additional file 1: appendix 1 2ndround v2.doc, 1286K

<http://www.implementationscience.com/imedia/4803148962526406/supp1.doc>

Additional file 2: appendix 2 matrix.xls, 35K

<http://www.implementationscience.com/imedia/1557006650252641/supp2.xls>