

Researcher Perspectives on Implementation Research

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A National Plan of Implementation Research

Meeting Goals

The purpose of the meeting was to develop an outline for a multi-site, multi-year (10 - 15 years) program of research to dramatically improve the practice and science of implementation. Based on findings from the recent monograph, "Implementation Research: A Synthesis of the Literature" (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005), a focus on implementation process and outcome results can inform the implementation of quality programs and practices across domains (e.g. mental health, substance abuse, prevention). However, the field of implementation research is still in its infancy and an in need of a long-term research agenda to focus efforts on successful approaches to implementation, the various influences on implementation, and the interaction effects among implementation factors.

As we continue to develop a longer-term program of research, it is likely we will consider the research that needs to be done and the sequence of studies needed to:

- Develop and evaluate measures of implementation outcomes that are distinct from intervention outcomes,
- Clearly identify, operationalize, and evaluate the contributions of individual implementation components with respect to implementation outcomes and intervention outcomes, and
- Evaluate the impacts (positive and negative) of interactions among individual implementation components (at a point in time and over time) with respect to implementation outcomes and intervention outcomes.

Meeting Agenda

Wednesday, April 2006

- Introductions
- A brief overview of one example of attempted implementation and research on implementation

Thursday, April 7th

- Review the major conceptual frameworks emerging from the William T. Grant-funded review of the implementation evaluation literature
- Discuss the implementation frameworks and modify as needed to develop a heuristic view of implementation components and their interactions

- Identify existing measures or approaches to developing new measures of implementation processes and outcomes
- Prioritize the work that needs to be done
- Outline designs to experimentally examine the priority factors

Friday April 8th

- Identify important interactions among components
- Prioritize the work that needs to be done
- Outline designs to experimentally examine the priority interaction factors
- Outline a plan that could be presented to a consortium of funders from a variety of domains (everyone stands to benefit from implementation knowledge generated in any sector)
- Decide on next steps (who, when, where, how) to implement the plan of research on implementation factors and their interactions
- Participant evaluation of the meeting

Presentation of Material

The following table outlines the research questions and related discussion that occurred on Thursday and Friday of the meeting. The Topic column presents the implementation issue under discussion. The Research questions in the next column were generated from the discussion related to the implementation topic presented to the group (e.g. Implementation Drivers). After the research questions were recorded on chart paper, they were typed and categorized under their appropriate topic label. The participants received a copy of the research questions for review and feedback during the meeting and reached consensus regarding the content and wording of the questions. The Discussion section of the table consists of excerpts of the actual conversation that occurred during the generation of the research questions and is included to contextualize the emergence of the questions. In a few instances the discussion material may be repeated across topics. The repetition of information occurred if the paragraph contained multiple ideas representing different topics or if the conversation surrounding the idea was needed to understand the content. The dashed lines in the discussion section are used to delineate either a new line of discussion or a new person's point of view. In the last column of the table, the Resource section provides links to material discussed at the meeting or resources related to the topics addressed.

Topic	Research Questions/Issues to Consider	Discussion	Resources
Stages of Implementation	<p>1. Do sites and communities that have a careful and inclusive planning phase result in better implementation/better outcomes?</p> <p>2. Is coaching useful during planning phases; role of linking agents (Drivers X Stage X Role of Purveyor)</p>	<p>-Some concerns based on adoption model – different stages of readiness people go through as they deal with change; moments when people are ready for their learning as well.</p> <p>-Use of a planning model framework; implementation model focus on planning process. The first two stages are identifying problems/need. The funded sites circumvented the first 2 steps. Other organizations not motivated by money did these steps. The funded sites had a lower level of commitment as well as lower rates of continuation after funding ended. The organizations were looking at the programs/practices as temporary add-ons – “as long as there is funding” attitude.</p> <p>.....</p> <p>-Want to have coaching/facilitation during planning phase/stages; a consultant to guide planning process? YES.</p> <p>.....</p> <p>-Re: stage of implementation: Assume that you initially have perfect fit between setting and program; relationship between fidelity and innovation.</p>	<p>Implementation Research: A Synthesis of the Literature: Chapter 2 Implementation on the Context of the Community</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 3 A Conceptual View of Implementation</p> <p>Theory of Planned Action</p> <p>Theory of Reasoned Action</p> <p>Fishbein’s Theory of Planned Action</p>

		<p>-How do you make sure prevention/intervention is workable? Need to work with people with different culture/consumers at beginning to make decisions.</p> <p>-Form and function/principles/degree to which organizations understand principles in their models (risk/protective) will impact the degree to which innovations and changes “fit”.</p> <p>-Inherent in exploration should be the critical components, end-users and consumers. Active involvement of consumers who will be end-users. Purveyor needs to know who is coming to the table from the community (end-user inclusion). As a purveyor, you need to help foster and prompt bringing consumers to the table.</p> <p>-New terminology; adaptations that change a practice and those that need to be done. And we don’t know what those core components of many EBPs are – this is an excellent area of research.</p> <p>-Likely can change form of core components but not the function of those components.</p> <p>.....</p> <p>-Full fidelity precedes adaptation (fidelity to core components). During exploration the</p>	
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		<p>community, etc. can look at those core components and decide that “yes” we can and do want this and then proceed into full implementation.</p> <p>-The organization and community needs to be fully informed. Informed consent goes both ways between purveyor and a new program site or location.</p> <p>.....</p> <p>-Exploration: perceived quality of evidence helps determine which choice is made.</p>	
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Topic	Research Questions/Issues to Consider	Discussion	<u>Resources</u>
	<p>3. What is the role of state mandates, policies and incentives? In what ways do these state interventions help and hinder?</p> <p>4. What are important measures of state functions with respect to supporting evidence-based programs and how do they relate to fidelity (e.g. SHAY measures)?</p>	<p>-The role of the state is very important – instrumental role in funding, leadership, etc. (e.g. SHAY)</p> <p>-It is important for states to know what they do well and what they don't. There are some roles/responsibilities left to the state that don't “fit”.</p> <p>-Difference between a state run mental health system vs. a county</p>	<p>Implementation Research: A Synthesis of the Literature: Chapter 7 Conclusions and Recommendations</p> <p>State Health Authority Yardstick (SHAY)</p> <p>Top 5 Reasons Not to Use Evidence-Based Programs</p>

<p>Vertical Integration and Influence</p>	<p>5. What roles and functions are a good fit for states (e.g. resources, funding, buy-in, implementing)? Do analyses of state-driven systems compared to county driven.</p> <p>6. Are practices and programs that fit the usual care context more likely to be implemented and sustained versus practices and programs that require significant changes in setting, organizations, and usual care context? (E.g. Fishbein’s Theory of Planned Action). (Alignment and fit with current state, organizational, community and practitioners).</p> <p>7. Is it better to implement evidence-based programs and practices in states that have hospitable structures and policies (e.g. dual enrollment)? What are hospitable structures?</p> <p>8. What are the variables at the multiple levels of context (government, regulatory, community, etc.) that impact implementation negatively and positively?</p>	<p>mental health system. Policy statements are one thing, if \$ doesn’t follow it is another.</p> <p>-Does implementation of EBPs in systems have negative impacts and how do you avoid them?</p> <p>.....</p> <p>-Programs/practices/purveyors need to start in areas where they will be successful and show success; selectively rollout in context where it is likely to lead to successful implementation.</p> <p>.....</p> <p>-Multiple levels of context; government/regulatory/community context- what are the variables at any one of these levels that will have a negative impact on implementation?</p> <p>Something may have no effect but use x amount of a clinicians time which can have a negative effect on the productivity of or access to the services of the organization.</p> <p>.....</p> <p>- Need to consider the multiple levels of context. The government/</p>	<p>State Initiatives</p>
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		<p>regulatory/community context- are there activities, behaviors and decisions that could occur at any one of these levels that will have a negative impact on implementation?</p> <p>-Something may have no effect but use x amount of a clinicians time which can have a negative effect on the organization.</p> <p>-What about people that experience bad treatment effects? What will be the impact of on the community's willingness to participate in demonstration projects in the future?</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
Measures of Implementation	<p>9. What are generic implementation outcomes/instruments? Can we develop measures that function across evidence-based programs and practices (e.g. strength of implementation)?</p> <p>10. Measures of purveyor, community and agency behavior during exploration and installation?</p>	<p>-Need to develop a fidelity measure for implementation; a scale across practices, generic.</p> <p>-A core instrument; general enough to use across practices but with additional items for particular practices.</p> <p>.....</p> <p>-How are they doing technical assistance? Need national survey to understand lessons learned, where there was successful TA; successful purveyor vs. unsuccessful purveyor.</p>	<p>Implementation Research: A Synthesis of the Literature: Chapter 3 A Conceptual View of Implementation</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 5 Research on Core Implementation Components</p>

		<p>How do we define ‘success’? Need measure of effective implementation, agreement about criteria for successful implementation across fields (core battery of measures). Need to use a common vocabulary and measure the same thing.</p> <p>-Need a strength of installation measure; overlap of planning models/set up and strength of implementation process.</p> <p>-Need findings across all areas – no silos; measures and typology of contexts. What are the various potential implementation sites? What is the unit of intervention (class, state, region, etc.)? Does implementation look different depending on what you are doing (larger org vs. smaller org)? A descriptive study of range of contexts for implementing EBPs?</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
	11. Does effective implementation vary by unit of intervention? How are units defined? Integrated or stand-alone?	-What about a team of practitioners vs. an individual practitioner? The difference between individual vs. team service delivery mechanisms	Implementation Research: A Synthesis of the Literature: Chapter 6 Organizational Context and External Influences

<p>Implementation Site Characteristics</p>	<p>12. How does implementation vary depending on team vs. individual practitioners? (Site Characteristics X Drivers X Characteristics X Sustainability)</p> <p>13. Do you start small with a “team” in the organization to implement an evidence-based practice or program and look for them to “infect” the rest of the organization or do you change the organization as a whole to support the new way of work?</p> <p>14. Are there advantages of having “critical mass” of implementation sites? Advantages for consumers, workforce development, local control issues, sustainability, problem solving?</p>	<p>and the differences or similarities in implementation strategies?</p> <p>.....</p> <p>-Are we better off changing whole organization or better off starting with a single team that becomes the seed that influences/infects the whole organization?</p> <p>.....</p> <p>-Are there challenges to implementing in too many sites at once; need optimal number of sites to implement at one time given the capacity of the purveyor</p> <p>.....</p> <p>-There are teams in mental health, you have leadership with team leaders; team leaders to carry culture (of practice/program/org)</p> <p>-If you designed an agency to deliver a range of EBPs what would it look like? Team leaders specified in each practice instead of an organization with just one.</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
<p>Purveyor Role and Characteristics</p>	<p>15. Study models of technical assistance/purveyors</p> <p>16. What distinguishes “successful” purveyors from “unsuccessful”?</p>	<p>- Why not look at natural variation now? Where implementation was closely attended to but still had a variation in outcomes.</p> <p>-ACT has some small studies like this.</p> <p>-Look at implementation drivers (influence) as opposed to fidelity.</p> <p>-How are they doing technical assistance? Need national survey to understand lessons learned, where there was successful TA; successful purveyor vs. unsuccessful purveyor. Success would be defined by? Need measure of effective implementation, agreement about criteria for successful implementation across fields (core battery of measures). Need to use a common vocabulary and measure the same thing.</p> <p>.....</p> <p>-Relationship between purveyor and group: purveyors identify with which groups and which groups identify with the purveyor. The purveyor needs to identify with all groups. Need a communication link.</p>	<p>Implementation Research: A Synthesis of the Literature: Chapter 3 A Conceptual View of Implementation</p>

Topic	Research Questions/Issues to Consider	Discussion	Resources
Implementation Drivers	<p>17. Confirmation of drivers – Do we need them all? Staff evaluation related to EBP will be a tough sell.</p> <p>18. To what degree do facilitative administrative practices facilitate implementation- who takes responsibility? Purveyor? Intermediary? (regulations and funding)</p> <p>19. What role can self-evaluation by practitioners play with respect to implementation and fidelity as a precursor to external fidelity and external evaluation?</p> <p>20. How “much” of each of the Implementation Drivers do we need? Will the need for various Implementation Drivers vary by practice?</p> <p>21. Study the range of coaching strategies; are they effective and what is the impact on implementation? How does strong coaching affect the use of the other drivers?</p>	<p>-Has anyone confirmed this (re: implementation drivers framework)? The toughest one to market -- staff evaluation for implementation -- but one of the most important things that we don't do.</p> <p>-Early adopters of ebps are motivated to do it themselves; those being encouraged later may have more problems. Early vs. late adopters may need different implementation strategies.</p> <p>-Are there staff evaluation/self evaluation models? As a precursor to external evaluation?</p> <p>-Can be instructive for people but don't use it in lieu of other evaluation.</p> <p>-Which things in driver framework – do you need all the drivers and how “much” of each do you need? Can you scrap training all together and focus on coaching? Some of these programs are more complex and others seem simpler.</p>	<p>Implementation Research: A Synthesis of the Literature: Chapter 4 Core Implementation Components</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 5 Research on Core Implementation Components</p>

	<p>22. Research on how to make the Implementation Drivers effective and efficient? What are the evidence-based practices for Selection, Training, Coaching, etc?</p> <p>23. Study evidence-based practices that use an iterative approach to selecting, training, coaching staff (e.g. MST uses “Do-Loop” at family and practitioner levels).</p> <p>24. What is the impact of creating “space” (e.g. time, place, and resources) for the intervention or new way of work vs. making it difficult to fit in or add on to existing work load (Facilitative Administration and Systems Intervention)</p>	<p>-Things may get overlooked like coaches, monitoring, and consultants.</p> <p>-What are the variables - team/individual, etc. by practice and by context that may benefit from a study of interaction effects?</p> <p>.....</p> <p>-What coaching/supervision techniques are more effective than others?</p> <p>.....</p> <p>-Of the six drivers in the literature review, how many are still black boxes?</p> <p>-With recruitment and selection, is it how to select or who to select?</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
<p>Implementation Drivers X EBP Characteristics</p>	<p>25. Differences between early adopter and late adopters with respect to the role of Facilitative Administration and Systems Intervention. Early adopters may be more able to tackle administrative and systems barriers than late adopters. (Implementation Drivers X Destination Characteristics/Climate X Purveyor Role)</p> <p>26. Purveyor's role and strategies may need to be different for late adopters than early adopters. (Purveyor Role X Adopter Characteristics X Systems Factors)</p> <p>27. What are the characteristics of the intervention that would indicate how robust or intensive the drivers need to be? (E.g. complexity of the intervention, context, transactional nature of the intervention, number and size of units impacted).</p> <p>28. Does the extent of need for the utilization of implementation drivers vary based on whether a discrete practice is being implemented or a complete program?</p>	<p>-Interest in implementation in broader areas; developers' contact with early adopters. Much different process than contact with groups that are not early adopters; need different strategies depending on audience. While always watching for fidelity drift.</p> <p>-Need for translator between purveyor and site; that engineering role is critical.</p> <p>.....</p> <p>-Has anyone confirmed this (re: implementation drivers framework)? The toughest one to market – staff evaluation for implementation, but one of the most important things that we don't do.</p> <p>-Early adopters motivated to do it themselves, those being encouraged have more problems. Early vs. late adopters will need different implementation strategies.</p> <p>.....</p> <p>Also consider practices know to have iatrogenic effects; have negative treatment effects vs. no effect – hurt one arm of the study a little less than the other does not equal better effects.</p>	<p>Diffusion of Innovation Theory</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 4 Core Implementation Components</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 5 Research on Core Implementation Components</p>

	<p>29. Are there iatrogenic effects associated with certain implementation strategies? What are they? Are they immediate or longer-term?</p>	<p>Are there iatrogenic implementation techniques and procedures?</p> <p>We don't have enough information to say anything has iatrogenic effects, we only know what doesn't help.</p> <p>-Iatrogenic and positive effects – what are you looking for? What about sleeper effects? Could get grant info from SAMHSA, etc., and find out who has been funded for implementation studies. Get to know the contracts, organizations, and researchers of the current grants</p>	
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Topic	Research Questions	Discussion	Resources
	<p>30. Do you need to do high fidelity first before making modifications?</p> <p>31. Is there an attitudinal dimension to fidelity?</p> <p>32. Should we take a chance on deliberately varying fidelity? Are</p>	<p>-There are ethical questions with fidelity measures and outcomes. How do we do adherence/outcome manipulation especially when higher adherence has been demonstrated to result in better outcomes?</p>	<p>HSRI: Psychiatric Rehabilitation Fidelity Toolkit</p>

<p>Fidelity</p>	<p>there ethical issues? Could we vary ‘dosage’ as a way around ethical issues?</p> <p>33. What is the impact of building in fidelity as a standard part of the new practices or program? (Fidelity X Implementation Drivers X Outcome)</p> <p>34. What is the impact of not implementing practices and programs with fidelity? Do and/or will people get worse? What is the impact on the community or state’s willingness to attempt implementation of programs and practices in the future?</p>	<p>-Need alternative ways of knowing – multiple baseline designs, wait list.</p> <p>-Can provide different dosages of components without withholding treatment/component.</p> <p>-Put fidelity measures into practice. -Fidelity also has an attitudinal piece. Commitment is another dimension of fidelity.</p> <p>-Also the alliance and the helping relationship piece. EBP structural vs. helping relationship – that is harder to measure.</p> <p>..... -There is variability in results between fidelity and no fidelity where no fidelity had some positive impact. (Washington study)</p> <p>-Assume that lack of fidelity means worse results; examine the question of fidelity; lower fidelity with greater impact in certain cases.</p> <p>-Have different types of fidelity. </p> <p>-Fidelity scales should not be too long or include superstitious behaviors; and if they are too broad</p>	
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		<p>they will have too many loopholes. In re: core components- which of these things do you really have to have? We don't know the core components because EBPs are packages. Ideally we want to have experimental evidence about the components.</p> <p>-Component analysis is really hard (in education, juvenile justice); Practitioners may already be on "overload". Often they are picking and choosing components to use. We need to get it down so at least they are picking from among helpful components.</p> <p>.....</p> <p>-What is the impact of misusing an EBP? What is the impact of not implementing with fidelity? Do people get worse? Are their similarities to medicine and can we do effectiveness studies.</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
Broad Influence Factors	<p>35. Descriptive study of the range of contexts for implementation of EBPs.</p> <p>36. Relationship of implementation effectiveness to chaos in the environment?</p> <p>37. What impact does the ecology of the implementation environment have on the implementation process and the effectiveness of the implementation process?</p>	<p>-Need findings across all areas – no silos; measures and typology of contexts. What are the various potential implementation sites? What is the unit of intervention (class, state, region, etc.)? Does implementation look different depending on what you are doing (larger org vs. smaller org)?</p> <p>A descriptive study of range of contexts for implementing EBPs?</p> <p>-What about a team of practitioners vs. and individual practitioner? The difference between individual vs. team delivery mechanisms?</p> <p>-Need to talk about settings where there is more chaos than in others (inner-city vs. suburban). *****</p> <p>-Didn't see organizational culture in framework. Culture of organization as experienced by workers. Glisson example: "relational capital" in education; teachers relate to each other. The data for a low performing school indicate that they had low social capital and were not able to turn it around. Those that were able to turn things around had high relational capital by that time. Support in change process influences the implementation process. There are aspects of organization culture both healthy and unhealthy for any change process.</p> <p>-Key aspects: culture, climate, leadership and resources, structure. There is a level of familiarity that all will need to have about distinct aspects of organizations (ex. Defensive culture which resists any kind of change).</p>	<p>Center for the Study of Complex Systems</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 1 Introduction</p> <p>Gareth Morgan: Images of Organizations</p>

		<p>Workforce in organizations has turnover about every 2 years (create culture to keep turnover low). Getting a handle on different aspects of organizations will influence initial implementation, adoption, etc. We know less about what organizational aspects can do to help the process.</p> <p>- How much change in essential components of the EBP happens with well-implemented EBP? There probably is not the same variation in org/staff turnover, etc., after well-implemented EBPs are in place.</p> <p>-Impact of EBP can be mixed; variety of EBPs pulling people in different directions. For ex. Schools choose EBP without requirement that they can be integrated, etc. Teacher may be asked to do multiple programs with conflicting processes/procedures.</p> <p>-Climate for implementation – a particular process; have dimensions for specific practices. Need to have a climate for specific practices. In organizations, some have more facilitative climates than others; a climate for implementation may relate to outcomes for practices. The climate for implementation might describe the variations in outcomes</p> <p>-Toolkits can be mutually reinforcing and compatible (not all EBPs have competing ideologies). There are broader principles of EBPs that can be mutually reinforcing.</p> <p>-The changes that we ask people to do may not appear to be consistent. Change can pull people in very different directions and moderate effects.</p>	
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		<p>-General organizational climate AND climate for implementation; organizational climate and role clarity related to the addition of multiple EBPs; may be related to change in staff attitude related to implementation.</p> <p>-Some practices inherently fit well together where others do not; create a synergistic effect.</p> <p>-Need to be careful about language used re: climate, etc.</p> <p>.....</p> <p>-There is the question of ecological validity and understanding the ecology in which implementation is happening. Not allowed to do anything to people doing the implementation? Need to act on things that act on the implementers (practitioners). How can you transform the building without doing anything to the teachers and kids? We create hazards in schools and instead of changing schools we prepare teachers and kids to cope with the schools.</p> <p>What are the conditions? How will teachers do it? What if changing the context is a part of the intervention? Is there a fidelity measure of that? There are structural limits and other things that shape the implementation environment in many ways.</p> <p>-It also doesn't work well to just focus on the context. There is a need for studies that look at context, organizational factors, social capital and communication across organizations and communities.</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
Scale	<p>38. What are the benefits of starting small (e.g. a more simple practice or a pilot)?</p> <p>39. Would starting small help create a climate or culture that would better support change?</p> <p>40. Given capacity of purveyors are there an optimal number of sites, how fast can you implement based on technical resources, etc.</p>	<p>-Implementing in too many sites at once can be problematic; need optimal number of sites to implement at one time given the capacity of the purveyor.</p>	

Topic	Research Questions/Issues to Consider	Discussion	<u>Resources</u>
End-User Consumer Interaction Effects	<p>41. What are the consumer and provider concerns regarding the use of EBPs (e.g. culture, choice, range of services, creativity)? Are these concerns realistic?</p> <p>42. How does the level of involvement and intensity of the involvement of the 'end user' impact the development, effectiveness and acceptability of the new practice or program?</p>	<p>-Relationship between purveyor and group: purveyors identify with which groups and which groups identify with the purveyor. The purveyor needs to identify with all groups. Need a communication link.</p> <p>-There is a subset of interventions in CMH arena, more than in others, where changing the behavior of the consumer is a way to change the practice. Wraparound- family manuals that delineate what to expect from wraparound and what</p>	<p>Implementation Research: A Synthesis of the Literature: Chapter 6 Organizational Context and External Influences</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 2 Implementation in the Context of Community</p>

	<p>43. Study the role of demand side strategies in relation to implementation.</p> <p>44. What is the impact of informed consumers on implementation?</p> <p>45. What are effective processes that are appropriate to diverse cultures that will allow those communities to create research agendas?</p>	<p>not to expect. And this should not exclude the consumers.</p> <p>-Consumer driven; support change and drive practice</p> <p>-Model can be a supply chain model- add consumer demand and you may increase adoption and implementation.</p> <p>-Consumer satisfaction – what would happen if the consumer were knowledgeable about what they could/should expect.</p> <p>.....</p> <p>-Consumer needs to be added to the vertical/horizontal integration piece. Supply side of framework here now we need to add consumer demand side. Needs to be included in frameworks/models,</p> <p>-Re: consumer/supply side model: need much more emphasis on consumer involvement; adds new research questions, etc. Consumers are absent now but that can be changed because implementation has not been thought to involve consumer side. Consumers can have</p>	
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		<p>real impact to influence the environment.</p> <p>-The consumer is not a unidirectional construct depending on the EBP. What do we know about forces that shape adoption when consumers of “new” practices and programs is a diversified construct? For example a juvenile justice agency that is spending money on locking kids up and consumers are involved in JJ and want something else to happen. What drivers change when one consumer is state government? Need to be clear when we say “consumer”- consumer of services, those that buy and pay for services, etc.</p> <p>-Canadian mental health system – define consumer on level of risk; risk/benefit analysis; calculate the consumer power (there is a 2002 paper on this).</p> <p>-Ex. Sandler implementing civil court system program – the relevant outcomes for court system is different than for the families being intervened upon. Focus on outcomes for multiple consumers.</p>	
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		<p>-Line up what consumers want; idea of purchaser and proximity to recipient; create strategies where there is a difference in alignment.</p> <p>.....</p> <p>-Inherent in exploration should be the critical components, end-users and consumers. Active involvement of consumers who will be end-users. Purveyor needs to know who is coming to the table from the community (end-user inclusion). As a purveyor, you need to help ensure that the consumers are at the table.</p> <p>.....</p> <p>-End-users of practices need to also be at the table for the creation of a research agenda. We can start now but will need to know how these questions will be meaningful to that audience.</p> <p>.....</p> <p>-Need to bring end-users into the process of building an EBP itself. And does that make a difference in uptake?</p> <p>-Create demand side mechanisms to influence quality.</p> <p>-What would be the impact of having informed consumers? Need approaches to educating the</p>	
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		<p>consumer. Will knowing what to expect influence behavior of those providing services? Impact of culture/history of cultural group; research to support needs of consumer.</p> <p>.....</p> <p>-Consider cultural fit, social class fit, alignment perceived by the consumer they will be more likely to stay with the program. Not just selection and recruitment of those using intervention but also administration staff.</p>	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
Workforce Development	46. What key skills need to be incorporated into higher education that would positively impact implementation of evidence-based programs and practices?	<p>-What is the role of higher education? Key skills need to be thought about; think about leadership training and that attention should be paid to implementation issues.</p> <p>.....</p> <p>- Turnover occurs for many reasons: “Turn out” is not meeting criteria,</p>	<p>Annapolis Coalition</p> <p>Implementation Research: A Synthesis of the Literature: Chapter 4 Core Implementation Components</p> <p>Implementation Research: A Synthesis of the Literature: Chapter</p>

		<p>“turn on” and “move on” (“turn on” means moving to career opportunities associated with the ebp; “move on” refers to maintaining the same role (e.g. practitioner) but going to a new location for more \$, new experience, more benefits) “Burn out” may be the least of those in EBPs.</p> <p>-Agree and disagree. Want to maintain continuity; people that are feeling good and move on may not be the best choice for principal or parent, etc. Those may not be good reasons from org/school perspective. (Programs) can look effective one year and less effective the next with a change in staff and leadership.</p> <p>-Introduce consistency in staff- reduce negative effects.</p> <p>.....</p> <p>-A core instrument; general enough to use across practices but specific items for practices. Re: to staff selection/recruitment: The first box is often neglected. Need to know how to do it, predictors of who would do better in a supported employment program (attitudinal characteristics, etc.). Recruiting from agency – we have</p>	<p>5 Research on Core Implementation Components</p>
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		<p>replicated that it is not a good way to do it! Supervisor is more critical in decisions to create a team.</p> <p>-And the nature of an interview itself. Need to define criteria; unstructured interviews are the least valued method; personality characteristics, past history, etc.; define characteristics that fit best; validity data.</p> <p>-Depends on who is doing the interviewing.</p> <p>-Consider cultural fit, social class fit, alignment perceived by the consumer they will be more likely to stay with the program. Not just selection and recruitment of those using intervention but also administration staff.</p> <p>-Can use the selection process to change the culture of the organization. Use as a longer-term strategy to change the culture of the organization.</p> <p>-Selection and recruitment research needs a local context. (Need more research that is generalized less with</p>	
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		a focus on the local context.) EBP defines who can do the program and those who cannot; many see this as a potential for expanding the workforce.	
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Topic	Research Questions/Issues to Consider	Discussion	Resources
Intervention Research Issues	<p>47. What are the core ingredients of interventions? What are the strategies for empirically answering this question since many programs are not clear about their core interventions? What are the frameworks?</p> <p>48. What are the dimensions of effectiveness research that impact the transportability or likelihood of replication? How to do effectiveness research with implementation in mind? (E.g. www.re-aim.org)</p>	<p>-How do you identify core components of an intervention? There is little agreement on method and content – we don't observe principles, we observe content.</p> <p>-How to establish empirically and use expert judgment?</p> <p>-Purveyors have all different kinds of ways to identify core components – talk to them about how to identify.</p>	<p>Re-Aim.org</p> <p>SAMHSA Model Programs: NREPP</p> <p>Promising Practices Network</p>

Topic	Research Questions/Issues to Consider	Discussion	Resources
General	<p>49. What sequencing of interventions may work best (e.g. would implementing one evidence-based practice before another be beneficial because they could build on one another)?</p> <p>50. What strategies facilitate the growth of evidence-based programs and practices?</p>	<p>-Need sequencing and measures of implementation scale.</p> <p>-There is a continuum from a practice to a global complex program – need a scale. Maybe an organization will want to try on a few practices before taking on a full-blown program – like training wheels first.</p> <p>-What sequencing of interventions may work?</p> <p>-You can get away with a practice not influencing an entire organization but an entire program definitely will.</p> <p>-Some practices inherently fit well together where others do not; create a synergistic effect.</p>	

Implementation: A National Plan of Research

Comments from David A. Chambers, Ph.D.

Thursday, April 7, 2005
Funding Mechanisms at NIMH/NIH

Dissemination and Implementation Research Program (DISR)

The program announcement, Dissemination and Implementation Research in Mental Health (PA-02-131), will expire in July of 2005 (the announcement can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-02-131.html>). NIMH is currently working with other Institutes to expand the scope of the program announcement across NIH.

Research questions related to the implementation frameworks described during the meeting are of interest. Proposals linked to conceptual and theoretical frameworks add value to the development of a body of knowledge. Research questions/ proposals can and should test such conceptual frameworks, theories, etc. Research efforts can target smaller more specific variables and the interaction effects of those leading to successful implementation. For example, the framework for Implementation Drivers can be tested by looking at main effects of each component and their interaction effects (e.g. are they integrated and compensatory?). Proposing to measure proximal implementation outcomes is appropriate. However, ultimately research efforts will want to investigate the relationship of implementation outcomes to public health benefits that subsequently lead to improvement services and outcomes for consumers. Proposals need to clearly lay out the chain of events that will lead to increased public health and consumer outcomes, logically at first, then with data.

Funding Mechanisms:

R03: (\$50,000 a year) This mechanism is useful for addressing a small, innovative research question/study that can logically lead to bigger grants (R21). These studies may be at a particular phase of research; may be based on a strong framework but the framework currently has limited empirical support.

<http://grants.nih.gov/grants/funding/r03.htm>

It may be useful to examine opportunities in the context of the 'natural experiments' that are occurring in service settings and within and across service systems. These initiatives can provide opportunities to review and investigate implementation variables related to the practices and context.

R21 (R34 as well): (\$450,000 2-3 years) <http://grants.nih.gov/grants/funding/r21.htm>

R34 NIH Clinical Trial Planning Grant Program: (\$100,000 per year)

<http://grants.nih.gov/grants/funding/r34.htm>

R13: Conference mechanisms (<http://grants.nih.gov/grants/funding/r13/index.htm>); this is an underutilized mechanism. The grant can be used to build a community of practice, create research agendas, etc. Proposals undergo a peer/mail review process and can be utilized for multi-year conferences. That is, proposals address plans for multi-year conferences, define activities occurring between conferences, organize topics/subtopics for conferences (such as training issues, selection, etc.), and can develop important new research agendas.

With respect to utilizing the R13 mechanism, the first set of meetings could focus on the frameworks outlined in the monograph. Participants could be expanded to include a broader array of content interest. Subsequent meetings could be focused on a sub-set of issues outlined in the monograph in order to generate theory and practice-based research hypotheses and RO-1 applications.

It may be helpful to connect with the NIMH Outreach and Partnerships Program that has representatives in every state. The aim is to develop collaborative relationships for work with a broader scope in natural laboratories where initiatives such as systems of care, safe schools are already underway. NIMH will accept applications related to implementation research done in conjunction with these efforts. Such research can incorporate multiple levels (especially more measures at the organizational level) of measurement to assess the impacts of system, community, and practice variables simultaneously:

Encourage the development of a science of implementation by:

- Collecting and communicating evidence that implementation is important (the monograph will help make the case that implementation must be attended to)
- Networking at relevant conferences; raising implementation questions; and connecting the community of implementation researchers.
- Synthesizing critiques/studies/information that have been marginalized and broadly disseminating the material
- Advancing common definitions related to implementation to reduce confusion, build common frameworks and increase scientific communication.
- Clarifying assumptions related to frameworks.
- Involving consumers, primary caregivers, and end-users from the very beginning to make implementation research a joint effort that is increasingly better understood and fully supported

Implementation: A National Plan of Research

Comments from Steven Banks, Ph.D.

Friday, April 8, 2005

Complexity and Implementation Research

Implementation research is by its nature going to be complex. However, complexity does not preclude being able to study a phenomenon. Engineering is often faced with complex issues. In engineering they change one variable at a time and then look to see where affects show up. Then they engage in subsequent changes based on the findings from the first studies. The goal is to eventually figure out how the complex set of events are related in order to produce desired outcomes.

A fundamental question in constructing a research agenda is whether you are trying to find "optimal solutions" or "better ways" to proceed than the current situation. Optimal solutions require very intensive and expensive research. Conducting research to determine better ways to proceed is less complex and less expensive.

Methodology and Complexity

New approaches to randomized clinical trials have been developed by Susan Murphy that are more suited to multiple layers of decision-making over time yet preserves the statistical benefits of randomization. She details sequential multiple randomized trials as an approach to developing adaptive treatment

strategies. In general, the process involves making decisions and new random assignments of participants as results are analyzed. As "better approaches" are identified, the remaining participants are then

randomly re-assigned to the new range of "better approaches". This allows for a better understanding of which interventions do and do not work in real time. This type of design might be applicable to implementation research.

* Websites related to sequential multiple randomized trials and adaptive treatment strategies developed by Susan Murphy:
<http://www.stat.lsa.umich.edu/~samurphy/papers/ExperimentalEvidence.pdf>

<http://www.stat.lsa.umich.edu/~samurphy/papers/MOST.pdf>

<http://www.stat.lsa.umich.edu/~samurphy/nida/seminars.html>

In addition to randomized trials, implementation research may lend itself to intensive case study approaches. Implementation takes place at the provider/practitioner/client level in the context of many local and state variations. These variations are unplanned (and therefore, not experimental in nature) but are still worthy of study.

A methodological challenge related to randomized trials is that it may not be practical to accumulate a large "n" for a randomized trial when the unit of analysis is an entire organizational

effort. However, the number of subjects available for a given study can be increased if and when it makes sense to have practitioners, rather than the organization, as the unit of analysis.

It also may be reasonable to do a meta-analysis across several programs of research when one particular implementation component (e.g. training, coaching) is done in a similar way, there is a good measure of the component as an independent variable, and good measures of the dependent variable. A meta-analysis can help determine if the effect size would make further study worthwhile.

Implementation and Iatrogenic Effects

Efficacy and effectiveness research help define an evidence-based program or practice that “works”. However, as these interventions are more broadly implemented there are likely to be “side effects” that purveyors will need to address as they work with new implementation sites. Some of these side effects will relate to the context and response cost of choosing to implement the evidence-based program or practice. For example, the implementation at a new site may have no effect or even a positive effect on the clinician’s outcomes but if the implementation uses too much time of clinicians to install the new practice and thus reduces services overall, there may be a negative impact on the organization as whole.

Similarly, there may be overall iatrogenic effects on organizations and communities as a result of attempted but ‘failed’ or ‘abandoned’ implementation efforts. For example, if a purveyor abandons an organization in the midst of the implementation process and many of the “old ways” of operating have been eliminated but the “new ways” are not yet in place, this could have problematic consequences for consumers, practitioners, and the organization as a whole.

Priorities for Research

The following are broad research agendas that may help advance the science of implementation:

- Descriptive studies that help define the range and context of current implementation practices in the context of what is known about “best implementation practice”. This will give a better picture of the context in which research can be done and the range of natural variation available for study.
- An analysis of the relative costs of implementation components and strategies in terms of time, money, and effort. More costly components might be studied first to determine the extent to which they are or are not critical to implementation outcomes.
- Research agendas should be crafted that have the potential to make a significant difference in terms of both implementation outcomes and consumer benefits.
- Research agendas also need to demonstrate the importance of sound implementation so that others see both the research and the practice of implementation as worthy of funding, support, and quality. Demonstrating that effective implementation results in effective service delivery will help states and communities develop appropriate infrastructures.

Implementation of Evidence-Based Interventions: Key Research Issues
Thomas E. Backer, PhD

Human Interaction Research Institute

Prepared for the National Implementation Research Network Meeting
April 2005

“The simple answer is there is no simple answer.”

The Challenge of Evidence-Based Implementation There is a persistent belief that evidence-based interventions in fields like mental health and substance abuse will almost automatically improve outcomes, simply because of the science behind them. Yet the above cliché better describes the reality for those who implement these interventions. They know that evidence-based interventions don't improve outcomes unless they are implemented properly, so that they'll produce good outcomes in a new setting, and last over time.

While implementation has been studied at least since the 1970s (Backer, 2004), most research to date has been uncontrolled and often qualitative rather than quantitative. Results from this research make clear, however, that in all too many cases (and despite good science behind an intervention), implementation in new settings is done poorly, with predictably poor results (Backer, 2000).

In fact, this is the reality in other fields as well. For example, in business, “execution” has become shorthand for effective, rigorous implementation of good practices that are essential to business success. Business leaders are increasingly aware that strategy, planning and resources aren't enough, unless they are catalyzed into effectiveness by good execution.

Now “execution” where evidence-based service interventions are concerned is beginning to get serious attention, partly due to the increasing number of well-validated interventions to implement. Increasingly, new work is focused on “evidence-based implementation” - that is, on developing strategies for implementing interventions that are themselves the result of carefully controlled research (pioneering work includes Emshoff et al 2000, Mihalic & Irwin, 2003; Spoth et al, 2004).

Research Issues for Implementation Research Results from these pioneering studies can help to shape a comprehensive implementation research plan the National Implementation Research Network now is developing. Five issues needing attention within such a research initiative are:

1 – Documentation

How can implementers document implementation, both as part of implementation research and in their own operations?

One way to improve implementation, and build the body of evidence about it, is simply to increase the willingness and ability of field implementers to document what they do - how they select an innovation, plan for its implementation, go about it, and what happens as a result. Documentation

is essential not only as part of implementation research, but for routine practice, so implementers can identify where they might have gone wrong if they're not getting expected outcomes, and adjust their course accordingly (Backer, 2004).

Insufficient documentation of implementation is not a new problem - in the mid-1960s, a Human Interaction Research Institute study found that more than half of all research grantees of a particular division of the National Institute of Mental Health didn't even file a final report on their research (Backer, 1991)! Then, as now, there is a need for implementers to document what they do and what immediate outcomes they observe. Implementation research can help teach needed skills to implementers, get them in the habit of documenting, and demonstrate through research data that become available where the value of such documentation lies.

2 – Sustainability

How can evidence-based interventions be implemented so they'll last over time, and how can principles for promoting sustainability be incorporated into implementation research?

Even the most rigorous implementation can be considered a failure if the intervention does not last over time - assuming that it is still needed, and nothing better has come along. This also is a not a new issue: in the mid-1970s, another NIMH study conducted by the Human Interaction Research Institute (Glaser & Backer, 1977, 1980; Backer, 1979) looked at the long-term survival of the Fairweather “Lodge” program, a well-validated community treatment program for persons with mental illnesses. Results showed that a key factor for sustainability was early planning for the program's continued operation. Another factor was the ability of program implementers to make certain changes in the program as their community circumstances changed, without altering the basic content of the program. It was through this study that HIRI first became interested in the complex factors of program fidelity and adaptation, as they bear on program success over time.

Program sustainability recently has emerged as a major issue for funders and implementers alike (Cutler, 2002; David, 2002; Cornerstone Consulting Group, 2000), resulting in a growing body of qualitative research and principles for promoting sustainability. This knowledge base needs to be integrated into the implementation research paradigms now being developed, as it is in the current PROSPER study being conducted in Iowa and Pennsylvania by Richard Spoth and Mark Greenberg (Spoth & Greenberg, in press; Spoth et al, 2004). At mid-course in a five-year experimental design, 11 of 13 PROSPER experimental communities have been able to obtain funds to continue one part of the program after it was no longer grant-funded, according to unpublished research data. This is an important, though preliminary, finding, since a major factor in sustainability is the continued availability of resources.

3 – Communication

How can information about evidence-based interventions best be communicated to implementers, and how can good communication practice be part of implementation research designs?

User-friendly communication methods - both to convey basic information about an intervention and evidence about its effectiveness - are central to successful implementation, as has been

demonstrated in nearly 100 years of research (Backer, 1991; Backer, David & Soucy, 1995). Typical scientific writing is *not* user-friendly, for instance. Lengthy implementation manuals often are not written or formatted in ways that make them readily usable by potential adopter audiences. Implementers want information tailored both to their mind-set and to their time schedule, and even well-validated interventions are not as likely to get implemented successfully if the information about them is not presented in this way, whether in publications or training and technical assistance.

As a national implementation research design unfolds, principles for user-friendly communication that come out of the considerable knowledge base on this subject need to be incorporated, so that the knowledge products and learning events used as the “content” for implementation are formatted in ways that will motivate use by implementer audiences serving as the focus for the research.

4 – Resources

How can the financial and human resources needed for effective implementation be obtained, and how can attention to resource needs be included as part of implementation research designs?

Many implementation efforts pay inadequate attention to the need for financial and personnel resources to do the work of implementation, as has been shown repeatedly in research on this subject (Backer, 1991, 2000). Implementation research designs need to incorporate what has been learned from this body of knowledge, so that implementers can address resource acquisition as part of the overall implementation process (and especially as part of sustainability, as already mentioned).

In addition, when resources are limited, it may be necessary to adjust the implementation research design in certain ways. For instance, recent work has shown that very high-fidelity implementations of evidence-based interventions can be achieved when there are significant resources of both funding and technical assistance available to implementers through the researchers studying the implementation process (Emshoff et al, 2000; Fagan & Mihalic, 2003; Mihalic & Irwin, 2003). However, in the larger, uncontrolled environment, where resources are almost always much lower, adaptations are much more common (Ringwalt, et al, 2003). Then pro-active efforts to guide adaptation, by developers or those promoting local implementations, may be necessary for success.

Mixed in with these observations, of course, are values arguments. Some may say that it is better for an intervention not to be implemented if adaptations must be permitted. But in most cases the developers, researchers and systems-level implementers of evidence-based interventions don't have control over the forces promoting implementation, any more than they do over resources! Then the situation becomes one somewhat akin to arguments about giving teenagers sex education and condoms if a by-product is encouraging them to have sex! But the reality is that many teenagers will have sex, and the drives promoting that are not under society's control.

In that case, as with adaptations of evidence-based interventions, difficult decisions may have to be made about harm reduction. Protocols that help implementers deal more strategically with

adaptations - documenting them, confining them to what developers identify as “non-core” aspects of the intervention - may increase the overall chances for rigorous implementation. This is even more critical because so many questions remain unanswered about what constitutes “core components,” and about the exact impact of program fidelity and adaptation. Dusenbury et al (2003) summarize recent evidence on this subject, indicating that poor implementation is indeed likely to result in loss of intervention effectiveness, but that research has yet to establish precisely how adaptations affect program outcomes.

5 - Human Dynamics

How can implementation strategy incorporate sensitivity to the complex human dynamics involved in implementing an evidence-based intervention, and how can these factors be included in implementation research designs?

No matter how good the intervention or the science behind it, no matter how good the implementation strategy, efforts to promote change in any complex system are very likely to fail unless the change effort has the support and active involvement of the people who live in that system (Backer, 1991; Backer, David & Soucy, 1995). In particular, those who’ll be implementing the intervention need to feel some sense of *ownership* for it, and some degree of active *participation* in developing the implementation strategy.

One force pressing for adaptation of evidence-based interventions is that people and organizations want to feel “it’s mine.” There is good research evidence (Backer, David & Soucy, 1995) that felt ownership increases the likelihood of successful implementation. Some intervention developers, such as Lynn McDonald and the Families and Schools Together (FAST) program, include as part of implementation encouragement for such felt ownership - by allowing adaptations of certain components identified as “not core” by the developer. Implementation research designs can include attention to these human factors, and to the impact of such tactics on outcomes - including “side effects” such as possible negative impact on fidelity of implementation in a new setting.

Methodological Matters There are also a number of more specific methodological matters that need to be addressed in designing a national research agenda on implementation of evidence-based interventions, such as:

1 - Integrating outside environmental factors Many forces in the outside environment affect implementation, and some of them can be meaningfully integrated into the implementation research design. For instance, Project ALERT, an evidence-based substance abuse prevention intervention, is now being conformed to state health education standards in the states where it is being implemented. This is likely to have a major impact on resources and administrative regulations that may shape implementation in the future. An implementation research design needs to include an “environmental scan” to identify such outside factors, and a decision-process about whether and how to include them in the research design.

2 - Obtaining input from in-process research on evidence-based implementation

The PROSPER project (Spoth & Greenberg, in press; Spoth et al, 2004), the work just mentioned with Project ALERT, and other in-process studies are not yet (at least fully) in the published literature. These projects are wrestling with many of the key research issues that a national implementation research design will need to address. Preliminary findings, strategies being pursued, and challenges observed from this in-process work needs to be incorporated in the national design, based on dialogue with these researchers.

3 - Dealing with the challenge of core components Until controlled research has been done to identify core components of evidence-based interventions and determine their relative contribution to overall effectiveness, there is a practical reality of how to estimate which are the most important components of evidence-based interventions in many fields. What reasonable process can be derived to help do this with various interventions?

* * *

These research issues and methodological matters all are part of the complex answer to the question: “how can evidence-based interventions be implemented successfully?” Training, coaching and performance assessments, combined with consumer, community and policymaker/funder involvement in the implementation process, are the general building blocks of success, as the National Implementation Research Network’s review makes clear.

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