Notes from TIDIRH All Faculty Q&A Session

10.9.18

Implementation strategies:

1) One question I have for the faculty and would like their perspective on is where do you draw the line between an implementation strategy/intervention and an evidence-based intervention? For example, is a clinical decision support (CDS) tool to improve delivery of palliative care the evidence-based intervention, and therefore the thing you are trying to implement, or is palliative care the intervention being implemented, and CDS becomes then becomes the strategy?

    a. Bryon Powell's response
        i. This paper could be helpful. Overall this is a gray area with no one right answer. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5219812/
        ii. Sometimes you will have to make a judgement call and go with it. You will make the case based off what is your strategy or what is your clinical intervention and just make the argument clear in a grant application or paper
        iii. Other cases, there is a clear evidence-based intervention based on what the thing is that you are trying to implement and how you are trying to do that.
        iv. However, often, it is not cut and dry and you could come up with different answers.
    b. Wynne Norton
        i. You need to ask, "What is your research question? What are you trying to answer? What is your hypothesis?" Also ask, "What is the evidence base?"
        ii. For this specific example, encourage people to look at evidence based for clinical decision support system and what does CBS entail. If there isn't an evidence base, then focus on hybrid design but if there is an evidence base then it will focus on how best to implement it.
        iii. Which leads into another issue of; how much evidence is enough? If we know that something works then the next step would be to implement it.
    c. Ross Brownson
        i. Look towards standards of care. Those are going to be evidence-based interventions. Any established evidence-based practice with patients or public health, usually will be the evidence-based intervention. Generally speaking or a good rule of thumb is that if you are working in clinical care at the patient level, like medicine or nursing, that is going to be evidence-based intervention. If you are working at system or organizational level, will be implementation strategy.
    d. Augie Diana via WebEx chat:
        i. I think in terms of 3 types of science. Intervention science includes studies of whether an intervention works. Implementation science tests the how,

where, when, etc. - what are the characteristics of the implementers? Where/when/how is it being delivered and are those features making a difference (e.g., physical activity intervention in a gym or a park? interventions delivered by family members or professional care providers?). Dissemination science focuses on how to move an intervention with demonstrated effectiveness out to a wider audience/population and testing the process of moving it out to those communities.

e. Bryan Weiner via WebEx chat:
    i. I see CDS as an implementation strategy in that it aims to support the adoption, implementation, or sustainment of an evidence-based practice (which in this case is palliative care). "Interventions" that focus on changing provider behavior (or the context in which they work) are probably implementation strategies. "Interventions that focus on changing health outcomes, health behavior, or health-related environments are probably evidence-based practices.
f. Christian Helfrich via WebEx chat:
    i. RE what's the thing (to use Geoff Curran's phrase) vs. the implementation strategy, I find this paper by Fisher & colleagues helpful just in terms of the different types of evidence-based practices that we implement: biomedical innovations, changes in care delivery, and new ways of engaging patients in their own care: https://jamanetwork.com/journals/jama/fullarticle/2484347. Like Byron said, it's often not cut-and-dry.

2) One thing I am still struggling with is identifying "evidence-based implementation strategies." In one of the readings they gave the example that regularly providing feedback regarding outcomes has been found to be effective in helping people to sustain an intervention. What other generalizable knowledge do we have within implementation science that can help us identify strategies that are likely to work?
    a. Augie Diana
        i. I believe the answer is no. Good developers do provide guidance on how to make interventions work. Usually require showing how they demonstrate effectiveness. This could deal with: recruitment issues, where it has to be delivered or that has been what is tested. If you stray outside those then it cannot be guaranteed.
    b. Denise Pintello
        i. NIMH D&I research portfolio, there are a couple models we are testing: “Trainer of Trainers” model. Also, “Implementation Teams” to start testing teams of folks in services agencies to address barriers.
    c. Lori Ducharme
        i. Many of our studies, the purpose is to test effectiveness of implementation strategies. It is okay if you cannot find the strategy list because you are going to help us build that list.

d. Byron Powell via WebEx chat:
    i. Send everyone to Cochrane EPOC, Health Systems Evidence. They are good resources for identifying evidence for strategies.
    ii. http://epoc.cochrane.org, https://www.healthsystemsevidence.org and https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-50
e. Lisa Saldana via WebEx chat:
    i. I think the implementation strategies that are selected should be tailored to what you are trying to implement. The strategies are highly variable. However, what is important is making sure that you have specified what you think the implementation strategy aims to modify/monitor/stabilize/etc.
f. Kate Stoney via WebEx chat:
    i. Many studies are finding that multi-level implementation strategies may be more effective than single level strategies

Design and Methods:

3) Guidance about conducting D&I research for pilot (or smaller) studies. New D&I investigators are challenged with having smaller studies with a limited number of sites. Other than using mixed methods, would appreciate any other thoughts or suggestions regarding approaches to obtaining good quality D&I data with a small-scale study.
    a. Ross Brownson
        i. Always think what the big study is. If you are doing a smaller study, it is really thinking about what I have to learn. In a small study, you are testing out in small scale and building the stepping stones to big study.
    b. Christian Helfrich
        i. Even with small studies, if you can spell out the mechanisms of the implementation strategy is having an effect, then you can measure those with interviews, surveys, etc.
    c. Lauren Brookman-Frazee
        i. This is where mixed methods really come in to help interviews, focus groups, etc. Qualitative and quantitative data are important.
    d. Lisa Saldana via WebEx chat:
        i. There are multiple approaches to address this challenge, though none are perfect. A lot can be gained from randomizing to "time" versus strategy. I encourage you to look up ongoing work from Hendricks Brown and colleagues. https://www.annualreviews.org/doi/abs/10.1146/annurev-publhealth-031816-044215
4) Concerning power for Implementation trials - when to focus on a primary endpoint that is quantitative, when NOT to, and how to know which to choose - examples would be great.
    a. David Chambers via WebEx chat:
        i. So much depends on what you expect to be the effect of one implementation strategy versus another, and if you thus have sufficient

power to detect a difference between groups. I think this is a great question that speaks to the need for relying on biostats expertise within your research team.

b. Wynne Norton via WebEx chat:
    i. Re: power analysis: Can refer to pilot studies as estimate of potential effect size for strategies (either comparative effectiveness of strategies or strategies vs. control or implementation as usual). Review HLM literature and longitudinal data analytic approaches. Can also review published protocols in IS on strategies for some details on sample size estimation, effect size, etc.

Fidelity/Adaptation:

5) How would you ideally approach fidelity versus adaptation measures taking into account the main five dimensions (adherence, dose, quality of delivery, participant responsiveness, program differentiation). What worked better/worse in your own research experience? What are the advantages and disadvantages of each dimension, which you consider more relevant? (particularly for low income countries).
    a. Rachel Sturke
        i. It is a balance. Not sure if in low income countries if there is any difference in adaptation. We have to look at adaptation more carefully.
    b. Gila Neta via WebEx chat:
        i. Re: fidelity vs adaptation and which dimension to focus on: I think it depends on the problem you are trying to solve.
    c. Lisa Saldana via WebEx chat:
        i. There is always a tension between fidelity and adaptation. The key is holding true to the mechanisms of action to the intervention. That is what should be monitored with fidelity and the context around that can be highly variable.
    d. Belinda Sims via WebEx chat:
        i. For the fidelity/adaptation measures question, I would add that it is important/useful to measure unplanned adaptation as a dimension of fidelity. Programs being implemented as originally planned or as adapted, should capture adaptations that take place during the implementation process.
    e. Lisa Saldana via WebEx chat:
        i. One of the biggest challenges to measuring fidelity is that often it is not well specified what the "magic sauce" is i.e., mechanisms of action. This must be clear in order to know what outcomes can be expected. When adapting it is important to ensure that the points of adaptation are equally well-specified to know what exactly it is that either enhances or detracts from (or maintains) the outcomes from the original intervention.
6) Does anybody have experience applying fidelity/adaptation measures using mhealth technology? Examples on how this was one would be helpful.

a. David Chambers
    i. Encourage people to look at some of the work that Gary Bennet from Duke has done. It is not just the mhealth technology we are using in our studies but also how technologies are changing in industry.
b. Bryan Weiner via WebEx chat:
    i. Worth remembering: fidelity/adaptation is a concept relevant to the EBP and the strategy.
    ii. Here's a question likely to stimulate debate: is mHealth an intervention or a strategy? (I would argue it's an intervention as it aims to change health behavior/ outcomes. An interesting IS question then becomes how to integrate mhealth into routine care/clinical settings.)
c. Wynne Norton via WebEx chat:
    i. I agree with Bryan above--conceptualizing mHealth as intervention instead of a strategy, since it focuses mostly on pt/individual outcomes
d. Augie Diana
    i. Suggest going to "NIH Reporter Tool" and look up small business grant programs as many of them have a m health component
e. Byron Powell via WebEx chat:
    i. Here is some nice work on implementation outcomes (reconceptualizing them) for mHealth: https://preprints.jmir.org/preprint/11752
f. Andy Tan via WebEx chat:
    i. mHealth as intervention vs. strategy question: the EBP is the behavioral change intervention or content embedded within (e.g., motivational interviewing, behavioral economics "nudging", and self-determination theory) vs. mHealth as the delivery or dissemination channel?
    ii. Bryan Weiner to Andy Tan: Andy, your question is a good one. I'm not an mHealth expert. I guess it depends on whether you consider the technology a core component (active ingredient) of the intervention or if you consider it an adaptable feature (inactive ingredient) of the intervention, that is, just another delivery mode. Regardless, I can't see it as an implementation strategy.
g. Note from Dara: This mhealth question is a good one. Please note that we have an opportunity for those of you who work in this space to connect at the in-person meeting so you can continue this discussion.

Frameworks/Models:

7) What are the general D & I frameworks that have been more tested/work better in low income countries (and why)
    a. Ross Brownson
        i. WHO has some broad scale frameworks
    b. Bryan Weiner via WebEx chat:
        i. The CFIR has been used to study implementation and scale-up in LMICs. We at UW found 20 or so studies that did so. The CFIR works reasonably well, but it needs adaptation to fit the LMIC context. RE-AIM is also used.

c. Christian Helfrich via WebEx chat:
    i. Implementation research: new imperatives and opportunities in global health
    Prof Sally Theobald, PhD
    Neal Brandes, MHS
    Margaret Gyapong, PhD
    Sameh El-Saharty, MD
    Prof Enola Proctor, PhD
    Theresa Diaz, MD
    et al.
    Show all authors
    Published: October 09, 2018
    DOI: https://doi.org/10.1016/S0140-6736(18)32205-0

8) Specific examples of how to apply the DSF (Dynamic Sustainability Framework) model to real life implementation interventions - especially if there are examples concerning large systems.
    a. David Chambers
        i. Unfortunately, we do not yet have a good example of how a study has fully applied the DSF within health systems. There are a few ongoing studies that mention the framework as background for their thoughts about adaptation of interventions over time, but not fully integrated in terms of optimal measures. That said, it would be a great opportunity to build upon, particularly in thinking through what existing measures within healthcare systems might suggest how the healthcare settings are changing, and how specific interventions that are being delivered are changing as well over time. If people are interested in taking this on, it could be a nice contribution to our thinking about tracking long-term sustainability.
    b. Ilana Streinger via WebEx chat:
        i. I found only one protocol using DSF - "A modified theoretical framework to assess implementation fidelity of adaptive public health interventions" Perez et al. Implementation Science

General Questions

9) Becoming “expert” in implementation itself feels like the heavier lift (compared to general research methods issues) given the breadth of where the evidence lies. I wonder if any of the faculty would care to share their own thoughts on this (suggestions for our professional development, what their own path was).
    a. Ross Brownson
        i. These fit together closely. Depends a lot on what you are trying to do and the focus of your study. Question 10 outlines it well. Expertise will depend on pilot study vs large study.
        ii. For example, with a younger field, you can set up training in your grant.

b. Augie Diana
    i. A challenge at NIH is to get good reviews on these. Make sure to apply to D&I specific funding opportunities. If the review goes well, then the program staff can have stronger case that we need more of these kinds of research.
    ii. Make a strong case that what you are doing is producing more evidence or building on evidence.

10) Building a compelling study team for successful completing D&I projects – what are the key expertise that would be important to assemble within the team? E.g., depending on the study aims, a D&I expert, qualitative and mixed-methods researcher, health services researcher, CBPR expert, subject matter expert on the health issue?
    a. Dara Blachman-Demner
        i. Planning on having a session at the in-person meeting; related to if you are thinking about applying to NIH and hearing from program staff about their experience and recommendations.

Additional questions:

1. Cheryl Vamos via WebEx chat:
    a. With regards to "is there enough evidence" to support an intervention: Are "provider guidelines" or "provider guidance statements/reports" in general thought to be evidence-based, and then a research study could focus on potential intervention strategies to translate the guidelines into daily/routine clinical practice? For instance, there are prenatal oral health guidelines co-endorsed by ACOG/ADA, which identify that providers should assess, advise and refer all pregnant women on oral health issues given the prevalence and importance of poor oral health and its association with potential oral-systemic impacts (e.g., association with low birth weight; increase risks for infant to develop early childhood caries, etc.). It is also such a critical time in the life course to intervene for general oral health promotion, etc. However, in a proposal is it needed to actual support that assessment, advisement, referrals have "shown" to be effective, or can the guidance statement be the evidence?
    b. David Chambers
        i. At the beginning of the program announcements at NIH, we struggled with this because there are a range of types of guidelines with varying levels of "evidence" behind them I would encourage people to try to give a quick summary of why you are arguing this specific guideline has evidence to support implementation.
    c. Barbara Jones via WebEx chat:
        i. Wonderful response, thank you! So... what if there is actually NOT adequate evidence behind some components of an "evidence-based" guideline? Would this be a good example of when to use a hybrid 2?
    d. David Chambers

        i. If there is a chance to extend the evidence base, you can use multiple contributions in the same study. If you find that it is unclear and there is a chance to design your study to fill in that gap, that would be awesome.
    e. Lisa Saldana via WebEx chat:
        i. If indeed your goal is to evaluate the effectiveness of the guidelines (along with the implementation) then yes, that seems like a great idea.
2. Is there going to be any training around de-implementation?
    a. Dara Blachman-Demner
        i. De-implementation is a topic that is getting more interest in the field and in the applications, we see. Number of participants are interested in de-implementation, there will be a lecture about this topic at the in-person training.
    b. Christian Helfrich via WebEx chat:
        i. Just a plug: we'll have a de-implementation workshop at the D&I conference too.
3. James via WebEx chat:
    a. What are your recommendations to obtain independent D&I funding for an investigator without prior independent funding when a NIH K award or VA Career Development Award are not options?
    b. Lisa Saldana via WebEx chat:
        i. That really depends-- but see if there is a way to join an existing team to get some IS publications under your belt. There are, of course, smaller mechanisms than R01, but really when I sat on DIRH review panel there were plenty of folks who were new to the IS field who proposed excellent studies. I think that the common recommendation is to make sure there is an IS expert on the team for a decent amount of time as you build your IS portfolio.