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Challenges and innovations in enhancing adherence ☆

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Abstract

Adherence is a complex phenomenon involving interactions among the individual, the environment and the community. In an adherence workshop, a small group of investigators discussed their experiences with challenges and innovations regarding adherence gleaned from clinical research. This article summarizes the information and outcomes of that meeting. Guided by theoretical frameworks for understanding and promoting adherence, challenges in the areas of measurement, community-based research, and interventions were explored and innovations for meeting these challenges suggested. The article concludes with recommendations for enhancing the adherence agenda: (1) adherence research must have a well-defined conceptual and theoretical basis; (2) individual perceptions and social context of behavior must be incorporated; (3) research must be undertaken as a collaborative process involving participants and the community. Looking ahead, it is clear that if we hope to develop a new and integrated model of adherence, we must continue to advance theory through theory testing, with particular attention given to mediators and diverse samples. Moreover, an interdisciplinary agenda is necessary to

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set the stage for bringing together researchers from various disciplines and backgrounds with both participants and community representatives.

Keywords: Adherence; Measurement; Clinical trials; Intervention

1. Introduction

In May 1998, investigators convened to discuss the challenges of adherence in clinical research with older adults. This conference focused on adherence within dietary, pharmacological and physical activity interventions in older adults [1]. At a second follow-up adherence workshop, a smaller group of experts convened to share their experiences with challenges and innovations regarding adherence gleaned from clinical research (see Author's Note for list of participants). The workshop was organized in a small, think-tank format bringing together researchers currently working with various adherence strategies to answer the call put forward in the original conference to identify innovative and tangible approaches for promoting adherence. This article summarizes the information shared at the meeting and begins with an emphasis on theoretical frameworks for understanding and promoting adherence. Guided by theoretical insight, challenges are revealed and innovations are suggested in the areas of measurement, community-based research, and clinical trials. These proceedings conclude with recommendations for enhancing the adherence agenda.

1.1. Elements of adherence

Inconsistent meanings and applications of the term "adherence" continue in spite of the clinical accounts and extensive research directed toward understanding this concept. Adherence refers to the level of participation achieved in a behavioral regimen once an individual has agreed to the regimen. Inherent in this definition is the active and voluntary role that the participant plays in an on-going, dynamic process. Critical to an examination of adherence is the understanding that adherence involves a motivational component [2]. This designation should guide the integration of theoretical constructs into practical guidelines that promote on-going participation in behavioral plans of action and to the development of theoretical frameworks necessary to advance our understanding of behavior change and its maintenance. Moreover, this motivational aspect of adherence is fundamental to theories drawn on to examine and predict behavior and promote behavior change [3].

2. Models and theories of adherence

Much of the adherence literature focuses on the identification of determinants that influence participation in behavior. Although these correlational relationships are important to the identification of common factors and themes, reproducible associations do not imply causation. Therefore, our ability to predict and change behavior is limited. Organizational and categorical

frameworks are often employed to catalog a list of behavioral determinants that provide a review of progress in the area of health promotion and help to identify the correlates to target for intervention [4,5]. Although guiding our development of behavior change interventions, much of this work is atheoretical.

Theories and models discussed in adherence literature include the Health Belief Model [6], the Theories of Reasoned Action and subsequently, Planned Behavior [7], the Transtheoretical Model [8] and Social Cognitive Theory [9,10]. Rather than providing a comprehensive review of these theoretical frameworks (see Refs. [10,11] for recent reviews), this section will present challenges met by those attempting to guide their examination of adherence with theoretical insight.

2.1. Construct isolation

Many clinical interventions to enhance adherence are not grounded within theory. Researchers often adopt a "cafeteria-style" intervention design in which constructs are selected from a range of theories and models and then "mixed" together [10]. Although moderately successful in enhancing adherence to a particular health behavior, this approach is limited. Examining constructs out of the context of a full model reduces the validity and utility of the construct as different theories are often based on contrasting assumptions. Thus, the construct loses its significance. For example, researchers utilizing the Transtheoretical Model (TTM) to examine exercise adherence [12] have included self-efficacy in intervention studies. However, the TTM assumes behavior changes in a stage-like manner, while self-efficacy assumes behavior is continuous. These assumptions are in direct opposition, as it would be inappropriate to explain stage-like behavior with a continuous variable, thereby limiting our understanding of behavior change by precluding the examination of mediating mechanisms responsible for change.

Thus, studies of single theory clinical trials would allow for unambiguous examination of full theoretical models and their utility for identifying the factors that predict sustained behavior change. Theoretical models that fail to adequately explain adherence could then be modified or discarded in favor of new models. Moreover, as Maddux, Brawley, and Boykin [13] argue, many social cognitive models have similarities and much construct overlap. In this situation, researchers could "incorporate the major features of the relevant models into a single model and then attempt to determine the relative importance of the features of the new inclusive model" (p. 191; [13]).

2.2. Underlying mechanisms

Adherence studies often rely on cross-sectional designs resulting in correlational associations or simple 'snapshots' of the relationships that do not capture the dynamic nature of adherence. Although researchers agree that human behavior is continuous and dynamic, changes in theoretical mediators are seldom included in analyses. Theories used to examine adherence must incorporate the dynamic and reciprocal nature of behavior over time. For example, an intervention aimed at increasing self-efficacy (mediator) for adhering to a medication regimen may increase self-efficacy, which may increase medication adherence, which may positively influence affect, and so on. Furthermore, these changes over time are most likely not linear, but curvilinear or even quadratic. Optimally, theory-based interventions should include multiple assessment time points and change variables in structural equation modeling. Taking this point further, some researchers argue for a

paradigm shift in the application of theories that are based entirely on changes over time (i.e., dynamical systems) [14,15].

Whereas mediators are mechanisms that underlie the relationship, moderators influence the strength or direction of the relationship and are often the target of adherence intervention strategies. Although identifying moderators of theoretical relationships offers important information, this approach limits the ability to identify determinants of the mechanisms responsible for behavior change. Furthermore, the studies that attempt to investigate mediating mechanisms typically do so in a post hoc fashion. That is, single point assessments of potential mechanisms are often entered into statistical analyses after the fact to 'test' for mediation. Consistent with recommendations by Baron and Kenny [16], statistical tests for mediation should demonstrate that the treatment is related to the mediator, variation in the mediator is related to variation in the outcome, and ultimately, when controlling for these relationships, the treatment is no longer related to the outcome of interest.

The optimal test of mediation involves an experimental manipulation of the mediator. To determine that change in the mediator causes change in the outcome, experimental manipulation of the mediator should be a primary goal of the intervention [17]. Thus, tests of mediation are identified as a priori study objectives and included in study design and assessment protocols. Theory-based mediators are integrated into the study assessment timeline at multiple time points, allowing for the assessment of change over time in not only the outcome of interest but the mediating variables as well. For example, an adherence study among older adults with diabetes, based on the Theory of Planned Behavior, may try to manipulate the participants' attitudes (mediator) about glucose monitoring. If the relationship between the study intervention and intention to practice this component of the diabetes regimen is negated when controlling for change in attitude over the course of the intervention, positive attitudes should be identified for future interventions aimed at promoting adherence to this health regimen.

2.3. Environment and cultural issues: missing from our models?

Researchers recognize and appreciate the significant influence of culture and the social environment. Translating this appreciation, however, is a challenge. Evidence supports the fact that social and cultural factors influence virtually all aspects of human behavior, including adherence to health regimens. Achieving cultural competence in study design involving diverse populations is complex and poorly understood. At the heart of cultural competence is the recognition that people vary in the ways they communicate, behave, interpret information, and problem-solve [18]. Cultural beliefs have an impact on health beliefs and help-seeking behaviors, the manners in which individuals interact with health care professionals, and health care practices and outcomes including adherence. For example, some cultures view illness as the result of an imbalance in the forces of nature within a person such as the balance of hot and cold, wet and dry; illness may be viewed by some as a punishment for a sin, and by others as an intentional illness caused by a hex or curse. Although many theories specifically account for some social environmental factors (e.g., subjective norms in the Theory of Planned Behavior), these factors are typically reduced to simple questionnaires. Workshop participants cautioned that such an approach neglects the rich information and vast influence provided by the social and cultural environment and that greater attention to social and cultural influences is needed within theoretical models of adherence.

3. Measures

3.1. Challenges in adherence

The major challenge of measuring adherence is the lack of "gold standards." Recent assessments of methodology demonstrate that traditional methods for measuring medical adherence are unreliable. Patient interviews, questionnaires, surveys, and diaries provide inconsistent data and when using these methods, patients tend to overestimate adherence levels [19]. Self-report measures are subject to recall bias. For example, women frequently overestimate their adherence to mammography guidelines and usually recall their last mammography as more recent than it actually was. Similarly, patients' adherence improves in the days leading to a medical examination ('white-coat compliance') [20]. As a result of these biases, researchers often use biologic and chemical markers to estimate adherence. However, these markers are also open to bias and misinterpretations.

In some cases, adherence is measured without the explicit knowledge of the participant and this information may be utilized to provide patient feedback. Thus, the outcome measure is incorporated into the intervention. Participants in a physical activity intervention, for example, are frequently given pedometers to wear in order to assess their adherence to the intervention. However, some participants may use the pedometer to judge their own activity levels (e.g., "Have I exercised enough today? Because my pedometer reading is lower than it was yesterday, I probably haven't.") This is a methodological challenge because the adherence measure has now become part of the intervention.

Treatment regimens frequently involve adherence to different components of the intervention. Continuing with our physical activity example, adherence may include the number of steps recorded via pedometer readings. However, it may also include the frequency, duration and intensity of exercise; the number of intervention sessions attended; and the biological changes caused by changes in activity. Although study designs and economics play an important role in the selection of adherence measurement methods, composite measurement strategies that incorporate multiple levels and types of measures are needed to assess adherence objectively. This does, however, pose a unique challenge to the interpretation of primary outcomes and therefore, a carefully planned battery of adherence measures is well-advised.

3.2. Innovations in adherence

Measurement of adherence will continue to remain an imposing challenge, until more patient-relevant and cost-effective approaches toward this issue are developed. To make sure that the most patient-relevant measures are being incorporated in studies, researchers need to partner with health care professionals such as pharmacists, nurses, and physicians who interact with patients on a daily basis. This enables targeting the patient health behaviors that are at highest risk of non-adherence, as well as developing measures that will facilitate the most effective measurement of patient behavior at least resource expenditure.

There is expert agreement that adherent behavior needs to be measured as a continuous variable, rather than categorizing it as adherent or non-adherent behavior, to ensure that all variations in treatment behavior are adequately captured. To facilitate a matched comparison with patient outcomes, researchers need to use measures other than the most commonly utilized dichotomous outcomes (such as deaths or adverse events). Additionally, researchers need to explore utilization of several outcome

measures, and several measures of adherence to fully characterize the relationship among these behaviors.

Ultimately, researchers should not lose sight of novel creative measurement techniques that can greatly assist in accurate and efficient measurement of adherence. The availability of technology-driven tools has proven to be a real panacea for researchers trying to deal with biases that result out of self-reporting and patient "dumping." The use of electronic medication monitors that record and provide feedback to patients on their adherent behavior, as well as utilization of palm-pilots to record and remind patients on their recommended therapeutic regimens are the first, but definitive steps towards overcoming the challenges posed in measurement of adherent behavior.

4. Community

4.1. Challenges in adherence

It is vital that researchers examining adherence are conscious of the differences between the objective environment and the environment as perceived by the participant. Although randomized controlled trials conducted on university campuses or in medical schools offer high levels of control, the manner in which the participants perceive that environment may have profound effects on adherence. Moreover, one's perceived environment may interact with the importance of the outcome. For example, in studies examining adherence to physical activity (e.g., for individuals suffering from obesity), the perceived environment (e.g., fitness setting) may interact with the importance of the outcome (e.g., physical appearance) resulting in a perceived aversive environment and low adherence. In addition, although a theory may explain significant variation in adherence in one population, it may not perform well with other groups. All of this highlights the importance of conducting community-based research.

Community-based research emphasizes external validity and generalizability to the population as a whole. It involves a complexity of relationships: the relationship of the research to the community, of the community to the institution, and of the institution to the community. Community research requires a good working relationship and reciprocity between the university and the community and establishment of agendas that meet the needs of both groups. Advisory or other boards comprised partly of community leaders and members should be involved from the earliest planning stage of the research project. University researchers should also be willing to serve on advisory boards for the community in a reciprocal manner.

Community-based researchers encounter a number of challenges that require ingenuity and resourcefulness. It may be expensive. Diversity in research, recruiting samples that include many ethnic/minority and socioeconomic groups, requires resources and necessitates being in tune with all of these groups within a community. Establishing and working with advisory panels and boards, an essential element in community-based research, requires a great deal of time and resources and may extend the research project timeline.

4.2. Innovations in adherence

A number of suggestions were put forward by the group as possible ways to enhance adherence and recruitment in community-based research, especially as they pertain to ethnic minorities and individuals of low socioeconomic status. First, researchers should strive to develop research projects that are salient

to the community and involve the community from the initial phases of a project. Participant belief systems and possible stigmas attached to the illness or condition under investigation should be considered in the planning stages of a research project. A mini-retreat of university and community leaders and lay people should be held prior to beginning a joint research project to promote discussion, build relationships and formulate a research agenda. Researchers should explore ways of creating visibility in the community without a predetermined agenda and establishing university/community relationships prior to the initiation of a joint research project.

How can an institution work toward establishing a community/institutional partnership? A first step is to gain visibility within the community to enable researchers to form relationships and establish trust prior to having a research agenda. This can be done by (1) having institutional researchers serve on community advisory boards and offer grant writing assistance to community groups and organizations and (2) including a line item in current grants to provide funds for going into the community and establishing relationships.

Secondly, researchers should take advantage of established channels of communication between the institution and the community, such as local radio talk shows. These avenues could be used to increase community awareness of the institution and of research in general; one way of doing this is disseminating research findings from prior studies as they apply to the particular community. Cultural brokers within the community, for example, ministers or community health care workers could assist researchers in this endeavor and enhance both the process and the outcome.

Third, community resources and local funding sources for supporting joint research projects should be explored. Lay health educators could be paired with university health educators in either an informal or paid relationship to increase ties between the institution and the community. Structural/ecological options within communities, such as restructuring neighborhoods and environments to promote physical activity, should be explored [21]. And finally, more systematic studies on recruitment and adherence in clinical trials are needed to identify ways to increase representative participation within these trials.

5. Interventions

5.1. Challenges in adherence

Interventions to enhance adherence include a broad range of designs, targets, and goals. One of the difficulties in the field is the lack of agreement regarding what actually causes adherence difficulties as well as the diversity inherent in multiple potential levels of analysis, resulting in solutions that are equally diverse. Often adherence interventions target personal barriers to appropriate adherence, including individual level issues, such as remembering to take pills in a certain pattern, through population level issues, such as changing the food supply to promote increased consumption of fruits and vegetables. This range of targets reflects the diversity of ideas about the causes of adherence problems.

This diverse set of targets for adherence interventions leads to varied success rates in promoting adherence and in obtaining the desired outcomes. In motivated self-selected samples, adherence promotion can be quite high, whereas in other, more population-based samples, adherence improvements are difficult to obtain, even in research settings. One difficulty in the field is that researchers often throw multiple intervention components at participants to demonstrate improvements. As discussed earlier, this type of approach is atheoretical and limits our understanding of the successful components within the

intervention. A truer test of the effectiveness of such techniques is experimental manipulation of those variables believed to increase adherence providing a richer understanding of their utility.

What exactly are the goals of adherence research? Often, adherence to the intervention is believed to result in some objective outcome, e.g., a decreased risk for heart disease. Preventive interventions only decrease the likelihood of diagnosis. Therefore, researchers cannot guarantee individual results derived from population-based evidence. Further, participants may not value the outcomes identified by the researchers. Currently, the relationship of adherence to beliefs about outcome is not well understood. By definition, however, participant input is a vital part of adherence-oriented research and needs research attention.

Related to this point, many adherence interventions tend to be directive: participants are given instructions regarding what they need to do to achieve successful adherence. Furthermore, because researchers and communities often have different agendas, a particular study may not be salient to the community. Rather than viewing participants as passive recipients of intervention services, trials need to move toward a more collaborative approach. For example, the level of interest of potential participants needs to be assessed early on and valued participant outcomes should be identified at the onset and when feasible, incorporated into the study intervention.

5.2. Innovations in adherence

Adherence interventions may be enhanced by providing training for the individuals promoting adherence in skills for negotiating adherence options with participants or patients. Although motivational interviewing, in which participants and staff discuss goals and methods of achieving them, has demonstrated limited success in behavioral trials, it is not the answer for all situations and cultures. What happens when the study goals differ from the participants' goals? For example, a participant may participate in a nutrition trial, not for the purpose of lowering HDL that is the main outcome of the study, but to lose weight. The difference between these two goals may account for adherence gaps in clinical and research settings.

Adherence interventions may also be strengthened to make the interventions more like "real life" often by conducting them in community-based settings. Highly structured controlled trials examining adherence to health behaviors tend to lack correspondence with participants' unique realities. In other words, highly controlled studies typically differ significantly from participants' normal living conditions. For example, controlled trials provide much individual attention to participants, such as behavioral monitoring (i.e., observing target behavior), social support, and accessible facilities. Individuals do not receive this type of attention following the conclusion of the study, resulting in a decrease in adherence at follow-up. Thus, controlled studies fail to mimic the "real world" and ultimately have a limited impact on public health.

Interventions aimed at enhancing adherence may benefit by adopting multilevel theoretical approaches that explicitly identify factors within the person, the organization, and the community that have been found to influence human behavior. For example, many community psychology researchers have utilized empowerment theory to implement diverse interventions [22]. This approach is consistent with the multilevel downstream, midstream, and upstream perspective articulated by public health researchers [5,23] and involves integrating individual strengths, natural helping systems, and proactive behaviors to social policy and social change [22]. Furthermore, this approach allows for the integration of many of the theoretical and community-based innovations discussed above. Although numerous empowerment studies exist across diverse behavioral domains (e.g., public health literature, community

psychology), clinical researchers have yet to systematically implement and evaluate the efficacy of empowerment theory relative to adherence to controlled trials.

6. Discussion

In this workshop, a small group of investigators discussed their experiences with challenges and innovations regarding adherence research. The common theme throughout our discussion on adherence was the importance of a 'collaborative process.' This translates not only to the importance of researchers working together, but also to the necessity of collaborations between the researcher and the participant, and between the researcher and the community.

The influence of the individual's, community's, and researcher's perceptions of both the behavior and the environment is noticeably lacking in theory-guided adherence research. From the study of peptic ulcer [24] to AIDS [25], health outcomes and adherence to health behaviors continue to be examined from a biomedical perspective. This search for underlying biologic processes, however, ignores the contributions made by those very factors highlighted at this workshop and, in the context of adherence, has actually limited our understanding. Ignoring the contribution of individual perceptions may lead to a 'blame the victim mentality,' insomuch as the responsibility for participant nonadherence is placed solely on the participant [26]. In fact, Brownell [26] suggests that when an individual's perceptions (e.g., expectations) do not coincide with biologic reality the end result may not only be nonadherence, but also increased participation in at-risk behaviors.

Within the guidelines set forth by the biopsychosocial model, any examination of adherence must begin with a clear, theoretically driven conceptualization and definition. This conceptualization will ultimately guide the entire investigation, from rationale to selection of assessment instruments to interpretation of data analyses. Furthermore, the motivational facet of adherence must be part of the established conceptualization.

Adherence is a complex phenomenon involving interactions among the individual, the environment and the community. In this workshop, we discussed the challenges and innovations encountered as researchers when examining and promoting adherence. Looking ahead, each workshop participant echoed the need for an ongoing dialogue to advocate the advancement of theory. However, it is clear that if we hope to develop a new and integrated model of adherence, we must continue to advance theory through theory testing, with particular attention given to mediators and diverse samples. Moreover, an interdisciplinary agenda is necessary to set the stage for bringing together researchers from various disciplines and backgrounds with both participants and community representatives.

7. Summary

- In order to advance our knowledge of adherence, research must have a well-defined conceptual and theoretical basis.
- Individual perceptions must be incorporated into research. A sole focus on biological mechanisms is insufficient to understand behavior. Cultural and social context of behavior must also be incorporated.
- Research is a collaborative process. Involve participants and the community from idea conceptualization to dissemination of findings. An interdisciplinary framework should guide research development.

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Author's Note

Members of the Adherence Workshop were, in alphabetical order by institution:

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