

MEDICATION ADHERENCE: MANY CONDITIONS, A COMMON PROBLEM

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The problem of adherence – why people fail to follow therapies intended to improve their health – has long bedeviled researchers in medicine, public health, nursing, pharmacology, psychology, and beyond. Most studies have focused on solving problems surrounding a specific condition (such as diabetes) or behavior (such as smoking cessation). This proposal presents a generalized, cross-condition model – the Adherence Loop model – that describes the role of beliefs, knowledge, and actions for designing better adherence programs. The model is based on studies from 4 diverse conditions: multiple sclerosis (MS), weight loss, osteoporosis, and erectile dysfunction (ED). The model suggests ways to support the design process and create programs, tools, and environments to promote adherence by better understanding patients' journeys and mental models of their conditions.

INTRODUCTION

How many of us follow medical instructions perfectly? We forget to take our vitamins, we don't always take our medications, and some days we just don't have time to exercise. And usually it isn't the end of the world. But for patients with life-threatening diseases, failing to adhere to medication can have consequences that may be slow and insidious or dramatic and terrible. Patients with diabetes who fail to keep their blood glucose under tight control may not notice anything immediately, but years later they may suffer unnecessary amputation or loss of vision. A person with asthma who doesn't use an inhaler during an attack may die.

This paper presents a process model of adherence to medical regimens. The model is the product of naturalistic design research, i.e., research done in the context of use, as close to reality as possible. The goal of the model was to inform the design of programs, tools, and environments to promote adherence. Successful programs and tools help people – caregivers and patients – anticipate success or failure in sustaining a treatment regimen, and adopt strategies that may increase the chance for adherence. We define adherence as taking a medication or performing a therapy as directed,

following both proper schedule and proper technique. While many other terms have been used in the literature, we use adherence because it includes both persistence (refilling medication regularly) and compliance (complying with physicians' orders). (For further discussion of nomenclature issues, see Fawcett, 1995; Lutfey & Wishner, 1999.)

The problem of adherence has been approached from many different perspectives (O'Brien, Petrie, & Raeburn, 1992). Physicians and nurse educators have tried to develop tools and materials to help people understand the medical consequences of non-adherence. Psychologists have described how a support network can help people stay adherent. Manufacturers have designed devices to help patients and physicians track and monitor adherence. Our work reflects all of these perspectives.

Adherence is hard to measure because people may deceive themselves and their physicians (Dunbar-Jacob & Mortimer-Stephens, 2001). Measures intended to improve adherence are also difficult to assess. How long should adherence be measured? How do you control for the increased attention given to patients in the test group?

In addition to the problems encountered in performing the research, another barrier is the lack of overarching theories to drive the design of better

adherence programs or tools (McDonald, Garg, & Haynes, 2002).

Previous research has taken two approaches. One focuses on the reasons for non-adherence associated with a specific condition, such as diabetes (for example, Brownlee-Duffeck, Peterson, Simonds, Goldstein, Kilo, & Hoette, 1987; McCann, Retzlaff, Dowdy, Walden, & Knopp, 1990). The other describes a single barrier, such as motivation (Ajzen, 1991; Bandura, 1989; Williams, Rodin, Ryan, Grolnick, & Deci, 1998). Neither provides a comprehensive account that can lead to designs to support adherence across diverse conditions.

In addition, past research from both approaches tended either to assign blame – to the patient, to the physician – or to emphasize the importance of motivation to improve adherence, rather than investigating the complex relationships that patients have with their physicians, with the regimen, and with the system. We believe that a comprehensive account is needed to explain why people behave in non-adherent ways or to design programs, tools, and environments to promote adherence and support people given their motivations and behaviors.

Our project was intended to formulate a comprehensive cross-condition process model of adherence that can help guide development of programs, tools, and environments to promote adherence. To increase the generality of our model, we studied adherence in a variety of different contexts, using naturalistic research methods. We examined the problem of adherence in multiple sclerosis, osteoporosis, weight loss, and erectile dysfunction. These conditions cover a wide range of variables: symptomatic vs. asymptomatic, stigmatized vs. not, higher vs. lower degree of patient involvement and motivation, gender of patients affected, etc.

Multiple Sclerosis (MS). MS poses unusual challenges to adherence. The condition is poorly understood and researchers are even unresolved about how and why therapy works. Therefore, physicians cannot present a clear story to patients to help them understand MS and its therapy. In addition, all currently available therapies involve injections. Therapies involving injections pose particular adherence challenges, as people must overcome needle fears while coping with diagnosis and acclimating to new routines.

Osteoporosis. One of the critical adherence challenges of osteoporosis is that it is, for many, an asymptomatic, invisible disease until the patient suffers a fracture. Without feedback, patients struggle to remain motivated to continue a medication regimen.

Weight loss. Behavioral change poses huge adherence challenges. The goal of weight loss, which

may encompass changes in diet, exercise, and possibly medication, is notoriously difficult to attain.

Erectile Dysfunction (ED). Therapy for ED is relatively new, highly stigmatized, and poorly understood by both physicians and patients. However, there is strong motivation for treatment.

METHODS

In these studies, we visited patients in their homes, conducted in-depth interviews with patients and family and/or caretakers, and watched them as they went about their daily tasks. We did this in order to closely investigate people's barriers to adherence, and to better understand their beliefs, their actions, and the larger context around their adherence. Using naturalistic research methods, which involved both interviews and observations of people in their natural environments, we were able to uncover latent needs and unrecognized workarounds, and could explore the motivations and emotions behind each person's adherence story.

It is critical to understand why people are not adherent, why they take medication vacations or change regimens. We favored a naturalistic approach over other methods, such as surveys, focus groups, or in-lab interviews, because of the complexity of the topic area and the importance of the activity context. It is time-consuming to understand why people are not adherent, and to diagnose the causes of the non-adherence. But methods that ignore individual differences and try to develop a one-size-fits-all solution have little chance of succeeding because people's situations and reasons for non-adherence are so individual.

We also interviewed medical professionals, pharmacists, and drug manufacturers about their role in supporting adherence. These interviews were aimed at understanding the factors influencing adherence, and the context in which adherence is maintained or challenged. We explored what the findings would mean to the design of programs, tools, etc. to increase adherence. The goals were to better understand adherence, and also to combine our findings with previous models to arrive at a process model that could be useful, usable, and effective in guiding design of adherence support.

Multiple Sclerosis (MS). We interviewed seven patients in their homes, learning about the challenges of developing routines around a possibly irregular injection schedule. We also interviewed four neurologists specializing in MS, a nurse, two sales representatives from a manufacturer, and experts at a manufacturer of MS medication.

Osteoporosis. We visited six women with osteoporosis to learn more about their adherence and preferred schedules for taking osteoporosis medication.

We also interviewed two physicians, a general practitioner, and a gynecologist, two pharmacists, and a manufacturer of osteoporosis medication.

Weight loss. For research on weight loss, we conducted naturalistic interviews with 10 men and women trying to lose weight, two nutritionists, a physician, and a pharmacist. We also spoke with a leading weight loss researcher and a pharmaceutical company involved in prescription weight loss medication.

Erectile Dysfunction (ED). To find out why men cease therapy for ED, we interviewed 10 men (and seven of their partners) about their adherence to erectile dysfunction drugs. In addition, we conducted in-person interviews with two General Practitioners (GPs) and a cardiologist and phone interviews with one additional GP and four urologists. We also interviewed a manufacturer of an erectile dysfunction medication about successes and failures in programs designed to increase adherence.

Each home visit was 1.5~2 hours long and attended by one to two interviewers. For the MS, osteoporosis, and weight loss interviews, the visits were recorded with video and photographs conversations for later review. Due to the sensitive nature of ED, no recordings were made. Interviews were organized loosely around a series of topics, but the participants were encouraged to discuss the challenges most relevant to them.

In addition to the four studies, we conducted a review of existing literature for adherence models.

RESULTS AND DISCUSSION

We found many commonalities in the journey people take, the factors that influence adherence, and variables that support success. These commonalities form the basis for a process model to improve adherence. Our results confirm previous research and provide a model with important recommendations for the design process.

Journey

Our literature review identified work by Prochaska and colleagues (Prochaska, DiClemente, & Norcross, 1992) and theories of patient motivation (Putnam, Finney, Barkley, & Bonner, 1994; Brownlee-Duffeck et al., 1987) as particularly relevant. Our data helped us to elaborate these theories.

Consistent with Prochaska et al. (1992) we found three clear phases of Adherence: preparation, initiation (a term developed by the authors to modify the

Prochaska et al. model to the context of medication adherence), and maintenance.

Phase 1: Preparation. In our interviews, we found that patients described the initial moments of diagnosis as a time of shock. Patients are coping with the news, absorbing information about their condition and the options for treatment, selecting a therapy, and starting to consider how this event will affect their lives. For one patient diagnosed with MS, the shock of the diagnosis and stress associated with having to select and begin a therapy was too much and it took her four months before she was able to initiate treatment. That was four months when her untreated condition could degenerate unchecked. Physicians understand that a diagnosis can be overwhelming, but many are unsure how to handle that. Particularly for asymptomatic conditions, a diagnosis may not be sufficient to motivate adherence. One physician told the researchers that he would often wait until after his MS patients had had their first flare-up to start them on medication. Before that, he felt that they just weren't sufficiently motivated.

Phase 2: Initiation. Initiation begins from the moment a patient takes medication. Patients described this phase as marked by a focus on learning to take the therapy, adjusting their lives around it and vice versa. Patients in this phase need feedback, and described wondering: Am I doing this correctly? Is it working? Are these side effects of the medication or are they unrelated? For one ED patient we interviewed, the mental and emotional pressure during Initiation virtually ensured that the phase would be marked with perceived product failure. This lack of positive feedback caused him to give up on that medication and continue to shop around.

Phase 3: Maintenance. When patients have developed a routine around the therapy, and each event stops feeling so monumental, they enter Maintenance. Patients find that their focus may stray from the therapy and they may become non-adherent. Weight loss is notoriously difficult to maintain over time. For one patient we interviewed, just when he had mastered the rules of a diet and was starting to see great results, the holidays derailed him. This had happened to him multiple times and with a variety of diets. None could get him past his seasonal *bête-noir*.

This three-phase model can be used to describe a range of therapy journeys, from acute to chronic. A literature review suggests that the curve is affected by many factors, around the individual (Horowitz & Horowitz, 1993), the type of condition, the therapy demands (McDonald et al., 2002), and the network of people, companies, and organizations that affect use (DiMatteo, Sherbourne, Hays, Ordway, Kravitz, McGlynn, Kaplan, & Rogers, 1993).

Beyond these factors, we found a cyclical process through which people progress to achieve long-term success. The factors above mitigate each stage of this cycle, but unlike the influencing factors, the “Adherence Loop” model is generative in suggesting ways to improve adherence.

The Adherence Loop

Across all four conditions and therapies, and from the review of literature, we found distinct common factors of failure and success. To achieve success, people must move through three different nodes of adherence (see Figure 1).

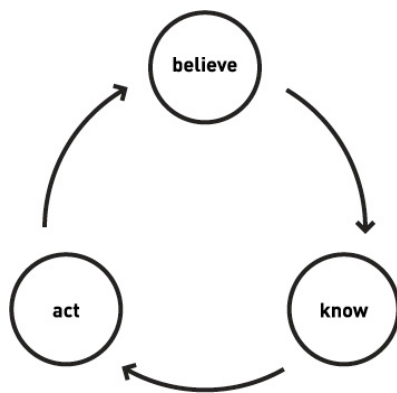


Figure 1: Adherence Loop

Previous research has elucidated parts of the loop, or has focused on one node, but pulling these data together into one model creates a process model that can better inform design.

Belief. The first node is Belief. People must believe in the accuracy of the diagnosis, the appropriateness of the therapy, their self-efficacy to perform the therapy, and the therapy’s validity and likelihood to succeed (Ajzen, 1991; Bandura, 1989). Once people have some basis to believe, they must develop a mental model of the condition and the effect of the therapy on it. As Lippa & H. Klein (2006) demonstrate in patients with diabetes, having a mental model supports adherence success. In our research, one patient with osteoporosis didn’t have a clear mental model of the condition and so didn’t believe in the importance of taking her medication until a friend suffered a broken hip. Our interviewee’s beliefs changed completely after she better understood the consequences of non-adherence.

Knowledge. A robust mental model will help a person Know what to do, and when and how to do it. Morrow, Leirer, & Sheikh (1988) argue that people need to know what to do in order to do it correctly. Clear

instructions and well-developed mental models help people take effective actions. In turn, a strong knowledge of when and how to perform the therapy will help a person develop the critical cues and reminders to stay adherent. An interview with a weight loss patient demonstrated the problems of conflicting mental models. Almost every diet she had tried gave her a different mental model. This made it very hard for her to know what to do.

Action. These cues and reminders lead to the Act of engaging in the therapy. It is not enough to remember – a person must be physically, cognitively, emotionally, and financially able to act. Cramer’s (1998) research on packaging aids demonstrated the host of physical and cognitive deficits that can derail the most determined patient. Her research also argues for the importance of action feedback. Several of the MS patients we interviewed had such strong needle fear that their ability to act correctly was compromised. Another patient had had a recent stroke and suffered from cognitive and physical impairments. This meant that he was unable to take his medications correctly, even though he believed himself to be highly adherent. Success in action, and success of the therapy, should provide feedback and, in turn, reinforce Belief.

People move through this loop on multiple levels. On a macro level, as people prepare, initiate, and maintain, they must believe in the purpose and efficacy of the therapy, know how to take it properly, and be able to take the actions required. On a micro level, every time a therapy is taken (or not) is a reaffirmation of belief, knowledge, and ability to act, from the first time and throughout the course of maintenance. While the focus during preparation may be on Believing, during later phases all nodes must be reinforced to maintain adherence. Mapping the phases of adherence over the journey for a group of patients helps identify where the Adherence Loop is breaking and where to focus design efforts.

In addition, we identified four critical factors that inform and shape the way that people move through their journeys and their long-term success in the Adherence Loop: characteristics of the individual, condition, therapy, and network. People differ in their motivation and engagement, conditions vary in how they impact a person’s life, therapies make different demands, and the breadth and strength of the network of clinicians and support surrounding each person is distinct. Understanding these factors and the specific roles they play can help guide specific adherence solutions. The factors can have an impact on each part of the Adherence Loop. Some individuals may not want to believe they have the condition, some conditions are easier to understand, some therapies are easier to follow,

and the support from medical professionals and friends and families influences the entire loop.

The loop of Belief to Knowledge, Knowledge to Action, Action back to Belief, while simple, describes what a successfully adherent person needs to succeed and also illustrates why someone might fall from adherence. We believe this model is trans-conditional; it describes the taking of short-term antibiotics as well as a life-long chronic therapy. And, it is generative, pinpointing the specific cause of non-adherence while identifying leverage points for the design of adherence programs. Exploring each of the nodes and the path that can guide people around the loop suggests ways to support areas of adherence vulnerability. Integrating the Adherence Loop with an understanding of the journey of medication adherence produces a more powerful and nuanced picture of adherence barriers and a powerful tool for designing condition-specific adherence support.

CONCLUSIONS

Through naturalistic studies of four diverse conditions and a meta-analysis of existing literature on medication adherence, we propose a generalized Adherence Loop model to identify barriers that can prevent success. We believe that the more the factors called out in the Adherence Loop model are taken into account, the greater the likelihood of success. We are currently investigating the ways the model can be used to create programs that successfully improve adherence. The generative nature of the model and how it can be used as a design tool for a wide variety of conditions makes it powerful. Another next step is to explore more fully the four factors which influence the journey: the individual, condition, therapy, and patient network. This exploration is in progress. Finally, we hope to extend the conditions studied to further expand the utility of the model for therapy adherence.

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