

Adherence Strategies and Fullscript Tools can be Incorporated into a Functional Medicine Approach

DeAnn Liska, PhD

The Challenge of Diet-Related Conditions and Adherence

Diet-related chronic diseases are leading causes of disability and death in the United States, with an estimated 10.5 percent of the population having diabetes, 6.7 percent diagnosed with coronary artery disease, and more than 70 percent of Americans overweight or obese.^{1,2} In the United States, diet-related chronic diseases cost an estimated \$50.4 billion annually.³ Further, the percentage of adults with diabetes increases with age, reaching 26.8% among those 65 years or older⁴ and 25 percent of the more than 800 000 myocardial infarctions (MI) that occur annually are recurrent events.⁵ Most concerning is that the prevalence of obesity in children and adolescents is greater than 18 percent and has been increasing over the past two decades.⁶ Notably, low-income, Black non-Hispanic, and Hispanic households, households with young children, and households headed by a single parent are disproportionately affected by diet-related chronic diseases. Moreover, it is important to recognize that diet-related conditions include more than just the chronic diseases that receive most of the press. For example, celiac disease, a debilitating food-related disorder affects one in 100 people worldwide.⁷ Therefore, diet-related conditions affect people of all ages and socioeconomic conditions, and strategies for implementation of both prevention and management interventions are needed.

Much research over the past three decades has indicated that diet-related conditions are complex, often developing over time with multiple precedents, thus, requiring complex approaches to understand and manage. A key component to addressing these conditions are lifestyle changes, such as diet and supplement interventions; however, adherence is an issue for many patients. For example, it is estimated that 50-60% of chronically ill adults are non-adherent, or consume less than 80% of their prescribed medications.^{8,9} In the US, non-adherence is associated with up to 10% of hospitalizations and 125 000 deaths annually.¹⁰ The cost of non-adherence to medical interventions is substantial, at an estimated \$289 billion for the US alone. Evidence on pharmaceutical interventions indicates eHealth and mobile applications, and approaches such as automatic refills may help with medication adherence.^{8,11} However, data on long-term adherence, and on adherence to integrative interventions is still emerging.

Findings of Keller and Colleagues

This issue of *Integrative Medicine- A Clinician's Journal* has a series of papers by Keller and colleagues on treatment adherence that address integrative medicine, with a focus on the Fullscript platform.¹²⁻¹⁴ Fullscript is a free supplement dispensing platform and treatment adherence tool that supports integrative practitioners and their patients at the point of care and beyond. The authors of this series have conducted an in-depth literature review and practitioner survey and provide insight into adherence concerns and strategies for integrative medicine. For example, the numerous factors that affect adherence include practitioner/patient education, cost, feasibility, and patient readiness to change. Helping patients through complex interventions, using approaches such as step-wise changes, and working as partners with patients were identified as helpful strategies to consider. Keller and colleagues also note that a key component of adherence is establishing trust with patients. A trusting relationship, along with using slow, simple, step-wise treatment plans, with regular follow-up appointments and clear, open communications can increase likelihood of adherence and, thus, improve outcomes. It is also important that the interventions be evidence-based, with labs and monitoring/ biological feedback tools to help patients understand the benefits of supplements and other interventions, and to monitor progress.

The recommendations outlined in this series are consistent with the World Health Organization's (WHO) report on adherence, which identifies five interacting dimensions that include systemic/ healthcare team factors, socioeconomic factors, condition/ disease factors, therapeutic factors, and patient factors.¹³ Specifically, non-adherence has been traditionally considered as a patient-centered problem and, thus, engaging in a systemic, patient-centered approach could help in addressing adherence factors. However, it places a burden on practitioners when addressing a wider range of conditions and or patient populations.

The Benefits of Functional Medicine

Functional Medicine is a model of healthcare that uses an individualized, patient-centered approach to implement precision medicine/ precision nutrition in care of patients. Functional medicine focuses on root causes, rather than just management of symptoms, and holds great promise

for addressing complex conditions. Functional medicine provides a framework for practitioners to understand how to address these multiple levels of considerations, and includes many of the factors that have been identified as key to promoting adherence. The essential components of Functional Medicine practice are:¹⁵

1. Listening to the patient's illness narrative on the initial intake.
2. Evaluating, prioritizing, and focusing on the patient's modifiable factors.
3. Organizing the patient's clinical imbalances by underlying causes into a systems biology matrix framework.
4. Creating a therapeutic partnership between doctor and patient.

Functional Medicine includes all forms of interventions, including diet, lifestyle changes, and supplements, and provides strategies for practitioners for communication with patients, as well as how to navigate the complex, multifactorial assessment and treatment plan considerations. In particular, the Functional Medicine approach provides strategies and a template for establishing trust with patients, which is a major component of promoting adherence. A trusting relationship between practitioner and patient includes communication and developing a partnership between practitioner and patient in addressing health concerns. As stated by Dr. David Jones, one of the leaders in developing the Functional Medicine approach: *"If we get in the trenches together here, we're going to find answers that have long term efficacy way beyond any drug I can give you."*¹⁶ The tools provided by the Functional Medicine approach can help in developing the initial communications, and then the trust that is needed for the long-term relationship to help a patient successfully address complex interventions and needed lifestyle changes.

Interventions addressing the root cause of these conditions, and including the multiple layers of lifestyle-related interventions are complex. We now understand that there is no silver bullet for chronic, diet-related conditions, and the complexity and need to address long-held habits and beliefs can overwhelm patients. Assessing readiness to change is an important part of knowing how to help patients implement interventions in a way that can lead to long-term changes. The Functional Medicine approach includes tools to help understand a patient's readiness to change and, together with tools such as Fullscript, help manage some of the complexity, as well as provide an additional communication component for understand as early as possible when a patient may be struggling with adherence to an intervention. This type of technology can be easily incorporated into a Functional Medicine approach, and can help both practitioner and patient, not only in providing improved communication,

but also simplifying the ordering and delivery process for supplements. The review in this issue also provides discussion of other healthcare technologies, noting that those that provide self-monitoring and/or feedback, which can also be incorporated into a Functional Medicine approach.

Cost as a Barrier to Adherence

A major barrier to adherence, and possibly the most difficult to address, is cost. Most integrative medicine approaches are not covered by insurance and require out-of-pocket costs. A recent study by Beidelschies et al.¹⁷ investigated a shared medical appointment (SMA) approach for helping in cost management for delivering Functional Medicine interventions. The study was a retrospective cohort analysis performed at the Cleveland Clinic Center for Functional Medicine and found a clinically meaningful difference in 40% of patients participating in SMAs compared to 30% using individual appointments. Further, greater improvement in health-related quality of life scores and weight loss, and similar decreases in blood pressure were seen in the SMA patients compared to those having individual appointments ($P < .05$). A possible reason for these differences related to the approach to providing nutrition recommendations. For example, the SMA group setting allowed for more time to be devoted to education and for open discussions among the group of participants with the healthcare practitioner. In this type of setting, patients can learn from each other and provide support to each other. Group learning and peer-support have been shown to improve outcomes such as weight loss and lifestyle changes for management of type 2 diabetes.^{18,19} The SMA group also had more appointments (average of 9 over 3 months) compared to the individual appointments group (average of 2 over 3 month), but cost less to deliver (US\$1549 vs. US \$1633 per patient) and with higher profitability. Combining the SMA approach with technologies that allow one-on-one monitoring and communications, such as Fullscript, could help manage cost and support the on-going individualized relationship needed for maintaining trust and patient engagement.

Future Needs

Finally, one challenge in advancing integrative approaches and obtaining more recognition in the broader healthcare field, such as needed for insurance and policy changes, is the lack of well-detailed research studies. For example, although the issue of adherence has become a focus of recent literature in pharmaceutical fields, there is limited data linking adherence rates to outcomes overall, and limited research on complex, integrative interventions. The Fullscript platform has the potential for developing a database that would benefit the field of integrative medicine and provide opportunity for further assessments of approaches such as Functional Medicine interventions. Use of consistent definitions for the stages of adherence

(i.e., initiation, implementation, and discontinuation) is necessary for furthering the understanding of barriers to adherence as well.¹⁰ It's notable that the recently published Strategic Plan for NIH Nutrition Research highlights both the need for database technologies, including the use of artificial intelligence (AI) applications, as well as better understanding of behavioral factors affecting adherence to dietary changes.²⁰ The increased funding that will come from this call to action in the NIH strategic plan holds promise for new developments in understanding barriers to lifestyle changes. The review by Keller and colleagues provides a solid basis for including adherence strategies in intervention protocols based on our current understandings, as well as addressing the issue of consistent definitions and database development to support further learnings, which are much needed to advance integrative medicine.

Conclusion

Healthcare practitioners need to consider strategies for adherence as part of the treatment plans for successful patient outcomes; however, this adds to the already complex interventions and can be burdensome to both practitioners and patients. Functional Medicine is a framework for addressing the root causes of complex, multifactorial conditions that has shown success for conditions such as chronic disease management. The Functional Medicine approach also includes listening to the patient's story and working as a partner with patients, which are key components to promoting adherence. Technologies, such as Fullscript, can help simplify some of the implementation steps in therapeutic approaches and provide another communication platform with patients, further supporting adherence. Research is needed as well, and development of robust databases, such as proposed with Fullscript, can also play an important role in supporting new knowledge on adherence and outcomes.

References

1. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017–2018. *NCHS Data Brief*. February;2020: No. 360.
2. Center for Disease Control and Prevention (CDC). Heart Disease Facts. <https://www.cdc.gov/heartdisease/facts.htm>. Accessed May 18, 2021.
3. Jardim TV, Mozaffarian D, Abrahams-Gessel S, Sy S, Lee Y, Liu J, Huang Y, Rehm C, Wilde P, Micha R, Gaziano TA. Cardiometabolic disease costs associated with suboptimal diet in the United States: A cost analysis based on a microsimulation model. *PLoS Med*. 2019; 16(12): e1002981.
4. National Diabetes Statistics Report, 2020. <https://www.cdc.gov/diabetes/library/features/diabetes-stat-report.html#:~:text=New%20in%202020%2C%20the%20report,1%20in%203%E2%80%94have%20prediabetes>. Accessed May 18, 2021.
5. Aggarwal M, Ornish D, Josephson R, Brown TM, Ostfeld RJ, Gordon N, Madan S, Allen K, Khetan A, Mahmoud A, Freeman AM, Aspry K. Closing Gaps in Lifestyle Adherence for Secondary Prevention of Coronary Heart Disease. *Am J Cardiol*. 2021; 145:1-11.
6. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of Obesity Among Adults and Youth: United States, 2015–2016. *NCHS Data Brief*. October 2017; No. 288.
7. Celiac Disease Foundation (CDF). <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>. Accessed May 18, 2021.
8. Kim J, Combs K, Downs J, Tillman III, F. Medication Adherence: The Elephant in the Room. *US Pharm.*, 2018; 43(1):30-34.
9. Price P. How can we improve adherence? *Diab/Metab Res Rev*. 2016; 32(Suppl. 1):201-205.
10. Zullig LL, Blalock DV, Dougherty S, Hendeson R, Ha CC, Oakes MM, Bosworth HB. The new landscape of medication adherence improvement: where population health science meets precision medicine. *Patient Prefer Adherence*. 2018; 12:1225-1230.
11. Tabi K, Randhawa AS, Choi F, Mithani Z, Albers F, Schnieder M, Nikoo M, Vigo D, Jang K, Demlova R, Krausz M. Mobile Apps for Medication Management: Review and Analysis. *JMIR Mhealth Uhealth*. 2019 Sep; 7(9): 13608. doi: 10.2196/13608.

12. Bailey R, English J, Knee C, Keller A. Treatment Adherence in Integrative Medicine Comprehensive Literature Review and Industry Insights: A brief Report. *Integr Med*. 2021 20(S2):4-5.
13. Bailey R, English J, Knee C, Keller A. Part One: Review of Literature in Treatment Adherence. 2021 20(S2):6-18.
14. Bailey R, English J, Knee C, Keller A. Part Two: Fullscript Practitioner Insights. *Integr Med*. 2021 20(S2):19-23.
15. Hathaway P. Form Follows Function: A Functional Medicine Overview. *Perm J*. 2016 Fall; 20(4): 125-126.
16. Benson- David Jones, MD: Shaping the Practice of Medicine. *Integrative Med*. 2014 October; 13(5):14-16.
17. Beidelschies M, Alejandro-Rodriguez M, Guo N, Postan A, Jones T, Bradley E, Hyman M, Rothberg MB. Patient outcomes and costs associated with functional medicine-based care in a shared versus individual setting for patients with chronic conditions: a retrospective cohort study. *BMJ Open*. 2021; 11: e048294.
18. Liang D, Jia R, Zhou X, Lu G, Wu Z, Yu J, Wang Z, Huang H, Guo J, Chen C. The effectiveness of peer support on self-efficacy and self-management in people with type 2 diabetes: A meta-analysis. *Pat Educ Counsel*. 2021; 104:760-769.
19. Raaijmakers LCH, Pouwels S, Berghuis KA, Nienhuijs SW. Technology-based interventions in the treatment of overweight and obesity: A systematic review. *Appetite*. 2015; 95:138-151.
20. National Institutes for Health (NIH). 2020-2030 Strategic Plan for NIH Nutrition Research. <https://dpcpsi.nih.gov/onr/strategic-plan#:~:text=The%20first%20NIH%2Dwide%20strategic,experimental%20to%20research%20training>. Accessed May 19, 2021.