Using Adherence Information to Improve Care: From Clinic Visits to Populations

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Electronic devices for measuring medication-taking have been available for decades, and have demonstrated substantial variability in adherence behavior.¹ These devices are integrated into medication packaging, and record the date and time when a pill container is opened or an inhaled medication dose is dispensed. Electronic adherence monitors have been used in many research studies² but remain uncommon in clinical practice. While the lack of widespread adoption of such devices has in part been due to persistent concerns about cost and technical reliability, a more formidable barrier to clinical implementation has been the lack of answers to several fundamental questions. These questions include: how to select medications for monitoring, how to present adherence information to clinicians, which clinicians should receive the information, when they should receive it, and how the information should be integrated into decision-making.

A study in this issue of *JGIM* sheds light on these questions. Kronish and colleagues report a cluster-randomized trial of an intervention that provided clinicians with data from electronic pillbox monitors.³ The study took place in two hospital-based primary care practices serving vulnerable populations in New York City. Twenty-four clinicians were randomized either to continue usual care or to receive information about recent adherence with antihypertensive medications. The information was presented at a single clinic visit along with a brief report suggesting responses to that information. Each clinician in the intervention group received information from a median of four patients, all of whom met JNC-7 criteria for uncontrolled hypertension on two consecutive clinic visits.⁴ These patients were complex, both socioeconomically and medically. Most were Hispanic (75 %), and 83 % received Medicaid or were uninsured. More than half the participants were taking three or more antihypertensive medications, and the clinician addressed a mean of four other health problems at the same clinic visit. Adherence monitoring demonstrated that 41 % of participants had taken < 80 % of their antihypertensive

medications over roughly the preceding 2 months. Although the evidence for using an 80 % threshold to distinguish adherence from non-adherence is scanty, at least one recent paper suggests that this threshold identifies individuals at higher risk for adverse outcomes after myocardial infarction.⁵

Identification of non-adherence is an important “branch point” in clinician decision making. For individuals whose hypertension is uncontrolled despite high adherence, clinicians should consider intensifying treatment by increasing medication doses or adding new medications. For individuals who are not adherent, clinicians should identify and remove adherence barriers and provide counseling to promote behavior change, since intensification of treatment is likely to be futile or counterproductive.⁶ Accordingly, these researchers designated clinician behavior in response to adherence information as their primary outcome. If the patient was adherent, appropriate care was defined as treatment intensification, evaluation for secondary causes of hypertension, or referral to a specialist. If not, appropriate care was defined as evidence of adherence counseling or regimen simplification.

Overall, clinicians who received adherence information provided appropriate care to 69 % of their patients, compared to 34 % in the usual care group ($p=0.001$). The rate of appropriate care was increased in both decision “branches.” Adherent patients were more likely to have treatment intensification (56 vs. 26 %, $p=0.01$), and non-adherent patients were more likely to receive counseling (84 vs. 39 %, $p=0.005$). These intervention effects were very large because physician behavior was the outcome of interest, rather than patient behavior or clinical outcomes. Adherence monitoring did not jeopardize the clinician–patient relationship. Rather, the patients rated physicians who received the intervention more favorably than comparison physicians on quality of care, patient centeredness, and collaborative communication (all $p\leq 0.05$).

The investigators recognized several limitations of their study. Since the intervention was cross-sectional, longer follow-up would be necessary to determine whether clinicians continued to incorporate this information into their decisions, and whether adherence or blood pressure control ultimately improved. Since the study included both adherence data and suggestions for management, the effect of these co-interventions could not be disentangled. The effectiveness of

the intervention may have been overestimated because the trial was stopped early, after reaching a pre-specified efficacy endpoint. Truncated trials have been associated with larger effect sizes than trials that continued until their planned conclusion, particularly if they are small.⁷

The generalizability of these findings is also uncertain. Of the 200 participants entered into a “run-in” phase, only 100 continued to have uncontrolled hypertension and were able to provide usable adherence information at the study visit. Thus, individuals were excluded if their adherence or blood pressure improved while they were being monitored, if they would not adhere to monitoring, or if there were technical problems with the device. Further concerns about generalizability are raised by the findings that no eligible patients were enrolled for 25 of the 49 randomized clinicians, and that the study required 4 years to recruit 100 patients.

Despite these limitations, the study advances our understanding of the uses of adherence information in clinical practice. The researchers tested a strategy for providing adherence information that can be characterized as “one patient, one clinician, one time, one place, one disease.” Although this strategy was effective in their small trial, it would not meet the demands of a large population. For example, in Kaiser Permanente Colorado, approximately 300 primary care physicians care for 125,000 patients with hypertension. If about 40,000 (30–40 %) of those individuals are not adherent with their antihypertensive medications, each physician must manage an average of 133 non-adherent patients with hypertension, many of whom are receiving other chronic medications that would also benefit from adherence monitoring. The time demands for review of adherence information and counseling with all these patients about all their medications would be substantial. Thus, in its extreme form (“all patients, all clinicians, all venues, all time points, all diseases”), a strategy that requires detection and management of non-adherence within the traditional model of primary care is unworkable.

Effective, practical and sustainable strategies for adherence monitoring and clinical intervention will need to steer a course between these extremes.⁸ One possibility is that clinicians could order electronic adherence monitoring much as they now order laboratory monitoring. Adherence could be monitored at critical care transitions, such as hospital discharge or initiation of a new, clinically consequential drug. Monitoring could also be focused on high-risk patients who have not reached a therapeutic target yet appear to be adherent on the basis of self-report⁹ or prescription refills.¹⁰ Consistent with the principles of

the patient-centered medical home, clinicians could integrate near real-time adherence information with other critical clinical, social and financial information during desk-top “population care” sessions (rather than during short and intensive clinic visits) and coordinate counseling efforts with pharmacists, nurses, social workers, or patient navigators. Whatever the best approaches ultimately prove to be, the paper by Kronish and colleagues prompts us to think more deeply about how to integrate adherence assessment into clinical practice, and to design research studies that test those interventions.

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