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The Medication Adherence Epidemic: How to KEEP Patients Healthy

Aditya Loganathan, Ishan S. Abdullah, Randall W. Lee, MD 02/07/2023

Every year, researchers work towards developing new therapeutics and treatments for various diseases and conditions. In 2021 alone, over <u>\$238 billion</u> was spent developing novel therapeutics. Despite the benefits of searching for novel therapeutics and the monetary profits that follow, some researchers believe that a portion of R&D funds should be focused on increasing medication adherence. For example, in 2003, the World Health Organization (WHO) reported: <u>"increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatment."</u>

In an effort to explore the root causes of medication non-adherence, some identify <u>primary and</u> <u>secondary</u> causes of medication non-adherence. Primary non-adherence refers to the failure to fill a prescription, while secondary non-adherence results from a patient incorrectly following the regimen prescribed by their provider. Research has found that over <u>30% of all medicine-related hospital</u> <u>admissions</u> resulted from poor medication adherence. This should not be surprising, as almost <u>60% of all</u> <u>chronically-ill patients who are prescribed medication are non-adherent</u>. Improper adherence can not only be dangerous for the patient's health, but it can also lead to unclear treatment efficacies, unnecessary use of diagnostics, and incorrect interpretation/conclusions of clinical trial data.

To mitigate what the New York Times considers an <u>"out of control epidemic,"</u> researchers are developing new subjective and objective techniques to measure and improve patient adherence. Subjective measures refer to a patient's self-reporting or a provider's evaluation of medication-taking behavior. Subjective data is relatively simple to collect but is <u>prone to biases</u> such as patients underreporting non-adherence, providers misinterpreting patient answers, or general recall bias. On the other hand, objective measurements are likely more accurate but are harder to obtain; they utilize methods that derive physical evidence of adherence, such as testing for medication metabolites in the bloodstream or urine. Objective methods are considered ideal for <u>compliance testing</u>, but this approach also has drawbacks. For example, simple binomial (yes/no) results lack context, specifically regarding therapeutic levels, mistimed or missed doses, or subjective social determinants. Objective methods can also suffer from adherence biases, as is described by <u>white coat adherence</u>. This phenomenon describes how patients are more likely to adhere to treatments immediately before appointments, which can skew objective testing results. Lastly, objective data can sometimes be costly and cause <u>unnecessary stress and anxiety</u> for the patient.

Electronic Medication Packaging devices, or EMPs, are a popular method of objectively measuring medication adherence without needing patient metabolite samples. EMPs are pill containers with microprocessors that provide digital display reminders and time recordings for when the medication was taken from the container. By objectively recording when the drug was taken, EMPs are <u>less likely</u> to cause stress than objective measures that require blood from the patient and are preferable to self-report methods, which are vulnerable to inaccuracies. While EMPs provide creative and innovative solutions, patients can still cheat the system if desired. For example, it is nearly impossible for devices to monitor if patients take or discard their medication after removing it from the container. Although this is true, researchers reason that intentional patient deception of adherence might be unlikely since it would take additional effort to open the pill container on a consistent schedule. Despite this potential limitation, companies continue to develop cutting-edge EMPs to improve adherence in a patient-centric fashion.

KEEP is one of the many companies attempting to revolutionize medication adherence through the development of their own smart storage device. The KEEP system, compared to other products, offers a customizable digital display, a dedicated cooling unit, an internal weight scale, an airtight seal, a multiple-day charge life, and it is easy to store. The electronic storage system can hold up to 8 standard prescription bottles. The container space can also support a variety of medication types, including solid pills, injectables, and oral dosages, whereas many other containers are only compatible with a single medication type. In addition to being a convenient medication dispenser, the KEEP system adds dosage information and personalized feedback to the user through a remote phone application. By working in unison with the HIPPA-compliant KarebyKEEP app, rather than only measuring adherence, the KEEP system encourages positive behavior change by adding various automated interventions such as behavioral nudges, motivational messaging, and support directly from providers that are notified of missed dosing events. Other app features allow users to set alarms, track progress trends, coordinate multiple KEEP devices (if larger storage space is necessary), and remotely monitor the container temperature and humidity.





The KEEP system supports multiple medication types, such as inhalers, injectables, and solid pills. The container is convenient to store, portable and features a customizable LED display. Images provided with the consent of KEEP Co-Founder & CEO Phil Wilkins.

A prominent concern with medication containers is the ease of access by non-intended users. Many non-electronic medication containers offer little to no protection from unwarranted access from children or others. This is a prevalent issue in the United States, as a child is brought to the emergency department <u>every 9 minutes</u> secondary to medication poisoning caused by unsafe storage. Dr. Sadiqa Kendi, a pediatric emergency room physician and medical director for Safe Kids DC, states that <u>"there are</u> <u>some cases in which one pill can kill a child.</u>" The KEEP system solves this security concern by using biometric face and fingerprint authentication to open the device, as well as incorporating an auto-lock feature in case the user forgets to close the lid fully. To further safeguard against accidental medication overdose or theft, the app is helpful in KEEPing a real-time log of container accesses; all container movement is monitored through the device's embedded accelerometer and sent to the app.

While EMPs like KEEP could prove to be a promising solution for medication non-adherence, there are still hurdles to implementation and acceptance. Manufacturing costs and end-user pricing are prohibitive to many, like elderly patients on a fixed budget. KEEP Cofounder Phil Wilkins states that other corporations are unsuccessful because they have focused "too much on advanced technology." For example, Wilkins shares that advanced technology aimed at measuring adherence, such as <u>ingestible</u> <u>Bluetooth pills</u>, are often "constrained by high regulatory hurdles and cost structures." Wilkins claims that the medication adherence market varies on a spectrum that has inaccurate self-reports on one end and highly expensive and regulated technology on the other. The KEEP corporation feels they have made progress in the field of EMPs by providing an affordable, accurate solution that also provides a self-defined support network and motivation.

A preliminary study conducted by KEEP involving 48 participants over 9,327 dosing events saw that the use of a KEEP device led to 95.8% of the dosing events occurring and 92.0% of them being on time. By uniquely combining subjective and objective feedback channels, the KEEP system can facilitate medication adherence through its holistic and patient-centered model. In doing so, the company's vision is centered around the ideology that <u>"lifesaving therapies only work when they're taken."</u>

The KEEP system, since its launch in late 2019, <u>received multiple awards</u>, such as the 2020 Consumer Electronic Show award for innovation, Esquire Magazine listed the device as one of the coolest gadgets of 2020, and TIME named KEEP one of the 100 Best Inventions of 2020. While KEEP seems to have produced a successful product, as shown by their accolades, hopefully, similar devices will continue to be developed in widespread efforts to improve adherence and improve outcomes of patients with chronic illness.

The authors have no conflicts to report.