Descriptive statistics were employed for the data analysis due to the small sample size. A non-parametric 2-independent sample test was used because of the small sample size. The test did not show any statistical significance between the variables in the pre- and post-test DASS-21 after the intervention. Subjects reported the project intervention was "helpful." Another participant said she could not fully engage in the interventions because of family obligations. Still, she enjoyed the resources, such as the weekly NAMI family support group meetings given by the SI. The pre-test DASS-21 mean score for N=3 was 26 and standard deviation was 15.62.

Discussion. The current COVID-19 has led to an increase in mental health issues. Because of the overwhelming increase in mental health cases, many individuals with mental health problems are being turned away. The decrease in the availability of mental health providers has led to an increased need for informal caregivers. However, studies show stress from caregiving can negatively affect the health of caregivers and result in loss of work productivity. However, specialized support for caregivers is frequently limited. Brown et al. (2016) said nonpharmacological self-help interventions such as bibliotherapy, stress-reduction techniques, and health literacy training could improve caregivers' health. Therefore, lawmakers and healthcare professionals need to come up with interventions to help caregivers.

AI-Based Adherence Prediction for Patients: Leveraging a Mobile Application to Improve Clinical Trials

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Abstract

Introduction. Medication nonadherence is a public health concern and can impact clinical trial data quality. Traditional compliance collection (pill counts, diaries) can be unreliable in central nervous system trials. As such, strategies such as adherence technologies may play a key role in trial outcomes. AiCure, a computer vision-assisted dosing mobile application (app), collects dosing data and connects patients to sites for dosing support. Phone-based computer vision algorithms confirm dosing and transfer videos for artificial intelligence and human review. Boehringer Ingelheim is partnering with AiCure on pilot trials using AiCure adherence data to improve patient retention and clinical trial data quality. Here we report initial findings.

Methods. This pilot used data from two Phase II trials on the efficacy and safety of BI 409306 in people with schizophrenia (NCT03351244) or Attenuated Psychosis Syndrome (NCT03230097). The AiCure mobile app alerted participants to dosing protocols. The dose event was visually confirmed, providing sites a real-time view of

adherence and allowing for targeted outreach and intervention. Adherence data from the first 2 weeks generated quantitative, machine-learning models to predict the individual adherence over the trial. Predictive modeling explored different monitoring periods (7-, 10-, and 14-day) and adherence cutoff points (0.8, 0.7, 0.6).

Results. Initial AiCure assessment identified 43% of participants in NCT03351244 as ≤80% compliant (definition of compliance >80% compliant). Variance in adherence rates between electronic case report forms (eCRF; 78%) and AiCure (26%) data was also observed in the highly compliant/adherent group in NCT03230097. Using the first 2 weeks of adherence data (both studies combined), a participant's adherence predicted their average adherence for the remainder of the trial. Observation of a participant's adherence for the latest 4 weeks predicted the probability of premature dropout from the trial. There were further correlations of lower predicted adherence with actual disposition-based dropouts.

The early adherence predictive model (0.6 adherence cutoff) identified 22%, 20%, and 19% of patients for trial NCT03351244 (total n=235) as high-risk patients (low-adherence prediction) across 7-, 10-, and 14-day monitoring periods, respectively. Of those high-risk patients, 81%, 90%, and 96%, respectively, were truly nonadherent based on actual adherence data. The 14-day monitoring period model provided the lowest false omission rate, indicative of a better performing model.

Conclusions. AiCure data provided insights into patient behavior and adherence patterns which would not be available via CRF. Predictive models developed with AiCure adherence data can identify and predict future poor adherers. This creates opportunities to plan interventions and mitigation strategies to improve patient adherence during trials, thereby providing test drugs the best opportunity at proving efficacy.

Patient and Staff Attitudes Toward Clothing Restrictions on a Pediatric Psychiatric Unit

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Abstract

Introduction. Pediatric psychiatric inpatients are among the most vulnerable individuals in society. While the use of seclusion and restraint is well chronicled in the field of research in this population, there is limited literature describing the effects, meaning, and attitudes of mandating the wear of clothing in hospital settings. This research explores the phenomenon of the practice of mandatory wear of hospital-issued clothing and its meaning to patients and the awareness and attitudes of this practice among staff caring for this population. This research aims to improve understanding of the experiences of patients regarding this practice at a large, urban hospital providing care for children using a mixed methods design. A qualitative, descriptive phenomenological analysis was conducted through individual interviews with