MOBILE HEALTH TECHNOLOGY AND PAIN MANAGMENT

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INTRODUCTION

- Chronic pain imposes a significant burden on individuals and society.
- Patient adherence to treatment protocols and medication regimes is a key contributor to successful patient safety and treatment effectiveness.
- Practical restrictions on a physician's time and payor limitations to support increased work reduce the providers' ability to closely monitor patients to ensure adherence.
- Limited patient/provider interactions also result in insufficient documented evidence to support treatment decisions and provide litigation protection.

INTRODUCTION

- A mobile health (mHealth) platform has been developed by PainScript[1] that enhances communication between clinic staff and patients and improves outcomes.
- The mHealth platform is innovative in its focus on practice management, providing a patient-monitoring capability between in-office visits.
- This capability provides support for adherence with treatments (pharmacologic and nonpharmacologic) and early detection of adverse events.
- Most pain apps introduced in recent years have focused on the physical characteristics of pain, and few have supported clinician access to real-time pain data and patient adherence.[2]

1. PainScript, a subsidiary of Optimum Healthcare, Washington DC
2. Zhao P, Yoo I, Lancey R, Varghese E. Mobile applications for pain management: an app analysis for clinical usage. *BMC Medical Informatics and Decision Making*. 2019;19(1):106. doi:10.1186/s12911-019-0827-7

METHODOLOGY

- Patients are enrolled in the mHealth platform in the physician's office during scheduled treatment and the mHealth app is installed on their Apple or Android smartphone.
- Each day, patients receive notifications to complete a Daily Check-In which typically consist of three clinically validated questions.
- The mHealth platform provides an automated triages of the patient’s responses, based on expected normative results, with thresholds that can be customized per patient.
- A designated qualified healthcare provider evaluates the responses, escalating the results to the appropriate level of provider for decision making.

METHODOLOGY

Process Flow Diagram

ONBOARDING

- Patients are enrolled in the mHealth Platform
- A monitoring plan is assigned
- The mobile app is installed on the patient's smartphone.

DAILY CHECK-IN

- Each morning, the mobile app notifies the patient that a Daily Check-In is ready
- Periodic reminder notifications are sent until completed
- Patients answer the day's three clinical questions
- Medications reminders are an available option

AUTOMATED TRIAGE

- The platform triages responses, highlighting surveys with out-of-normative range values for prioritized review

SURVEY REVIEW

- All Check-In responses are reviewed by a qualified healthcare provider (QHP)

ESCALATION

- If follow-up is needed, Check-Ins may be escalated to the appropriate level of clinician for decision making

METHODOLOGY

- Medication adherence is self-assessed by patients reporting metrics such as when they (1) take all meds as described and (2) are not taking meds not prescribed.
- Other measures, such as pain levels, feelings of anxiety or depression, fatigue and cravings are based on standard 0 – 10 scales.
- Data collection began in November 2021 and has continued to the present. No results have been excluded.
- Regardless of *when* an individual response was collected, the data is normalized to when the answer was received relative to when they enrolled (e.g., their first week in the program, their fifth week, etc…)
- Responses from weeks 1 & 2 were used as the baseline.

METHODOLOGY: STATISTICAL APPROACH

- A linear trend in means across the 6 two-week intervals was tested using a simple time series analysis.[3]
- This analysis fit an ordinary least squares linear regression through the means observed for the 6 intervals, while adjusting for auto-correlation up to some lag[4,] specifying the number of required lags identified by the Cumby-Huizinga general test for autocorrelation.[5]
- There was a statistically significant linear trend across the 12-week time period for all outcomes except cravings.
- Cravings had a downward trend over time, but the pattern was more cyclic than linear, as can be seen in the Table 5 and Figure 1.

3. Linden A. Conducting interrupted time-series analysis for single- and multiple-group comparisons. *Stata J* 2015;15(2):480-500.
4. Newey WK, West KD. A simple, positive semi-definite, heteroskedasticity and autocorrelation consistent covariance matrix. *Econometrica* 1987;55:703–708.
5. Cumby RE, Huizinga J. Testing the autocorrelation structure of disturbances in ordinary least squares and instrumental variables regressions. *Econometrica* 1992;60:185–195.

RESULTS

- Through June 30, 2022, patients provided more than 55,000 individual daily clinical responses to their physicians in diverse locations across the United States.

- Through 12 weeks, patients achieved a 99.8% adherence to their prescribed medication regime – including taking/not taking prescription and non-prescription medications as directed.

- The following measures were examined to determine the change over time in the five tested values from the baseline through Week 12:

    - Reported levels of Pain
    - Reported levels of Fatigue
    - Reported levels of Depression
    - Reported levels of Anxiety
    - Reported levels of Cravings

RESULTS: REPORTED LEVELS OF PAIN*

TABLE 1	WEEKS 1-2	WEEKS 3-4	WEEKS 5-6	WEEKS 7-8	WEEKS 9-10	WEEKS 11-12
Avg Pain Scale	5.91	5.76	5.65	5.65	5.64	5.61
# Responses	2,268	2,527	2,636	2,621	2,421	2,301

IMPROVEMENT FROM BASELINE	REGRESSION COEFFICIENT (MEAN CHANGE PER 2 WEEKS)	95% CONFIDENCE INTERVAL	LINEAR TREND *p* VALUE
5.5 %	-0.05	(-0.09 , -0.01)	.022

* Standardized pain scale with “0” representing no pain at all and “10” representing the worst pain imaginable

RESULTS: REPORTED LEVELS OF FATIGUE

TABLE 2

	WEEKS 1-2	WEEKS 3-4	WEEKS 5-6	WEEKS 7-8	WEEKS 9-10	WEEKS 11-12
Avg Fatigue Scale	4.05	3.82	3.88	3.77	3.65	3.53
# Responses	593	659	694	661	616	557

IMPROVEMENT FROM BASELINE	REGRESSION COEFFICIENT (MEAN CHANGE PER 2 WEEKS)	95% CONFIDENCE INTERVAL	LINEAR TREND *p* VALUE
13 %	-0.09	(-0.12 , -0.07)	.001

* Standardized fatigue scale with “0” representing no fatigue at all and “10” representing complete exhaustion

RESULTS: REPORTED LEVELS OF DEPRESSION

TABLE 3	WEEKS 1-2	WEEKS 3-4	WEEKS 5-6	WEEKS 7-8	WEEKS 9-10	WEEKS 11-12
Avg Depression Scale	2.14	1.95	1.91	1.76	1.81	1.74
# Responses	728	806	866	864	785	747

IMPROVEMENT FROM BASELINE	REGRESSION COEFFICIENT (MEAN CHANGE PER 2 WEEKS)	95% CONFIDENCE INTERVAL	LINEAR TREND *p* VALUE
19 %	-0.07	(-0.11 , -0.03)	.007

* Standardized depression scale with “0” representing no depression at all and “10” representing the most complete level of depression imaginable

RESULTS: REPORTED LEVELS OF ANXIETY

TABLE 4	WEEKS 1-2	WEEKS 3-4	WEEKS 5-6	WEEKS 7-8	WEEKS 9-10	WEEKS 11-12
Avg Anxiety Scale	2.86	2.57	2.35	2.24	2.19	2.07
# Responses	586	656	696	667	620	561

IMPROVEMENT FROM BASELINE	REGRESSION COEFFICIENT (MEAN CHANGE PER 2 WEEKS)	95% CONFIDENCE INTERVAL	LINEAR TREND *p* VALUE
28 %	-0.15	(-0.21 , -0.09)	.002

* Standardized anxiety scale with “0” representing no anxiety at all and “10” representing the highest level of anxiety

RESULTS: REPORTED LEVELS OF CRAVINGS

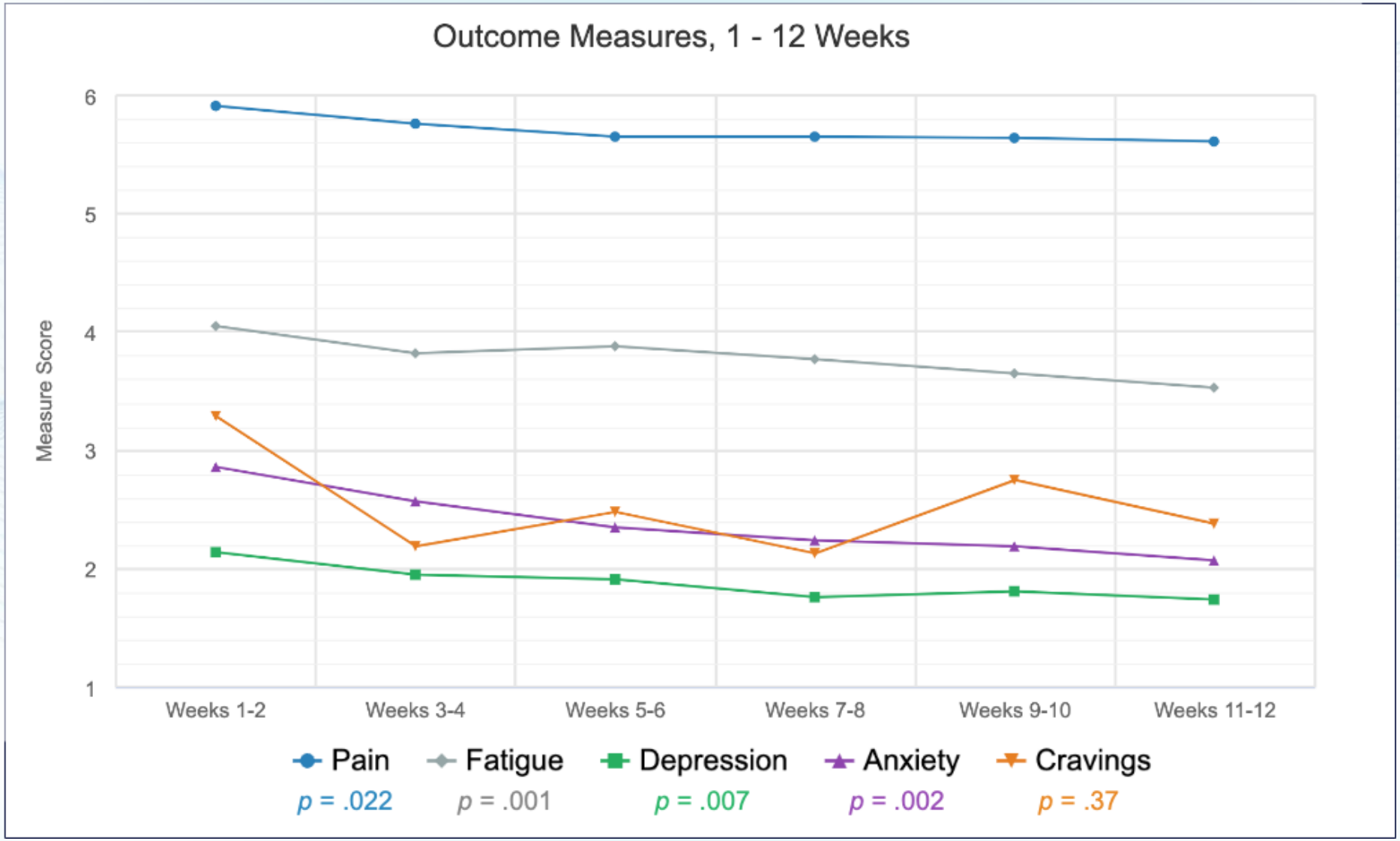
TABLE 5	WEEKS 1-2	WEEKS 3-4	WEEKS 5-6	WEEKS 7-8	WEEKS 9-10	WEEKS 11-12
Avg Cravings Scale	3.29	2.19	2.48	2.13	2.75	2.38
# Responses	69	48	66	67	48	13

IMPROVEMENT FROM BASELINE	REGRESSION COEFFICIENT (MEAN CHANGE PER 2 WEEKS)	95% CONFIDENCE INTERVAL	LINEAR TREND *p* VALUE
28 %	-0.09	(-0.34 , -0.16)	.37

* Standardized craving scale with “0” representing no cravings at all and “10” representing uncontrolled cravings for inappropriate behaviors

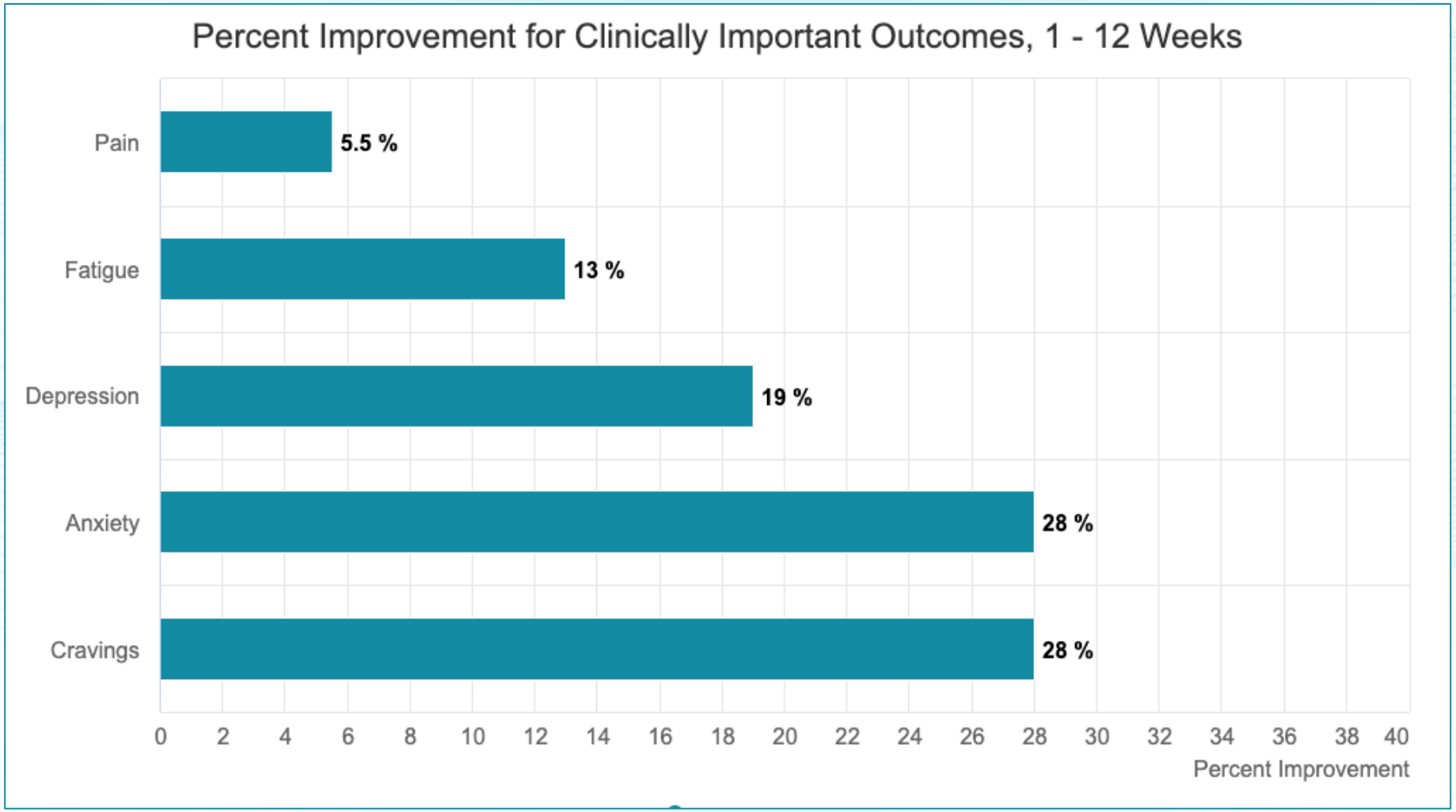
RESULTS: OUTCOMES IMPROVEMENT, 1 – 12 Weeks

TABLE 1



RESULTS: OUTCOMES IMPROVEMENT, 1 – 12 Weeks

TABLE 2



CONCLUSIONS

- Preliminary observational data suggests that mHealth telehealth technology can improve patient care through increased treatment plan compliance and medication adherence.
- The platform appears to improve patient treatment maintaining a treatment protocol in the gap that occurs between office visits.
- Improving physician-patient communication and patient monitoring may reduce the risk of opioid misuse and addiction and provide clinicians with information that can help differentiate addiction from tolerance and physical dependence.[6]
- The mHealth platform may also provide the practice a means to be compensated by payors for the time and expertise of providing daily contact with patients
- The documentation in the mHealth platform is compliant with “Ruan vs. U.S.” and may serve as a safeguard against legal liability due to enhanced communication and affirmative documentation.

6. Volkow ND, McLellan AT. Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies. *New England Journal of Medicine*. 2016;374(13):1253-1263. doi:10.1056/NEJMra1507771

DISCLOSURES

- Dr. Webster, Mr. Cashon, Dr. Gudin and Dr. Argoff are PainScript stockholders