MOBILE HEALTH TECHNOLOGY AND PAIN MANAGMENT

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INTRODUCTION

- Chronic pain imposes a significant burden on individuals and society.
- Adherence to treatment protocols and medication regimens is a key contributor to patient safety and treatment effectiveness.
- The ability to more closely monitor patients to ensure adherence and safety requires time and reimbursement to support increased workload
- Limited patient/provider interactions can result in insufficient documentation to support treatment decisions and provide litigation protection.

INTRODUCTION

- A mobile health (mHealth) platform to improve clinical outcomes has been developed by PainScript[1] that enhances communication between clinic staff and patients.
    - The mHealth platform is innovative in its focus on practice management, providing a patient-monitoring capability between in-office visits.
- 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]
- This technology provides support for adherence with treatment (pharmacologic and nonpharmacologic) and early detection of adverse events.

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 Med Inform Decis Mak*. 2019;19(1):106. doi:10.1186/s12911-019-0827-7.

OBJECTIVE

Using the mHealth platform, use patient self-reported data to:

- Assess clinically important changes in pain, 1-12 weeks
- Assess clinically important changes in fatigue, 1-12 weeks
- Assess clinically important changes in depression, 1-12 weeks
- Assess clinically important changes in anxiety, 1-12 weeks
- Assess clinically important changes in cravings, 1-12 weeks.

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 consists of three clinically validated questions.
- The mHealth platform provides 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 whether they take all meds as 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.
  - Daily patient self-reported data was the source for all analysis
  - All patient responses were included; there were no exclusion criteria

- 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 are 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]

3. Linden A. Conducting interrupted time-series analysis for single- and multiple-group comparisons. *Stata J.* 2015;15(2):480-500. doi: 10.1177/1536867X1501500208.
4. Newey WK, West KD. A simple, positive semi-definite, heteroskedasticity and autocorrelation consistent covariance matrix. *Econometrica.* 1987;55:703–708. doi: 10.2307/1913610.
5. Cumby RE, Huizinga J. Testing the autocorrelation structure of disturbances in ordinary least squares and instrumental variables regressions. *Econometrica.* 1992;60:185–195. doi: 10.2307/2951684.

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 regimen – including taking/not taking prescription and non-prescription medications as directed.
- 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.

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

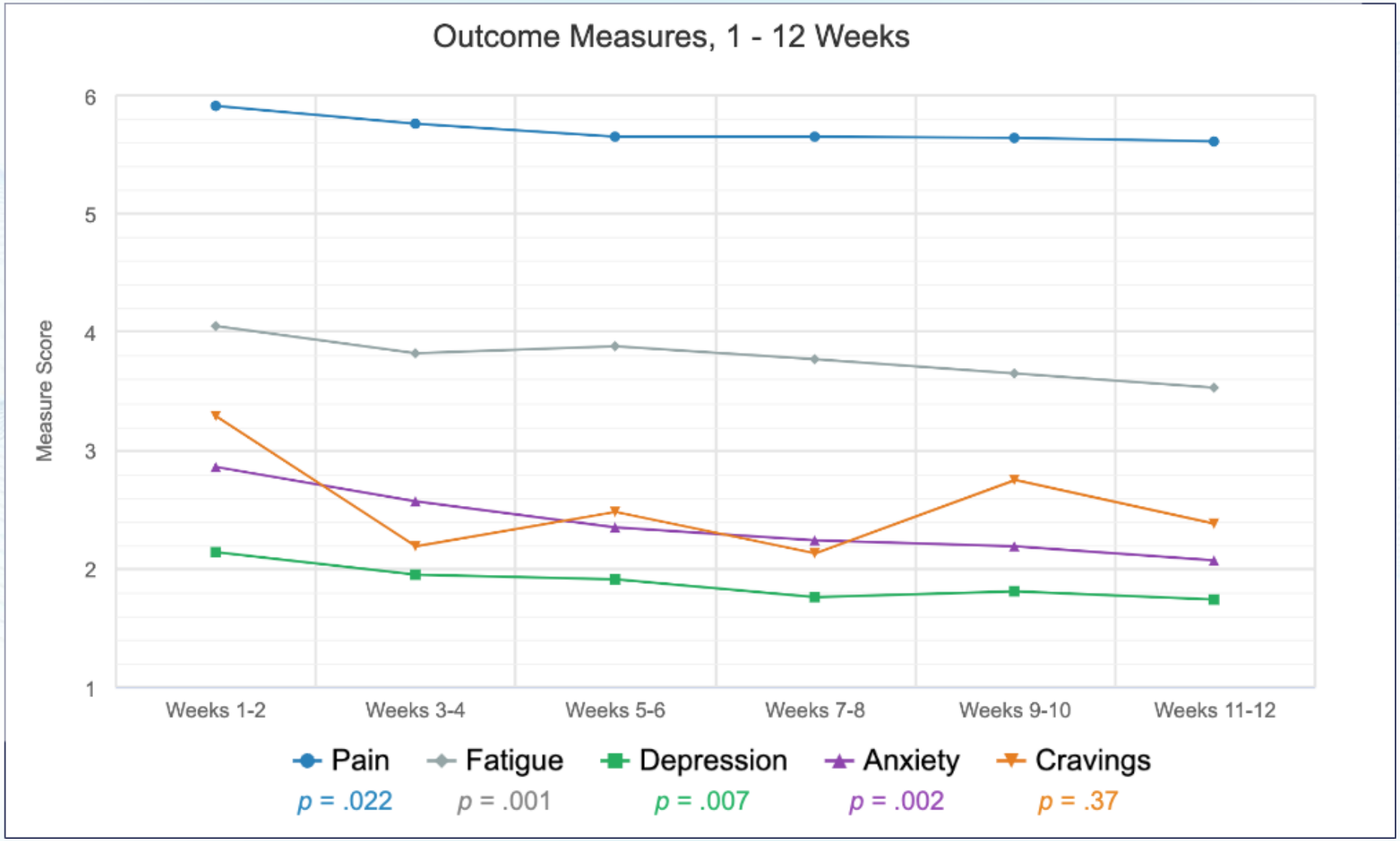
TABLE 5	WEEKS 1-2	WEEKS 3-4	WEEKS 5-6	WEEKS 7-8	WEEKS 9-10	WEEKS 11-12
Avg Cravings Scale	3.29	2.19	2.48	2.13	2.75	2.38
# Responses	69	48	66	67	48	13

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

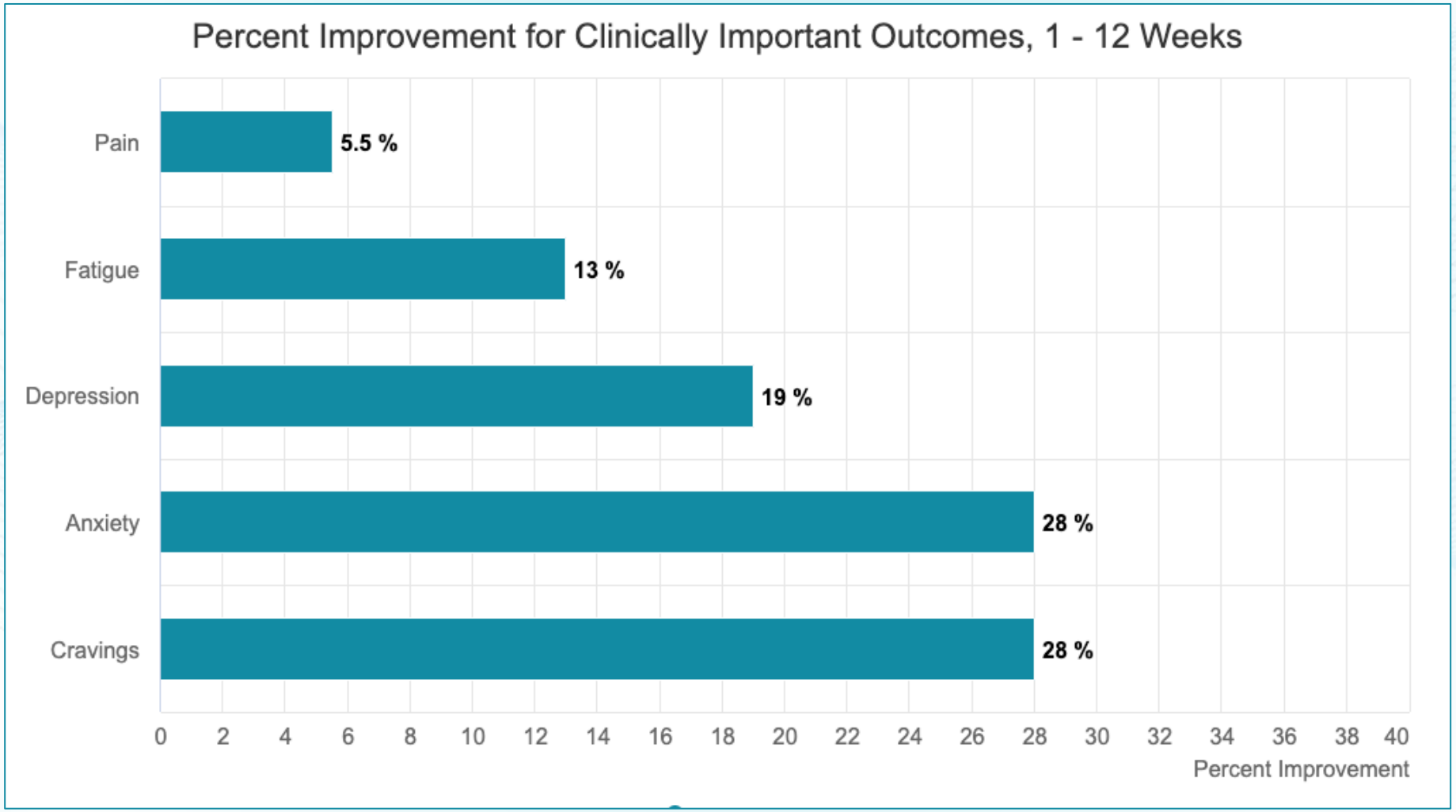
RESULTS: OUTCOMES IMPROVEMENT, 1 – 12 Weeks

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/provider interaction 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 substance use disorders 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. *N Engl J Med*. 2016;374(13):1253-1263. doi:10.1056/NEJMra1507771.

REFERENCES

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DISCLOSURES

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

- The Observation Study relied on data reported to PainScript and all costs associated with the review and publication of the data were borne by PainScript.