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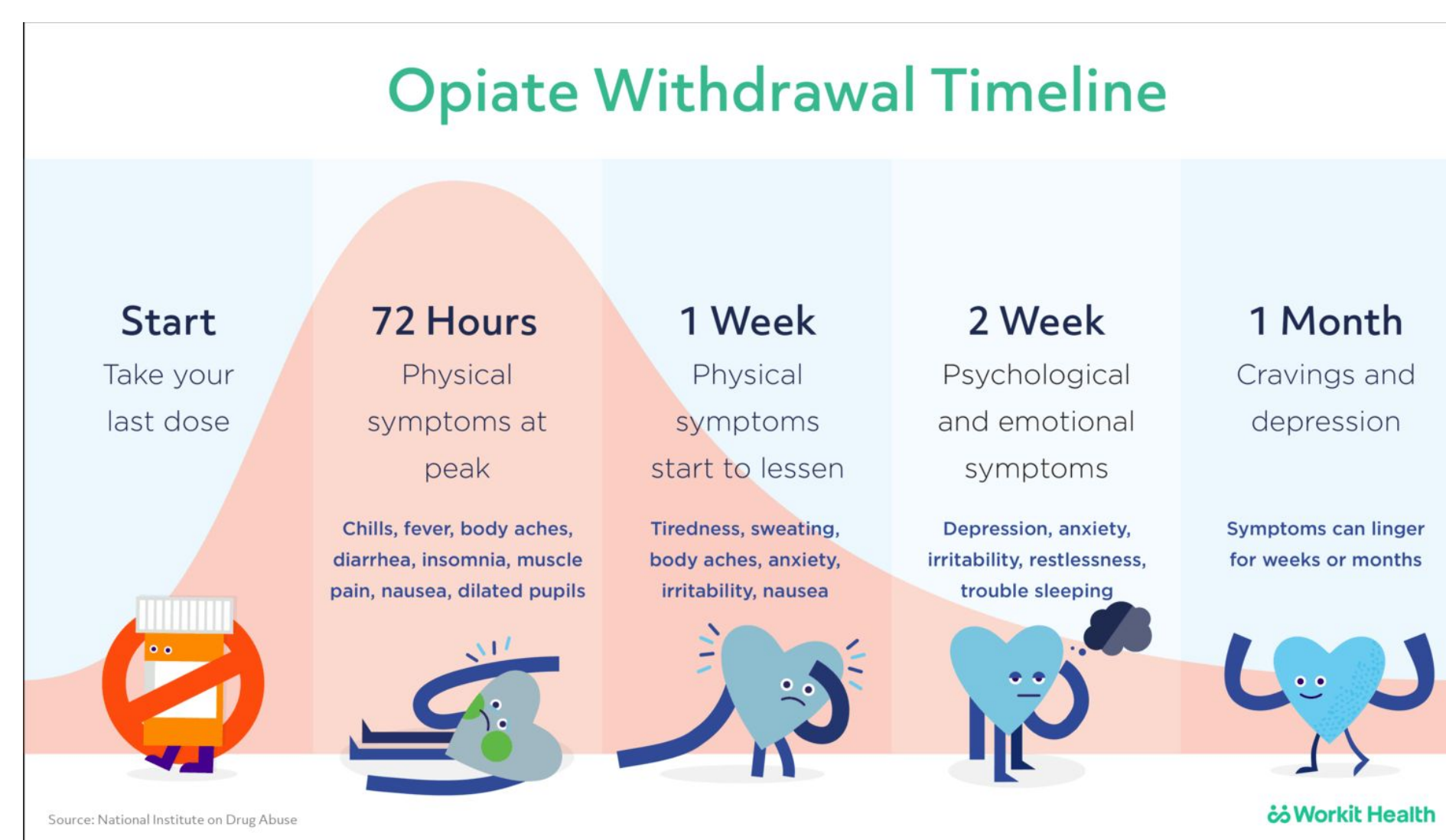
## Background

- Opiate addiction is an **EPIDEMIC**<sup>1</sup>
- Over 100 Americans die daily from an opioid overdose<sup>1</sup>
- Leads to a massive economic burden<sup>2</sup>
- Increasing healthcare costs and unemployment rates
- Can tear families apart
- Consequences can cost up to 3% of the GDP<sup>3</sup>
- Withdrawal has **SEVERE** physiological impact

**Clinical Opiate Withdrawal Scale (COWS)**  
Flow-sheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptoms. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Resting Pulse Rate: (record beats per minute) Measured after patient is sitting or lying for one minute					
0 pulse rate 80 or below					
1 pulse rate 81-100					
2 pulse rate 101-120					
3 pulse rate greater than 120					
Swearing, over past 12 hours not accounted for by room temperature or patient activity:					
0 no report of chills or flushing					
1 subjective report of chills or flushing					
2 flushed or observable moisture on face					
3 beads of sweat on brow or face					
4 facial flushing off face					
Restlessness Observation during assessment					
0 able to sit still					
1 reports difficulty sitting still, but is able to do so					
2 frequent shifting or extraneous movements of legs/torso					
3 Unable to sit still for more than a few seconds					
Pupil size					
0 pupils pin-point or normal size for room light					
1 pupils possibly larger than normal for room light					
2 pupils moderately dilated					
3 pupils so dilated that only the rim of the iris is visible					
Bone or Joint aches If patient was having pain previously, only the additional component associated to opiates withdrawal is scored					
0 not present					
1 mild diffuse discomfort					
2 patient reports severe diffuse aching of joints/muscles					
3 patient is rubbing joints or muscles and is unable to sit still because of discomfort					
Runny nose or tearing Not accounted for by cold, symptoms or allergies					
0 not present					
1 nasal stuffiness or unusually moist eyes					
2 nose running or tearing					
3 nose constantly running or tears streaming down cheeks					



## Goals

- Build a system that could be used to determine if this approach would be equivalent to doing the scale on paper
- Design a user-friendly system that can evaluate opiate withdrawal

## Objectives

- Develop a one platform system where the data from all sensors comes together for evaluation
- Gather sensors or ways to measure all 11 symptoms on the opiate withdrawal scale
- Determine if the system is cost effective, user-friendly, and timely through research and testing

## Criteria

- The device needs to measure and quantify the majority (at least 5) of the items measured by the current COWS system
- These measurements must fall below a 15% error rate in order to provide patients with accurate information
- The device must have a system to receive the data from sensors to process, and interpret it for an output

## Constraints

- Final design should be low-cost
- Device should be safe
- Device should also be comfortable and easy to use

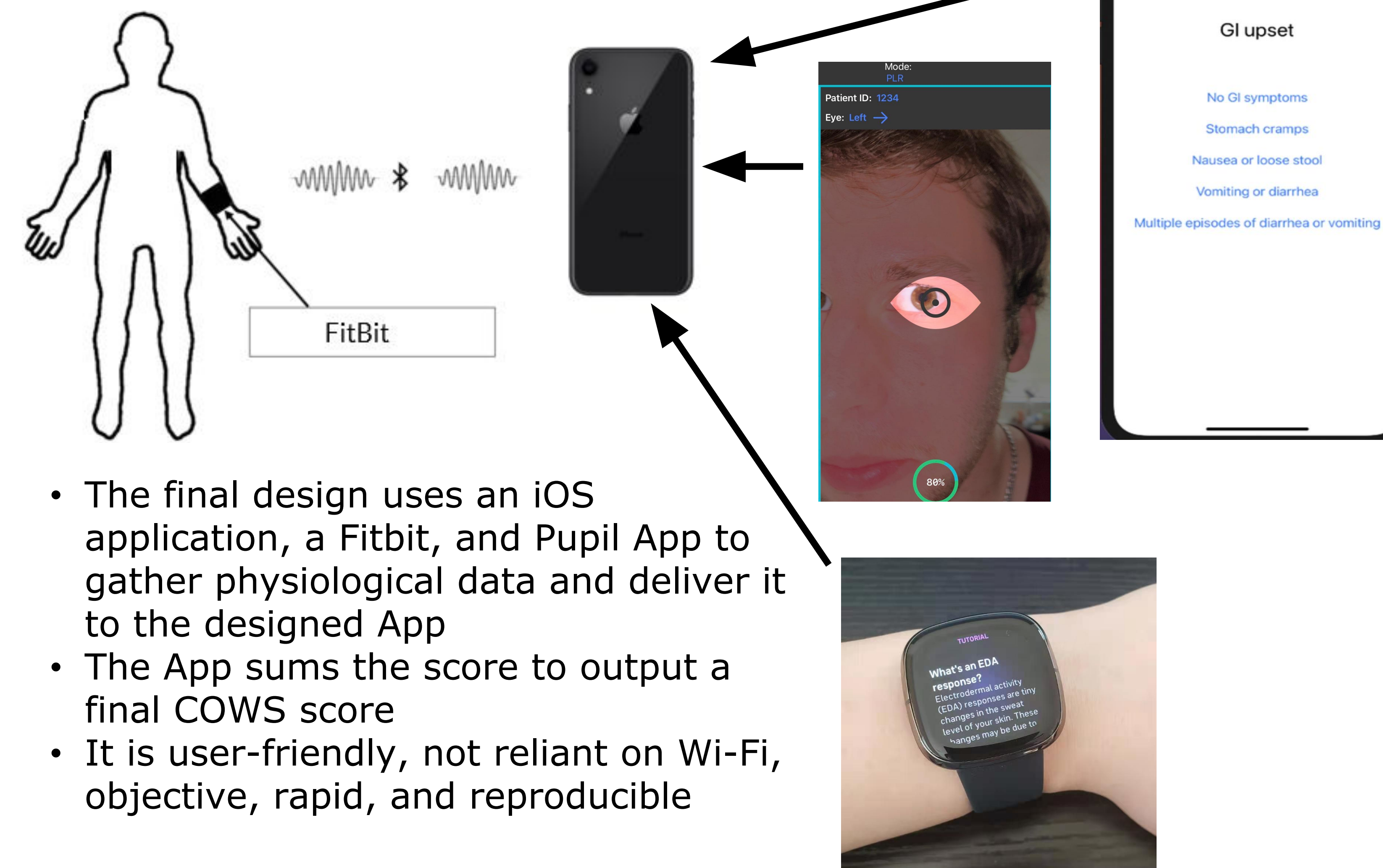
## Standards

- ISO 13485:2016
- ISO 10993-1:2018
- ISO 9001:2015
- IEC 62366-1:2015

## Problem Statement

Currently, the Clinical Opiate Withdrawal Scale (COWS) is used by physicians to evaluate opioid withdrawal. This pen-and-paper assessment is frankly outdated, and in need of a more immediate, objective electronic assessment for clinical use: an electronic Clinical Opiate Withdrawal Scale (eCOWS). A user-friendly iOS app can accomplish this goal, with a graphic user interface that can seamlessly monitor different physiological effects based on the clinical opiate scale in real-time with help from wearable sensors, then communicate back to the physician a final score indicating the level of withdrawal the patient is experiencing.

## Final Design Solution



- The final design uses an iOS application, a Fitbit, and Pupil App to gather physiological data and deliver it to the designed App
- The App sums the score to output a final COWS score
- It is user-friendly, not reliant on Wi-Fi, objective, rapid, and reproducible

## Steps to Use System

- Attach Fitbit to patient
- Open eCOWS iOS App on iPhone
- Proceed through assessment
- Assessment includes subjective questions to answer, input from Pupil App, and input from Fitbit
- eCOWS App calculates withdrawal score using all sources of input
- Doctor/nurse acts according to score to serve patient going through withdrawal

## Economic Cost Analysis

Component	Cost
Fitbit Sense	\$347.44
Pupil Diameter App	Free
Apple iPhone 8 64gb	\$173.99
App Development/User Training	--
<b>Total</b>	<b>\$521.43</b>

## Ideal Way to Measure Symptoms

COWS Symptom	Measurement
Resting pulse rate	Fitbit PPG
Sweating	Fitbit Skin Temperature <sup>4</sup>
Restlessness	Fitbit or iPhone Accelerometer
Pupil size	Pupil Size App
Bone or joint aches	Questionnaire
Runny nose or tearing	Questionnaire
GI upset	Questionnaire
Tremor	Fitbit Accelerometer
Yawning	Fitbit PPG <sup>5</sup>
Anxiety or irritability	Fitbit EDA Stress Tracker
Goosebump skin	Fitbit Skin Temperature <sup>6</sup>

## Threshold Example: Pupil Size

- Normal pupil size for room light
- 4mm (+0 in assessment)
- Slightly larger than normal
- 5mm (+1 in assessment)
- Pupil dilated
- 6-7mm (+2 in assessment)
- Pupil severely dilated
- 8-9mm or greater (+5 in assessment)

## Future Work

The goal of this project in the future is to transmit data from the Fitbit to iPhone application in real-time with set automated thresholds that could contact the physician if the summed score is greater than 36. In the end, research and development of the application should be continued to create a more objective, rapid, and continuous eCOWS system.

## Acknowledgements

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