# Recap PCA

Process Book 2018

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# Executive Summary

In this project, my team explored how to build an opioid dispenser to help manage post-operative pain medication. Over the course of three months, we researched, designed, tested and built a final prototype for a future device that users could rent after a surgery.

# The Team

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*Special Thanks To*

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# Timeline

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Week 1-2

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# Objective

- To design and prototype a way for patients to better manage their post-operative pain medication.
- Currently there is an opioid misuse epidemic in the United States that is impacting many lives, but opioids are often an important part of the healing process after surgery. Doctors need more information on how to make prescriptions to curb abuse, and patients need to feel and be safer while taking their dosages.
- How can we support and improve mindful and data-informed post-operative pain management to maximize patient comfort while deterring medication abuse?

# 1. Research

- Literature Review
- User Interviews
- Competitive Analysis
- Design Considerations

- The goal of this milestone was to gain a greater understanding of the context of our problem. In designing a product, it's essential to understand what the specific pain points are in the current system and utilize the gathered information to build a list of design considerations for when we begin ideating the product.

# Literature Review

- Read and summarized 9 articles pertaining to the current problem of the opioid epidemic
- Synthesized information to understand the situation around current pain management systems, medical devices and user interactions
- Conclusions:
  - Users want a device that isn't obviously medical
  - The closest analogy existing right now is the IV-PCA, which patients use in the hospital, but there available at home for similar use.
  - Device has to be very simple and easy to use/intuitive including error recovery

# Interviews

- Sent out a survey to find people who had taken opioids after a surgery in the past few years
- Wanted to better understand the process of taking medication after a surgery
- Interviewed 6 people of an age range from 20-80 years old
- In-Person and Over the Phone

| | Demographics | Behaviours | Goals |
|---|---|---|---|
| P1 | Retired OB/GYN | Experience prescribing, used adjuncts, doctor's perspective | Reduce opioid dependence as soon as possible |
| P2 | Retired General Practitioner | Aware of addiction risk, closely tracked use, increased adjunct use | Reduce opioid dependence as soon as possible |
| P3 | Retired Orthopaedic Surgeon | Aware of addiction risk, closely tracked use, increased adjunct use | Reduce opioid dependence as soon as possible |
| P4 | Retired, 75 y/o | Had trouble opening pill bottle, had trouble returning pills to pharmacy | Return extra pills to pharmacy |
| P5 | University student, early 20s, family history of opioid abuse | Closely monitored by family members, did not know how to dispose of excess opioids | Manage pain with as little opioid use as possible |
| P6 | University student, early 20s | Actively tried not to use opioids | Manage pain with as little opioid use as possible |
| P7 | 56 y/o Dental Assistant, knee surgery | Active research on opioids beforehand, attended a pain management class | Reduce opioid dependence as soon as possible |

# Competitive Analysis

- While there isn't anything currently on the market for post-operative pain medication or opioids, there are current pill dispensers on the market
- Evaluated 12 different current systems to see what they do and what works or doesn't work
- Major Takeaways:
  - All Expensive
  - Either focus on complicated long term prescriptions or just storage
  - Main goal was Pill Adherence

| Device Name | Application | Protected? | Connected? | Size | Price | Notifications | Programming, Extras | Storage |
|---|---|---|---|---|---|---|---|---|
| HERO Health | Smart table-top dispenser for daily medications and vitamins | Locked and password-protected | Device connected to WiFi and HERO phone app | Coffee maker | $599 purchase<br>No rentals | Sound (chimes) from device<br>Text alert when dose is taken | ? | Pills loaded in cartridges by type<br>Holds 10 different pill types<br>Any size/shape |
| Livi at Home | Smart table-top dispenser for drug adherence | ? | Device connected to Livi Cloud<br>Plugged, has 6-8 hr battery | Large coffee maker<br>13+ pounds | $99 monthly rental<br>$2,000 purchase | Interface glows green at dose time, recognizable beep<br>Text alerts | Programmed via web portal<br>Can dispense portable travel packs (up to 14 days of meds) | Up to 15 medications<br>Any size/shape<br>Dispenses up to 24x daily |
| Philips Automated Medication Dispensing service | Medium-sized table-top dispenser for drug adherence, meant for Seniors | Cabinet is locked | Rechargeable battery (18 hours) | Large coffee maker | $99 one-time installation plus $50 monthly rental | Connected to telephone line<br>Audio reminder | Philips programs the device once you provide them with a dose schedule | Dispenses up to 6x daily<br>Holds up to 40 days of medicines<br>Each medicine loaded into cups |
| AiCure | Artificial intelligence smartphone application for drug adherence in clinical trials | HIPAA-compliant facial recognition | (Platform is smartphone app) | N/A | ? | Phone notification, pill/facial recognition for dose adherence | ? | N/A |
| Catalia Health | AI driven robotic | N/A | Plugged | Soccer | ? | Text notifications | Chatbot reminders | N/A |
| "Mabu" | wellness coach (for at-home use) | | Cloud-based, sends real-time data | ball, table-top | | sent by device | confirmed by patient | |
| AdhereTech Smart Wireless Pill Bottles | Smart pill bottles | Encrypted | Sensors, cellular chip send real-time data<br>6+ month battery | Pill bottle | ? | Text, phone call, on-bottle lights/chimes | Data analytics on online dashboard<br>API integration upon request | ? |
| MED-Q Pill Dispenser | Digital double pill-pack | N/A | Double-A battery powered | Alarm clock<br>1" H x 4.5" W x 8.75" L | $70 purchase | "Blasting audio reminders" every 25 min until dose is taken | Online videos for set-up instructions | Each compartment stores 23 full-size Aspirins |
| MedMinder Jon/Maya | Digital pill box with individual compartments for doses | Locked pill dispensers (Jon version) | Cellular connection | 4x7 pill box<br>Size of a small laptop | $40-65 monthly rental | Compartment blinks during dose interval<br>Call/email/text when dose is not taken<br>Medical alert button (optional) | Pre-filled trays can be filled online and shipped to user | Pre-fill tray options |
| PillDrill Kit | Smart-scanning pill packs, bottles, tags and connected hub | ? | Scanned places connect to hub<br>Plugged<br>Wi-Fi enabled<br>Smartphone app | Alarm clock + pill bottles | $280 purchase<br>No rentals | Audio-visual alerts<br>Reminders and dose logging on mobile application | Weekly adherence reports<br>Schedule created on mobile app | ? |
| Pillo Health | Smart counter top dispenser for daily medications and vitamins | Facial recognition<br>Secure pill storage | Connected to WiFi and Bluetooth<br>Plugged, has backup battery | Coffee maker | ? | ? | Managed via Pillo mobile application | Stored within Pillo |
| Pillsy | Smart pill bottles | Child-resistant bottle | Yes, connects to smartphone app<br>Bottle is battery-powered | Pill bottle | $50<br>Price for one pill container | Phone notifications<br>Bottle beeps and blinks<br>Automatic dose-logging when cap is opened/closed | ? | In pill bottle |
| PillPack | Sorted and delivered medications dispensed by dose<br>Roll-out dose dispenser | One dose can be ripped off at a time | 24-hour management and support | Filling box | ?<br>30-day co-pay | Shipment/refill tracking and status emails | Email/Online refill and shipment scheduling<br>Phone support | Short-term medications are not recommended with PillPack<br>Does not handle Schedule II medications (most opioids) |

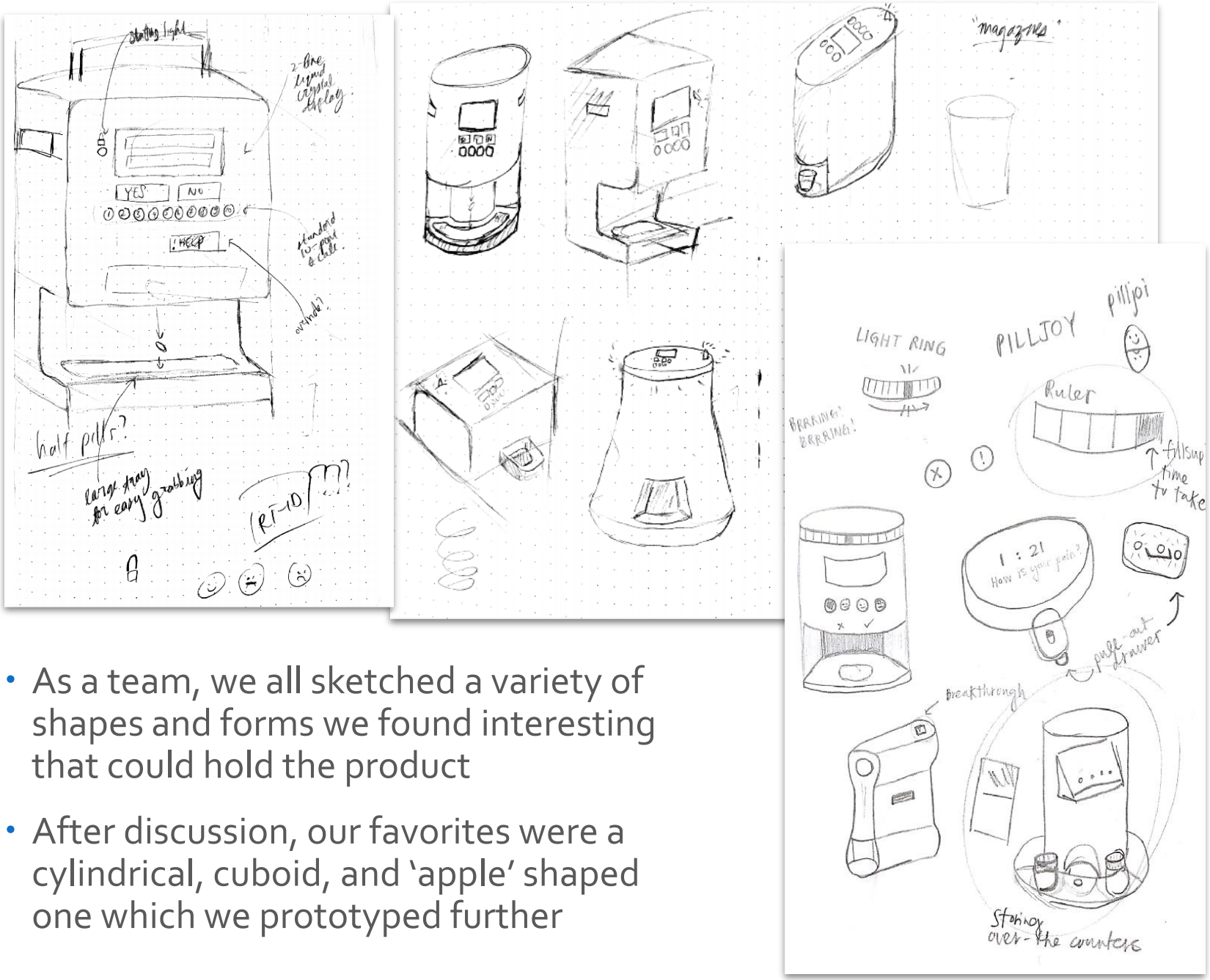
# Design Considerations

- From a synthesis of the above research, we identify the following design requirements. These will guide and constrain our mid-fidelity prototypes in Milestone 2 and beyond.
- Pain must be recorded and rated on a numeric pain scale (NPS) on a 0–3 scale before dose is delivered. Zero indicates no pain, 1 indicates mild pain, 2 moderate, and 3 severe, disabling pain.
- Since the lockout period is designed to prevent overdose, an override option (after a specific amount of time to prevent "stacking" dosages) is acceptable.
- Device should have a wireless connection capability in order to do one or more of the following:
  - Upload the user's recorded pain when they request a dose.
  - Send an alert to pharmacy if too many overrides have been attempted.
- Device will record user-reported pain, time dose delivered, and whether a lockout was overridden locally for any authorized inspection.
- This medical device will be rented from pharmacies to those prescribed opioids and thus needs to be reusable.
- Device needs only to support one medication and user.

# 2. Ideation

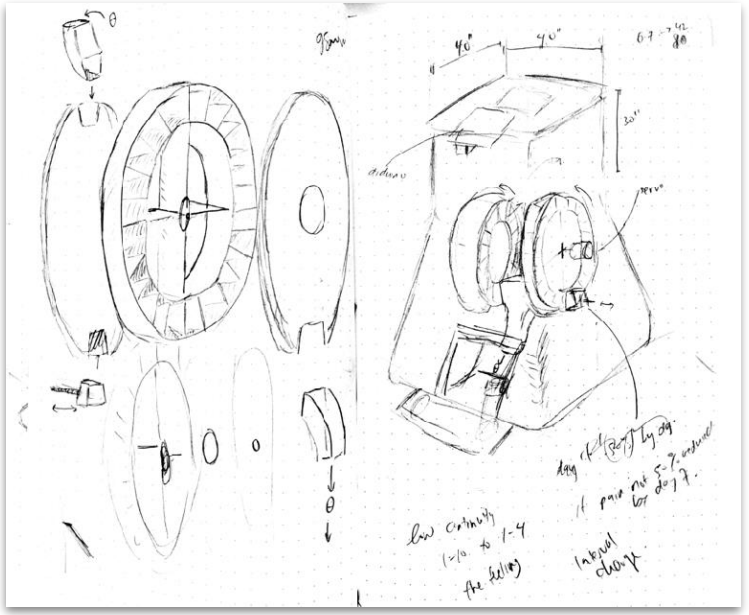
- Now that we had design considerations, we could begin figuring out how to build the device
- We started by sketching and building using simple materials
- 4 major areas:
  - Form Factor
  - Dispensing Mechanism
  - User Flow
  - User Interface

# Form Factor

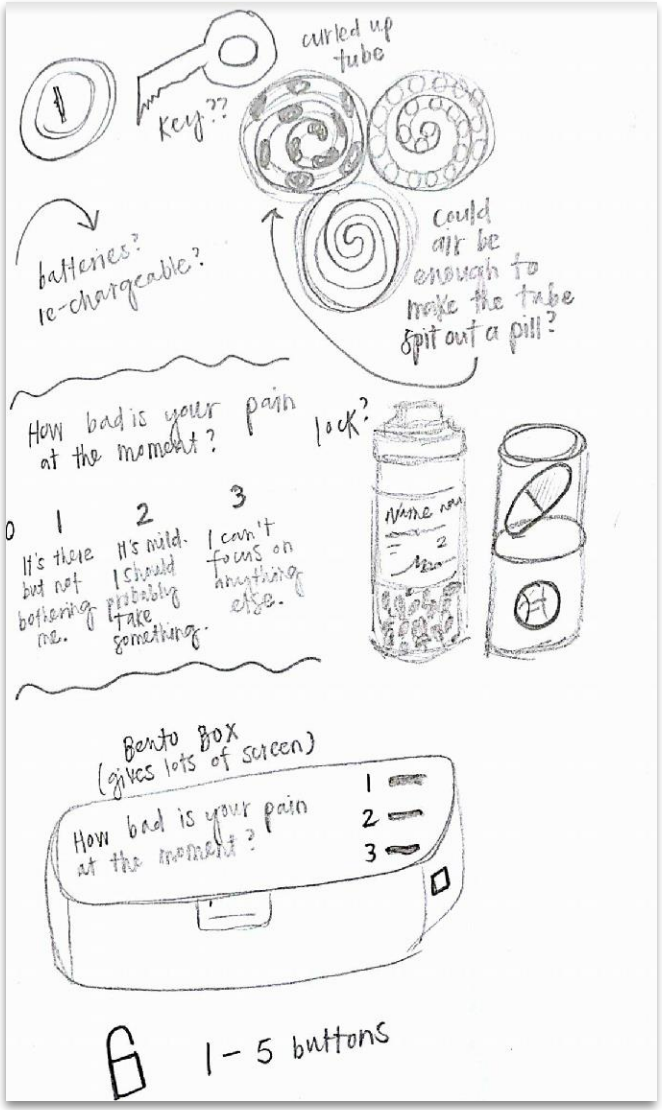



- As a team, we all sketched a variety of shapes and forms we found interesting that could hold the product
- After discussion, our favorites were a cylindrical, cuboid, and 'apple' shaped one which we prototyped further

# Dispensing Mechanism

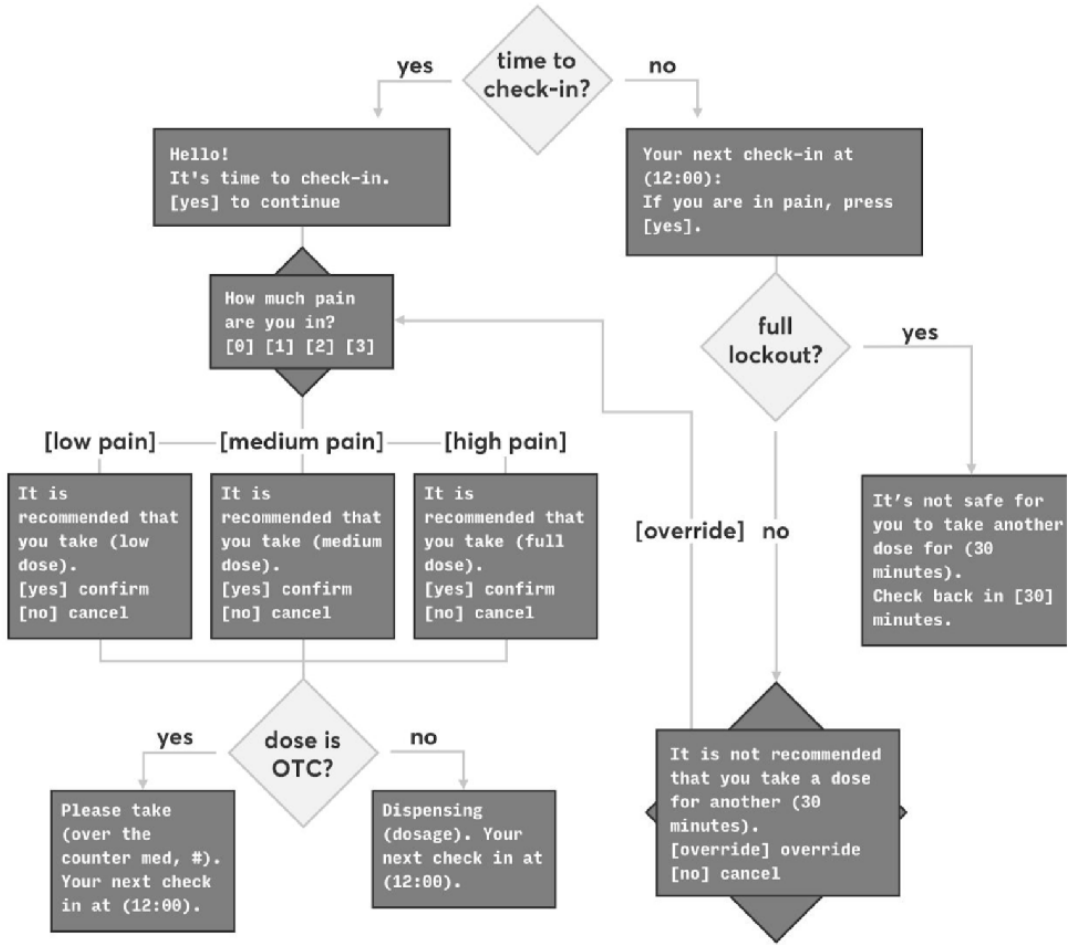


- We knew we wanted the pills to come out of the machine, as opposed to the current system of self-regulated pill bottles. This meant we had to devise a dispensing mechanism. We came up with a variety of ideas, from spirals to slots, and eventually found the simplest and most possible to be an upright wheel.



# User Flow

- The core of our device was a user flow that would determine how each person would utilize the machine
- We simplified the National Pain Scale from 1-10 to a 1, 2, 3 rating level
- Based on their pain level, they would be given an appropriate dose
- User could override and ask for more medication after a lockout (the time when it was unsafe to take multiple doses)



# Interface

- The main goals of the interface was that it would be easy to use and extremely clear
- Not only would a medical device have to be very easy to understand, people would be using this after surgery when potentially confused or in pain
- The goal was to be friendly without swaying the user to make certain choices so they don't feel 'manipulated' by the machine
- We experimented with buttons for the pain levels: 0-3, verbal or faces

| Original Prompt | Augmented Prompt | Rationale |
|---|---|---|
| *It's time for your dose/medication.* | It's time to check in. | Routine doses will abruptly miss the point of gently stepping a user off prescription pain medication. Instead, the device will prompt for a user to check in, mirroring the behavior of a nurse making routine rounds to gauge pain management. |
| *How are you feeling right now?* | How would you rate your pain? | Since we are utilizing a 0-3 Numeric Pain Scale (NPS), prompts for pain critique should be numeric to reflect the discrete nature of this data. |
| *I can't give you more medication.* | It's not safe to take another pill for [x] minutes. | The device should always make the user feel in control. Safety warnings reflect this nature. |
| *I'm giving you half a dose for a pain level of [x].* | It is recommended that you take [x] pills. | The device should always make the user feel in control. Dose recommendations reflect this nature. |

# 3. Iteration

- Now that we had our research completed and had developed some ideas, we had to build and test these on our way to the final prototype
- The main facetsthis were building our prototypes and conducting User Testing

# User Testing

- We tested 10 people from a variety of backgrounds with an age range of 20-75
- Was given two scenarios and asked to navigate the user flow for each
- Then showed the form factor and asked for feedback on what they thought
- This was incredibly vital because we were able to see how they interacted with the device and what the problems were
- Major issues:
  - Error recovery (more with younger users)
  - Issues with the interface

## Scenarios: Check-in Scenario

Scenario:

Your device beeps. It wants to know your current level of pain.

You're feeling ok but it's a little hard to focus. You still need to

check-in with the device.

Prompt:

Check-in and choose an over-the-counter medication.

## Scenario 2: Non-Check-in Scenario

Scenario:

You wake up in the morning earlier than your alarm because pain

from your surgery woke you up.

A device check-in will not occur for another 2 hours.

Prompt:

Interact with the device to get it to dispense an opioid to manage

your pain.

# Form Factor

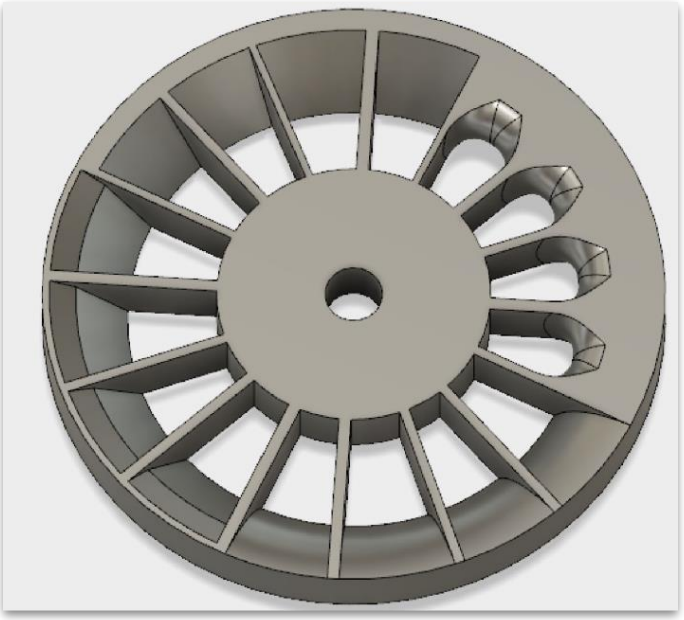
Our first form factor was a cuboid device with rounded edges. This housed the dispensing mechanism with room for the Arduino, had a flat top to store the screen and buttons, and a large square mouth for easy pill accessibility.

It was made of cardboard, then modeled in Fusion 360, then 3D printed and used for User Testing.

Users found the opening to be wide enough but the size large and unfriendly. They suggested lighter colors and more rounded edges.

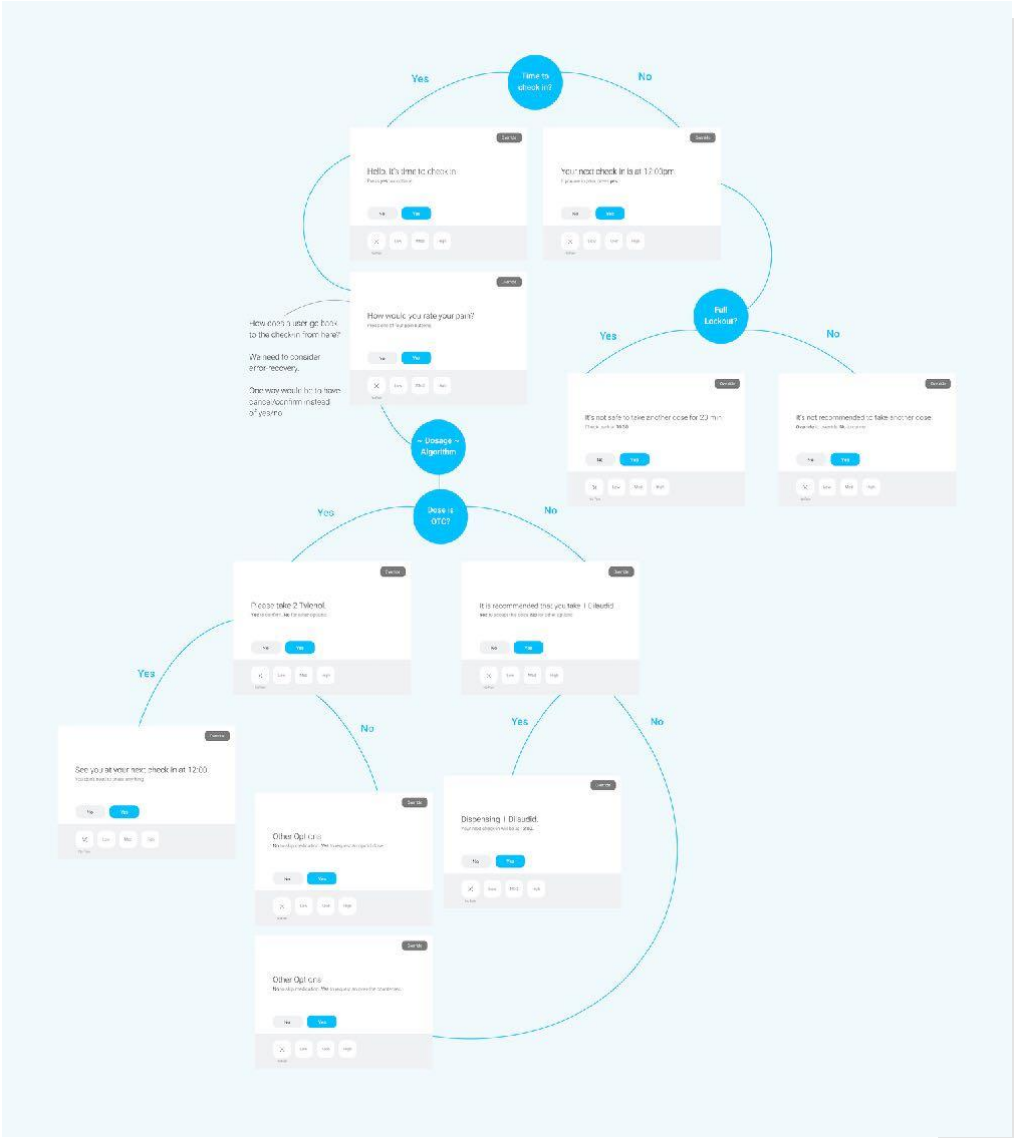
# Dispensing Mechanism

- One of the major aspects of our wheel was an angled edge so the pills could fit and slide out when appropriate without any extra pushing mechanism
- We tested a variety of edges, angles and sizes with different sized pills to determine the final wheel format that would fit a multitude of pills well
- The designs were modeled in Fusion 360 and then 3D printed
- We tested the mechanism to ensure it was very consistent, as users wanted a device that works



# User Flow and Interface

- The user flow needed significant iteration
- Users had no form of error recovery
- Many didn't like the way the machine 'controlled' what they took and tried to game the system
- The physical buttons were confusing
- Prescriptions are currently not given based on pain level. We need to focus on tracking both and letting the user make their own choices

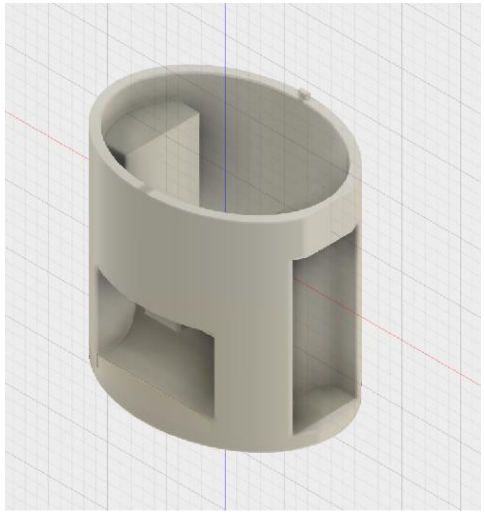


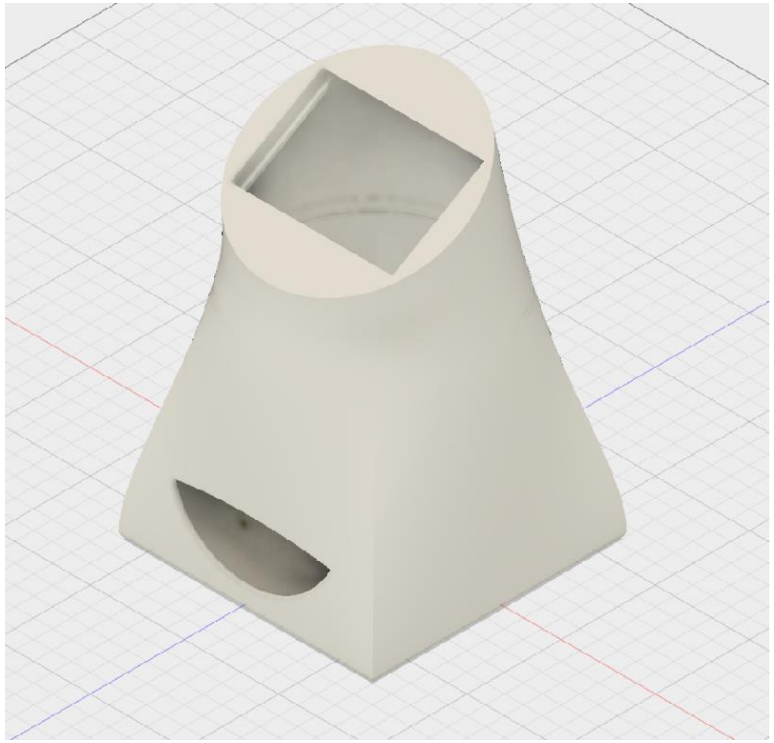
# 4. Final Prototype

- With our user testing data and iterations, we were ready to begin building our final prototype

# Form Factor

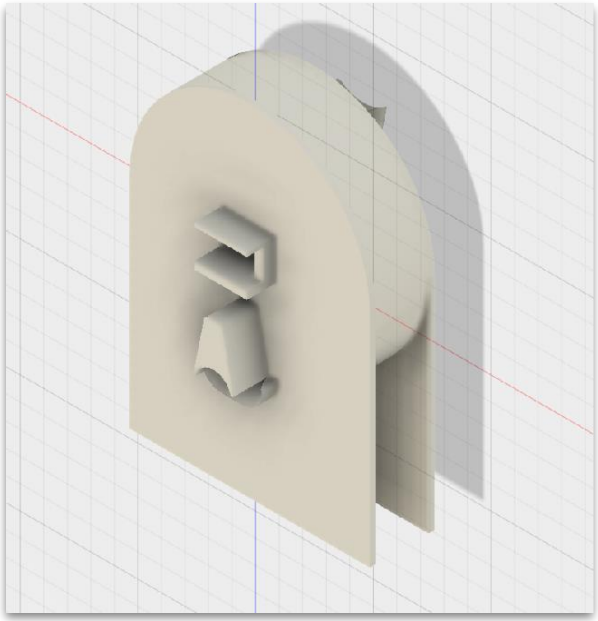
- The user feedback wanted a device that was rounder and friendlier
- We had an idea for a device that had an opening for a cup to be inserted that would be easier to clean, and have side pockets for holding bottles of Over-The Counter Medication (top)
- Our final design incorporated a sleeker model with an angled lid holding a touch screen that could easily be easily accessed
- The final design was easy to hold and interact with. The square base is stable and the overall form is unique.

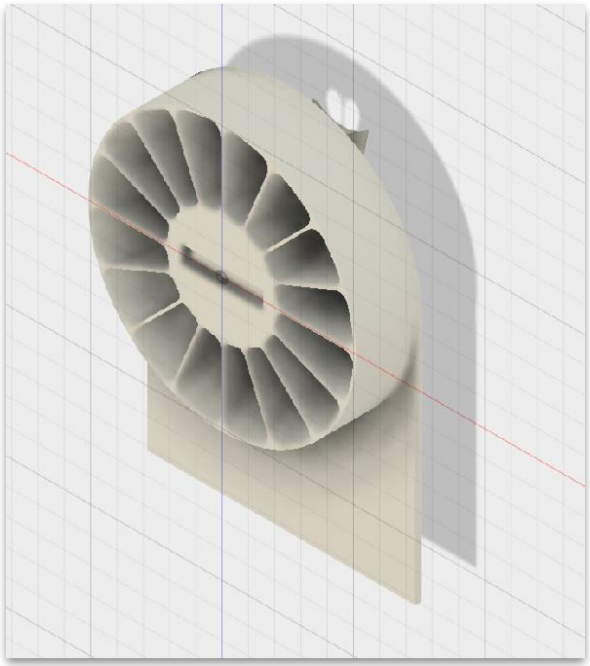




# Dispensing Mechanism

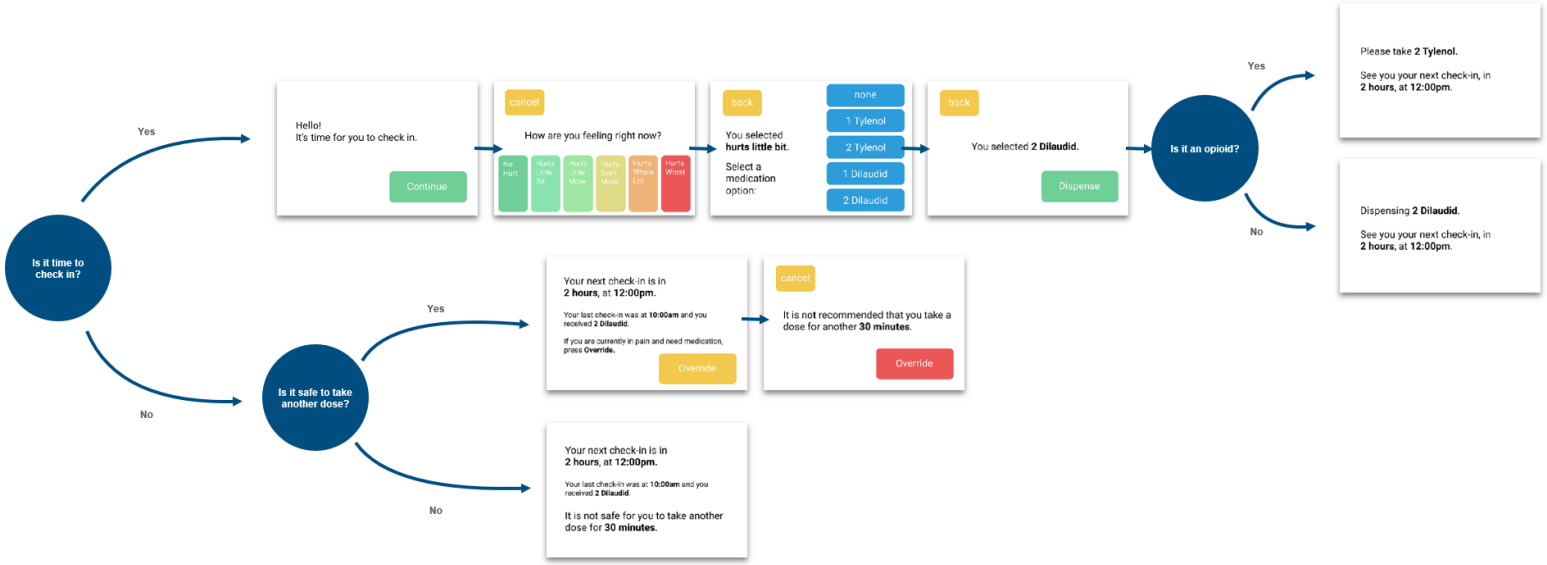
- The final dispensing mechanism went through a variety of changes
- A slot was made to create space for the continuous rotation servo
- We went from holding 20 pills to holding 16 in order to maintain accuracy
- The size was determined after a variety of iterations to ensure sizing was accurate
- The loading back and dispensers worked consistently





# User Flow and Interface

- Since we switched from the buttons to a touch screen, we were able to make a more colorful interface that was very easy to use
- User was given many options
- The pain scale was changed into 6 levels all determined verbally with very simple language for easy reading
- The back button was prominent for easy error recovery



# Final

- The final device was made in pieces so it could be printed in multiple pieces
- Presented at capstone
- Touch screen is easy to use
- Dispensing mechanism works but isn't yet consistent

# Reflection

- This process was both illuminating and a lot of fun. I relished the opportunity to use skills practically and this journey has been a learning experience. Being able to build a product from scratch was very challenging in a lot of ways. Even though I came in with a smattering of skills in a variety of fields, it was so valuable to develop each of those skills further with the help of my incredibly talented teammates. We started with conducting research, consolidating that into design considerations, building the prototype, testing it out, and finally creating a final prototype. Throughout that process, many things had to change. Our initial user flow didn't work at all, the form factor was iterated upon many times, and we are left with a variety of dispensing mechanisms that didn't work. However, we utilized all the information we gathered, through testing and talking to others, to build our final device that was extremely sleek and easy to use.

- In retrospect, I wish we had enough time to user test and iterate upon the current prototype. Our one round of user testing was illuminating, and having a second round with the working prototype would have led to an even better final. I also wish we had gotten the dispensing mechanism working more consistently, possibly by getting the servo and testing it sooner. While I don't regret the amount of time we spent on research, I think we should have built more in the ideation stage so we had more to test out and more time to test it.

- Overall, I learned so much about building a product. From research and thinking about how to solve an issue from a human perspective, to improving my sketching, 3D design and printing skills, to designing and branding, to just figuring out what to name our team, this was an extremely thought-provoking problem that I count myself luck to have been able to tackle and work on with this incredible team.