Digital Health Project

Using Digital Health for Adherence with Prescription Opioids

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Biomedical and Health Informatics 505

Helping involved individuals take control of their opioid usage.

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Abstract

A person dies in America approximately every 16 minutes from opioid overdose (CDC, “Understanding the Epidemic,” 2017). It is estimated that “one in four patients receiving long-term opioid therapy in a primary care setting struggles with opioid addiction” (CDC, “Prescription Opioids, 2017). Medication non-adherence causes unfavorable healthcare outcomes and raises healthcare costs through increased service utilization. Developing a digital health application to run on a smartphone is an inexpensive solution for addressing medication non-adherence. Objective data captured on a digital device can facilitate better communication between patients and their providers. It is the purpose of this project to develop an open-sourced application for helping patients to better control the medications they use “as needed.” The open-sourced application will be customizable for various patients’ needs. Additionally, emerging digital health technologies can be interfaced with the application in the future to create novel solutions to address medication non-adherence.

Introduction

The Centers for Disease Control and Prevention (CDC) reports that deaths from prescription opioid usage has more than quadrupled since 1999 (CDC, "Understanding the Epidemic," 2017), accounting for over 40 deaths every day in America (CDC, "Prescription Opioids," 2017). When you add non-prescription opioids, a person dies in America approximately every 16 minutes from opioid overdose (CDC, "Understanding the Epidemic," 2017). It is estimated that "one in four patients receiving long-term opioid therapy in a primary care setting struggles with opioid addiction" (CDC, "Prescription Opioids, 2017).

Medication adherence is a problem that has been estimated to cost the United States between $100 and $300 billion per year (Iuga and McGuire, 2014). Approximately 75% of Americans have difficulty complying with their daily medication regimen (Benjamin, 2012). Medication non-adherence is a cyclical problem that causes poor healthcare outcomes, increased healthcare service utilization, and increased healthcare-related costs that results in poorer medication adherence (see Figure 1; Iuga and McGuire, 2014). To break the non-adherence cycle, patients, in partnership with their doctors and pharmacist, need to commit to a mutually agreed schedule for optimal medication compliance. Adherence is a team effort involving the patient, healthcare providers, and other supportive individuals (spouse, friends, etc.).

Figure 1:

For “as needed” pain management, patients need to be aware of a more complex decision-making process for choosing the appropriate time for taking their medication. Arbitrary usage of medication has been correlated with a decreased measure of “Specific Internal Awareness,” which means that some individuals do not have an appropriate self-awareness to understand the appropriate time to take their “as needed” medication (Mawhinney et al, 1993). Instead of creating technology-mediated reminders for a patient to take a medication at a specific time, an “as needed” pain medication reminder needs to be focused on not taking too much medication or not taking a medication too soon. As with any medication adherence program, patients need to have a realistic expectation of the benefits they will derive from appropriate usage of their medications.

Medication non-adherence is often hidden from healthcare providers. There is generally a lack of objective data to verify adherence (Bussell et al, 2017). Using a patient sensitive manner of discovering medication usage information is crucial for discovering non-adherence (Bussell et al, 2017). Developing a method for objectively measuring the non-adherent behaviors of taking too much of a medication or taking a medication too early will help facilitate more honest conversations between providers and patients.

Background

The CDC suggests that we need to “provide tools and information for healthcare professionals working on overdose prevention and treatment,” and “increase awareness and share best practices with providers and patients” (CDC “Help and Resources”, 2017). Misono and associates (2010) concluded that using digital health technology for medication tracking does improve adherence at a relatively low cost for implementation. Using digital health technology, including a smartphone device, can help patients track their medication usage and disease progression resulting in a better understanding of appropriate medication usage and support their medication self-management (Merchant et al, 2016).

Due to proprietary information and a lack of published results, it is hard to learn from past successes and failures of medication adherence programs (Hubbard, 2013).

We need to understand that a method that works for improving medication adherence for one patient will not be the ideal solution for all patients. Creating a versatile digital health platform is necessary for allowing a patient to choose with whom they share their goals, plan their optimal treatment schedule, and customize the amount of interaction necessary for an environment of ideal compliance. Users of such a platform could involve doctors, pharmacists, patient caregivers or family, or anyone agreed by the patient. It is important that patients control which individuals have access to their medical data.

It is the purpose of this project to develop a smart phone application that would act as a personal assistant for many patients in their quest for an ideal medication treatment experience. A goal is to create an application that can help patients to better manage their "as needed" medications. To capture "best practices and lessons learned" (Hubbard, 2013), the created application will be provided as an open-sourced platform to be customized for the needs of various end users.

Design

Three Android apps were reviewed for this project. The first app was "*Medisafe* iConnect" which is distributed by Medisafe®. *Medisafe* has been downloaded millions of times from Google Play and is evaluated favorably by most users. The second app was "*Dosecast* – Medication Reminder" from Montuno Software, LLC. *Dosecast* has been downloaded fewer times than *Medisafe* and has received slightly poorer user-review scores. *Dosecast* has the added option to identify medication to be taken "as needed." The third app evaluated was "*Memo Health* – Smart Pill Reminder and Tracker" by Tinylogics Ltd. *Memo Health* was designed to interface with the "Memo Box" pillbox sensor which records each time the medicine container is opened and closed. When the container is opened within the time interval of 60 minutes before to 30 minutes after a scheduled dose, the *Memo Health* app assumes the user has taken their medication and the app will automatically update the medication as "taken." Functionality of the *Memo Health* app is inferior to both *Medisafe* and *Dosecast*, but the interface with the pillbox sensor makes the app a unique consideration. All three apps are best suited for creating reminders for users to take their chronic daily medications at a designated time and have

little applicability for encouraging a person to take their "as needed" medications appropriately. For example, even though *Dosecast* allows a user to designate a medication as "as needed," the app will not warn a user if they are taking a dose too soon. A summary of the app evaluation can be viewed in Table 1.

A pain management App (*myOpioidManager*) was also reviewed. Apps designed to help patients become better educated and more aware of the progression of their pain disorder are great tools. An app like *myOpioidManager* would serve as a nice companion to the digital health application designed for this project. Effective pain management and education can help encourage medication compliance. (More information about *myOpioidManager* can be found in Pereira, 2015.)

Table 1: Comparison of 3 digital health options for medication adherence

Function or Characteristic	*Medisafe*	*Dosecast*	*Memo Health*	Comment
Free Option	Y	Y	Y	
Google Play rating	4.6	4.3	3.2	
Number of downloads	Millions	> 100K	> 500	
Price for premium	$2.99/ month	$2.99/ month	N/A	Or: *Medi*:$23.99/year; *Dose*:$27.99/year
Ease of download/install	5	5	5	
Ease of setup	5	3	3	*Dose*: Setup is confusing due to premium options being visible.
User-friendly	5	4	3	
Usability for intended user	5	3	3	*Dose*: Again, extra options can be confusing.
Ease of navigation	5	4	3	
Visual Clarity	5	4	4	
Configurability	5	4	3	
Usefulness of interface	5	4	4	
Supports Medication Compliance	5	4	5	
Encourages Compliance	5	4	4	
Tracks "As Needed" medication use	N	Y	N	*Medi* & *Memo* could 'skip' scheduled doses, but not the same as "as needed."
Dose interval	N/A	Y	N/A	*Dose* can specify a "next dose available" interval
Max doses per day	N/A	Y	N/A	*Dose* lets you know when you have taken the maximum doses per day
Adjusted scheduling (ie: M,W,F)	5	3	5	*Memo* is adjustable, but the interface is not friendly
Automated tracking available	Y	N	Y	Tracking with sensors
Hardware Cost	$89.95/2	N/A	$39.95 - $89.90	*Medi*: minimum order of 2 sensors; Memo: Smallest pill box sensor=$39.95
Push notifications / reminders	Y	Y	Y	
Picture of medication	Y	N$^{\Delta}$	Y	What each pill looks like
Refill Reminders	Y	N$^{\Delta}$	Y	
Number of doses remaining	Y	N$^{\Delta}$	N	
Family/friends notified	Y	N	N	
Tracking by family/friends	Y	N	Y	
Historical log	Y	N$^{\Delta}$	Y	
Personal diary	Y	N	N	
Physician connection	Y	N$^{\Delta}$	N	
Pharmacy connection	Y	N$^{\Delta}$	N	*Medi*: CVS, Rite Aid, or Walgreens
Usefulness of documentation / help	N/A	N/A	2	
Overall satisfaction	5	3	4	
Likelihood to recommend	5	4	4	

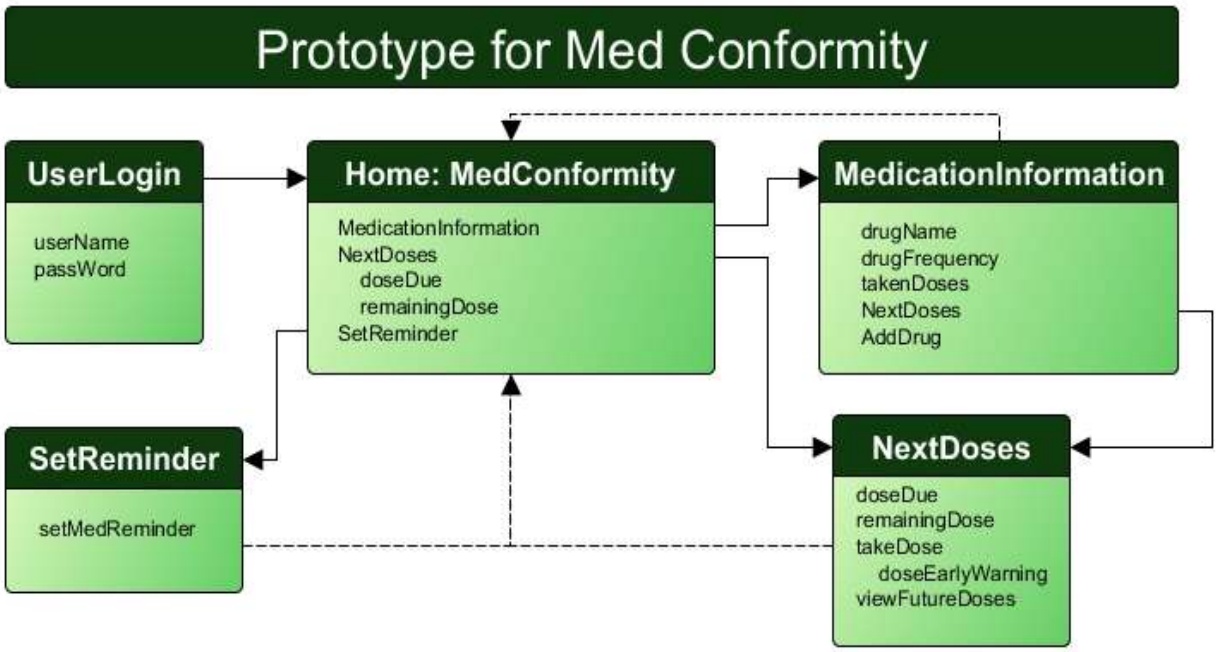
Score translation: 5=best; 4=good; 3=neutral; 2=undesirable; 1=bad; N/A=not applicable; Y = Yes, N = No.

Δ = Available in premium option only.

Methods

Several open-sourced Android apps were evaluated for potential use as a starting point for the current project. It was decided that a simpler interface would be ideal for prototyping this project, so a program called *DrugBug* was chosen as the base (https://github.com/ahjr/DrugBug). Alterations were made in *DrugBug* to change "*late dose"* alerts and "*missed doses"* to doses that are "*due to be taken when needed*." Instead of warning when doses are "late," it is important to warn when doses are taken "early." The functional prototype for the new app, *Med Conformity,* was designed according to the diagram in Figure 2. (A proposed design for a fully functioning *Med Conformity* can be found in Appendix 1.)

Figure 2: Prototype design for Med Conformity

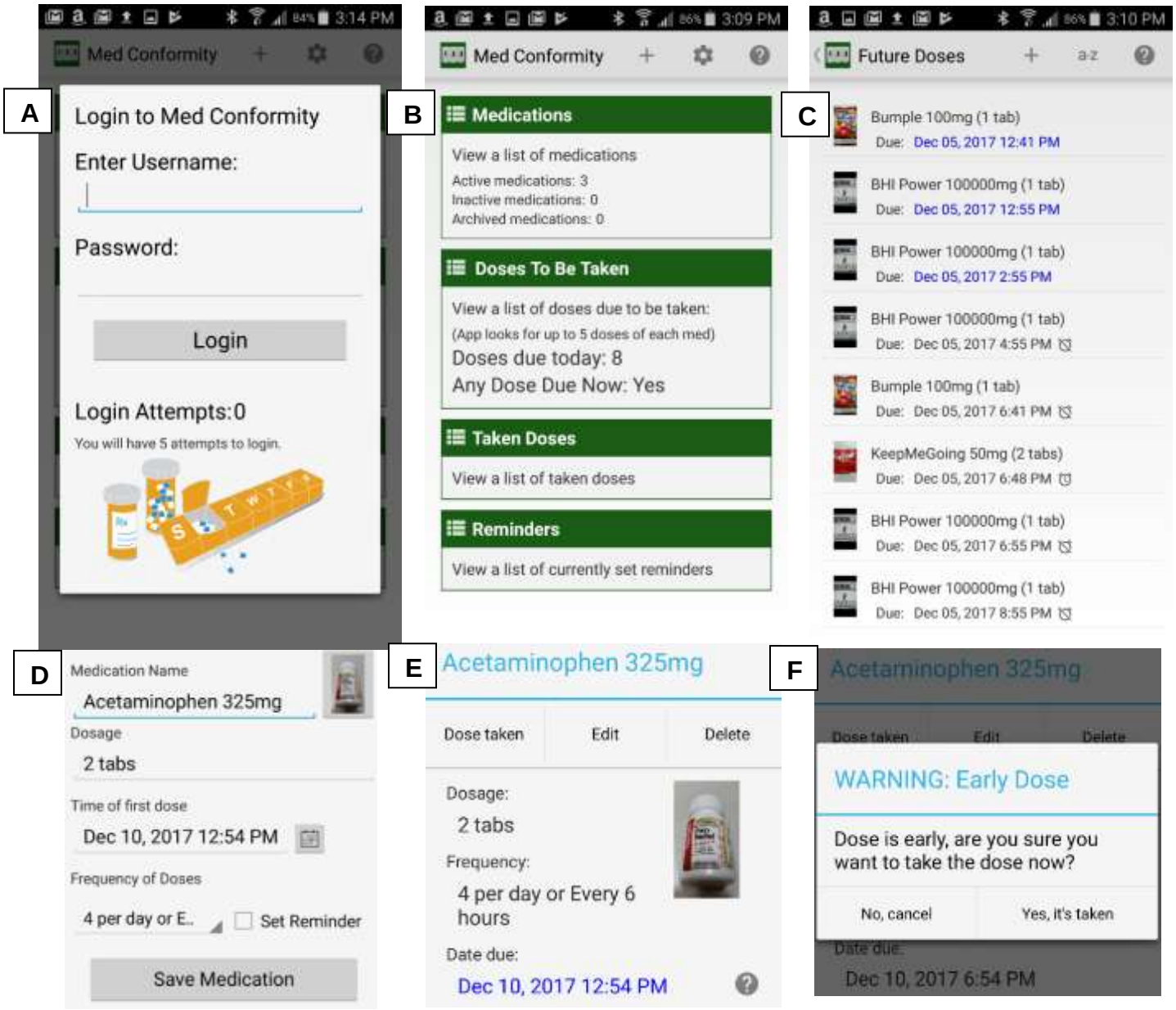


A full production version of *Med Conformity* would have 4 user personas: medication user, medication misuser, medication prescriber, and a user advocate (family member or friend to share information with). The prototype of *Med Conformity* will focus on the first two personas. Their user story scenarios can be found in Appendix 2.

Results

Android Studio (version 2.3.3) was used as the integrated development environment for creating *Med Conformity*. First, *DrugBug* was imported into Android Studio. A login screen was added to the startup sequence for an added measure of user privacy (Figure 3**, A**). The main home screen was altered to emphasize the number of doses due "today" and to indicate if any dose is "due now" (Figure 3**, B**). By default, *DrugBug* had more emphasis on the management of reminders. Since *Med Conformity* emphasizes taking doses only after they are due, the medication reminder functionality of *DrugBug* was maintained only as an option for users that want to add a reminder notification for when a dose is due ("Set Reminder" in Figure 3**, D**). For functional aesthetics, the red colored text used in *DrugBug* to draw attention to dose times that are past due was changed to blue text to indicate doses that are now due to be taken (Figure 3**, C & E**). For dose times that are not yet passed, a new method was created to warn a user that it is too early to take their medication dose (Figure 3**, F**). In the current prototype of *Med Conformity*, this warning is set for any dose that is early without any lenience, but the program will still allow the user to document the early dose if they choose to bypass the warning. Future modifications of the program may consider a small "early" window, such as a 15-minute tolerance for an early dose. This modification should be tailored to the end-user because allowing a tolerance for early doses could lead to medication misuse as some users may attempt to abuse that lenience for each subsequent dose. Adding a new medication (Figure 3**, D**) is a little easier in *Med Conformity* as the '+' option for adding a new mediation is now present in the top menu bar of most views within the app (Figure 3, **B & C**). "Frequency of Doses" choices were also updated in *Med Conformity* to emphasize a quantity of doses allowed per day (Figure 3**, D & E**).

Figure 3: Screenshots of *Med Conformity* on an Android smartphone.



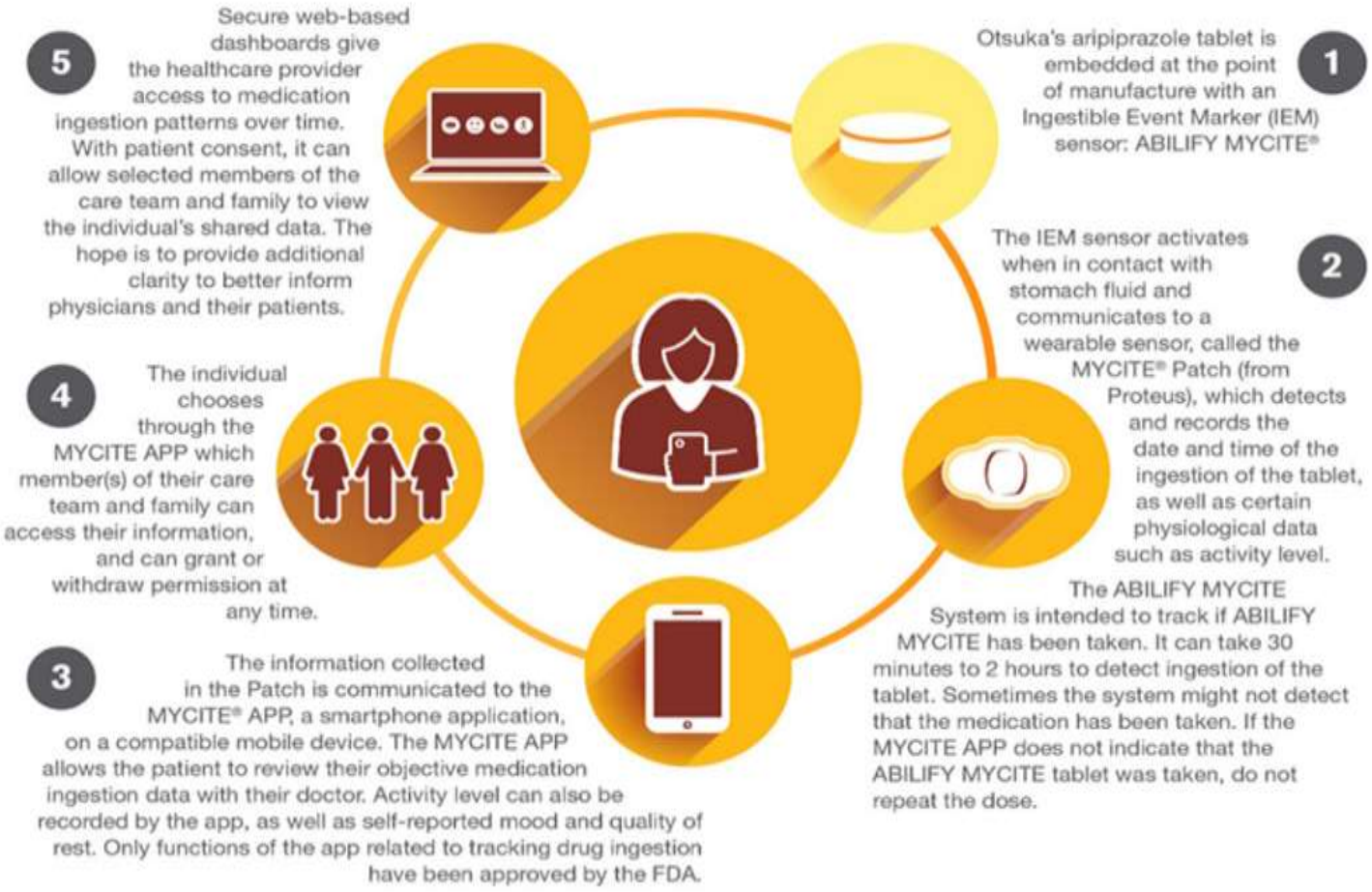
Med Conformity is fully functioning and has undergone some limited testing (partially seen in Figure 3 above.) Further updates and modifications of *Med Conformity* can be facilitated through the open-sourced Android Studio project at https://github.com/tevabob/MedConformity.

Discussion

The review study by Misono and associates (2010) concluded that interactive systems with 2-way communication need to be developed to increase patient engagement and adherence with their therapy. An initial enhancement of *Med Conformity* would need to be the addition of an interactive forum for patients to document the nature of their pain, if and how the medication has helped, and record any difficulties there have been with medication adherence. I refer to this forum as the "Discussion Sanctuary" as seen in the diagram in Appendix 1. The term "sanctuary" is used to emphasize that the forum would be a safe place for patients to openly discuss their therapy with their healthcare provider or their personal advocate. In conjunction with the "Discussion Sanctuary," there should also be a personal journal available to the user that stores information that is not shared but could be shared in the future at the patient's discretion.

Functionality of *Med Conformity* could also be enhanced in the future by incorporating other forms of digital health technology, such as automated sensors. On November 14, 2017, the United States Food and Drug Administration (FDA) approved the first sensor enabled medication. The medication is called Abilify Mycite® and is used for controlling certain psychiatric conditions. The sensor is made by Proteus Digital Health and is referred to as an "Ingestible Event Marker" (Otsuka Pharmaceutical Co, 2017.) Previous research with the Proteus IEM was conducted by Moorhead, Zavala, Kim, and Virdi (2017) to affirm the safety and efficacy of the sensor system. It was found that using the Proteus IEM system does correlate with improved patient adherence (Moorhead et al, 2017). Noble and associates (2016) correlated the Proteus IEM with enhanced patient self-care and improvements in clinical measures of medication effect. Figure 4 is a graphical representation of how the Proteus IEM is utilized for Abilify Mycite® in the continuum of patient care.

Figure 4: How the ABILIFY MYCITE System works:



Another digital health technology that could be incorporated with *Med Conformity* would be a sensor enabled pill container. Examples include the "Memo Box" (interfaces with *Memo Health)* and the "iConnect iCap" (interfaces with *Medisafe*.) Both devices sense when the container is opened and closed, and the data is transmitted to a smartphone app via Bluetooth. The associated apps assume a medication is taken if the container was opened and closed at a time near a scheduled dose. Depending on a chosen implementation with *Med Conformity*, information concerning opening and closing the medication container could be logged as objective data by the app. This automated data could be reviewed by healthcare providers when there is concern about possible misuse or diversion (stealing, selling, etc.) of medications.

Conclusion

Digital health software could help a patient adhere with their medication regimen. As discussed earlier, adherence to medication therapy needs to be a team approach. In partnership with digital health, a provider should still attempt to establish a pattern of non-adherence based on previously missed scheduled appointments and by asking questions like: “When are times that you take your medication in a way other than the way it was prescribed?” or “How many times have you run out of your medication before your next prescription was due?” (Jamison et al, 2016) Digital health offers a means of providing objective data into the dialogue between patients and healthcare providers. As sensor technology becomes more ubiquitous, as seen with the Memo Box, iConnect iCap, and the Proteus IEM system, patients will be able to document more objective medication usage data without needing to manually update information in a smartphone app. Having open-sourced digital health software will allow professionals to continue to update the software to better assist patients with managing their complicated “as needed” medications. It is easy to imagine an approaching future where digital health technology will seamlessly interface with digital health software to offer ideal solutions for each patient’s healthcare needs.

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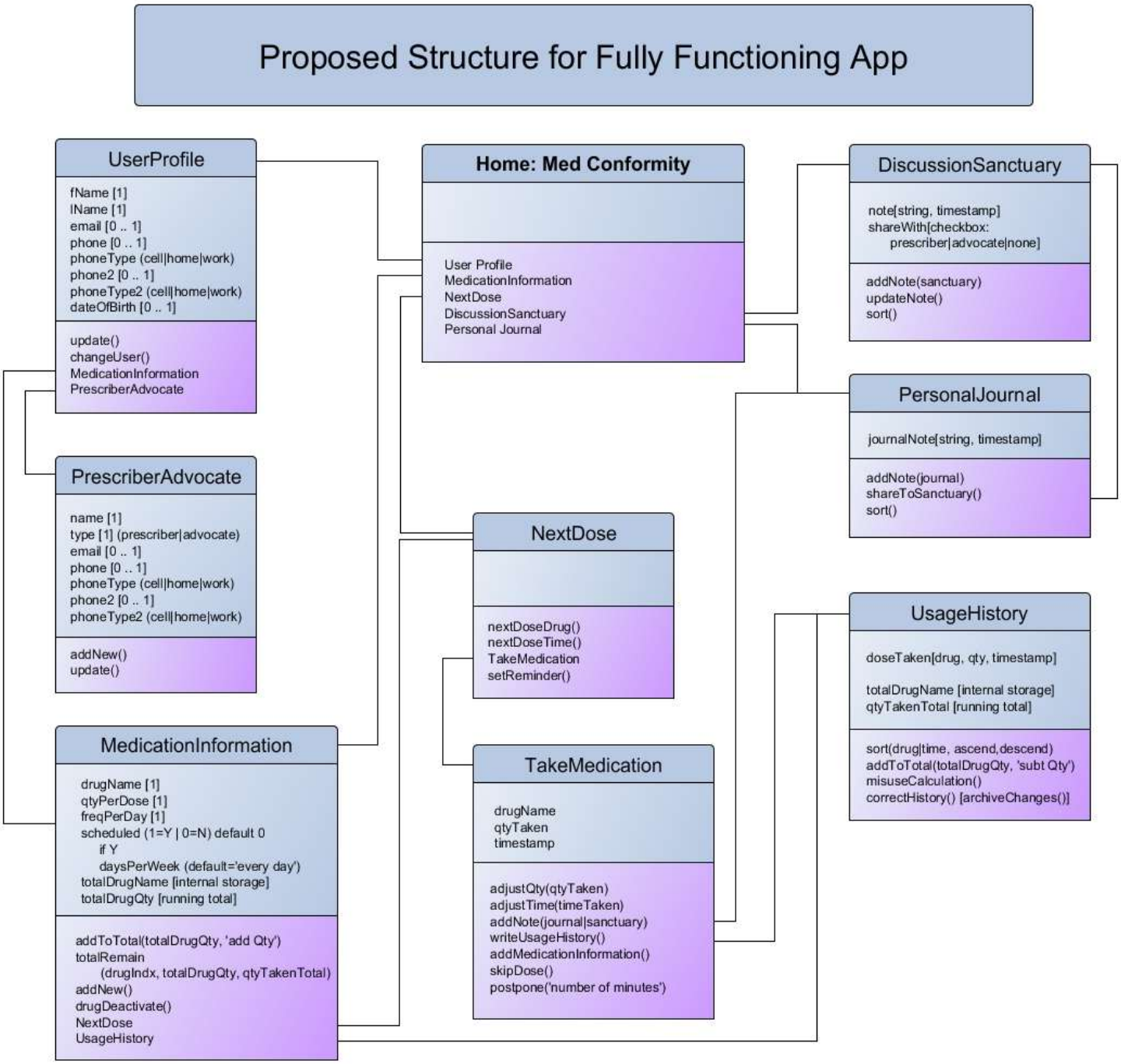
Android Studio (version 2.3.3) was downloaded from: https://developer.android.com/studio/index.html

The current open-sourced *Med Conformity* project can be accessed through GitHub: https://github.com/tevabob/MedConformity.

Appendix 1:


Proposed Structure for Fully Functioning App
UserProfile
fName [1]
lName [1]
email [0 .. 1]
phone [0 .. 1]
phoneType (cell|home|work)
phone2 [0 .. 1]
phoneType2 (cell|home|work)
dateOfBirth [0 .. 1]
update()
changeUser()
MedicationInformation
PrescriberAdvocate
Home: Med Conformity
User Profile
MedicationInformation
NextDose
DiscussionSanctuary
Personal Journal
DiscussionSanctuary
note[string, timestamp]
shareWith[checkbox:
prescriber|advocate|none]
addNote(sanctuary)
updateNote()
sort()
PersonalJournal
journalNote[string, timestamp]
addNote(journal)
shareToSanctuary()
sort()
PrescriberAdvocate
name [1]
type [1] (prescriber|advocate)
email [0 .. 1]
phone [0 .. 1]
phoneType (cell|home|work)
phone2 [0 .. 1]
phoneType2 (cell|home|work)
addNew()
update()
NextDose
nextDoseDrug()
nextDoseTime()
TakeMedication
setReminder()
UsageHistory
doseTaken[drug, qty, timestamp]
totalDrugName [internal storage]
qtyTakenTotal [running total]
sort(drug|time, ascend,descend)
addToTotal(totalDrugQty, 'subt Qty')
misuseCalculation()
correctHistory() [archiveChanges()]
MedicationInformation
drugName [1]
qtyPerDose [1]
freqPerDay [1]
scheduled (1=Y | 0=N) default 0
if Y
daysPerWeek (default='every day')
totalDrugName [internal storage]
totalDrugQty [running total]
addToTotal(totalDrugQty, 'add Qty')
totalRemain
(drugIndx, totalDrugQty, qtyTakenTotal)
addNew()
drugDeactivate()
NextDose
UsageHistory
TakeMedication
drugName
qtyTaken
timestamp
adjustQty(qtyTaken)
adjustTime(timeTaken)
addNote(journal|sanctuary)
writeUsageHistory()
addMedicationInformation()
skipDose()
postpone('number of minutes')

Appendix 2: User Story Scenarios

All Users:

Scenario 0: Taking Medication

Given that I am prescribed medication
And *Med Conformity* has accurate information about my medication.
When I notify *Med Conformity* that I have taken my medication,
Then I am informed when my 'Next Dose' is due to be taken.

Persona: Medication User

As a user of medications
I want a tool like *Med Conformity*
So that I can keep track of the medications I have taken and when my next dose is due.

Scenario 1: Medication Reminder (for medicines taken on a schedule)

Given that I am prescribed medication
And *Med Conformity* has accurate information about my medication.
When I receive a reminder from *Med Conformity* for my next dose,
Then I take my prescribed medication
And a reminder for my 'Next Dose' will be created.

Scenario 2: Next Dose Lookup

Given that I am prescribed medication
And *Med Conformity* has accurate information about my medication
And I am concerned about taking too much medication.
When I check *Med Conformity* for information about my next dose,
Then I can take my prescribed medication if enough time has elapsed
Or, I can set a timer to have *Med Conformity* remind me when my next dose would be due.

Persona: Medication Misuser

As a misuser of medications
I want a tool like *Med Conformity* to track my medication usage
So that my prescriber can be assured that I am using my medication appropriately.

Scenario 3: Taking a Dose Too Soon

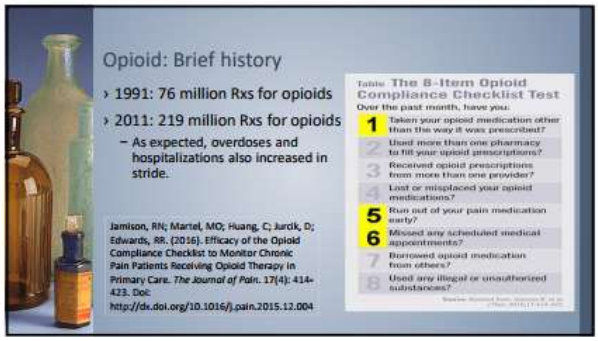
Given that I am prescribed medication
And *Med Conformity* has accurate information about my medication.
When I want to take a dose before the next dose is due,
Then I am warned that the dose is too early
And I am cautioned to wait until the dose is due
And *Med Conformity* will allow me to take the dose, but the dose will be marked as early.

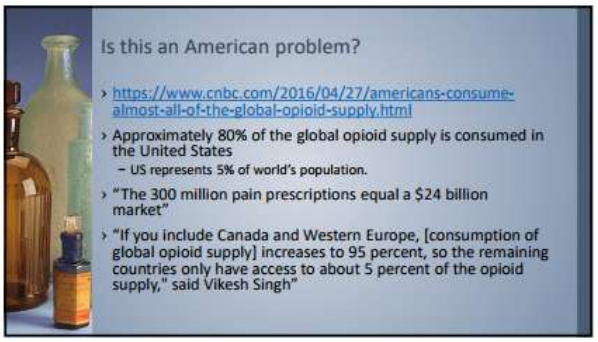
Scenario 4: Drug Diversion

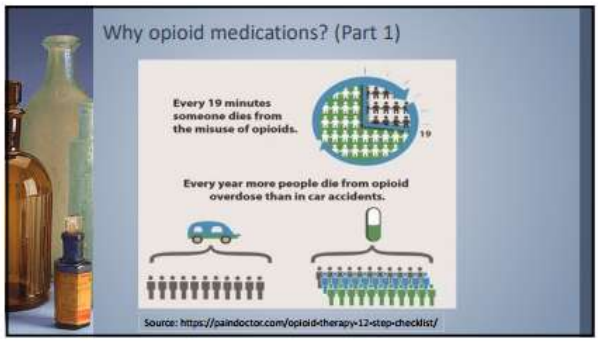
Given that I am prescribed medication
And *Med Conformity* has accurate information about my medication.
When I divert some of my medications to a different person,
Then *Med Conformity* will have no record of me using the medication
And my prescriber will be able to look at my usage history and discover that medication has been diverted (stolen, given, or sold) to a different person.

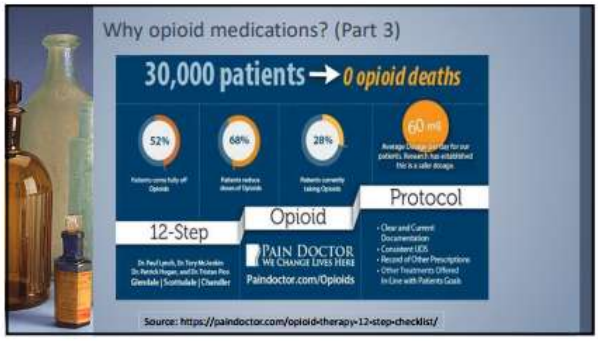
Appendix 3: Med Conformity Presentation. Page 1 of 3.

Download available: http://pi.cs.oswego.edu/~jmiles3/bhi/Miles-Med_Conformity-presentation.pdf









Appendix 3: Med Conformity Presentation. Page 2 of 3.

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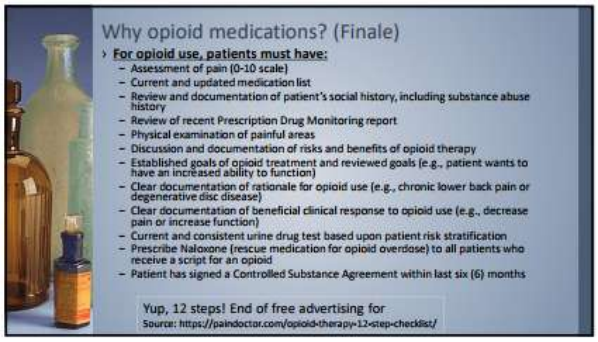

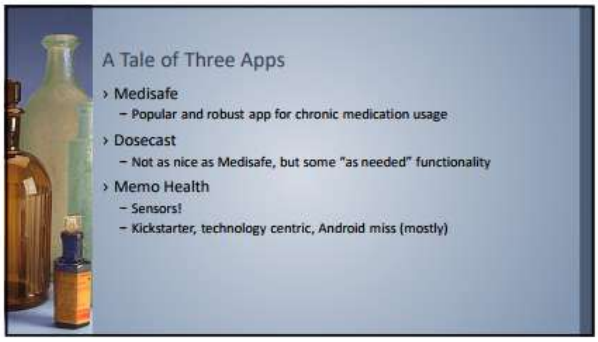

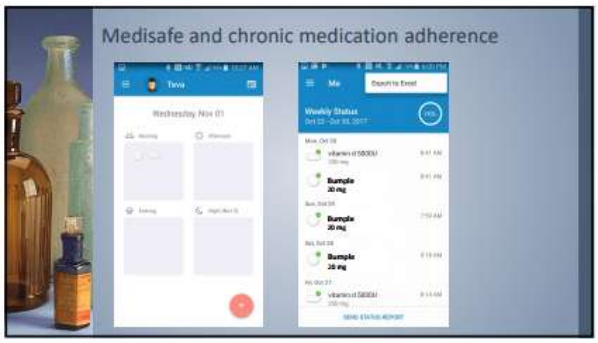

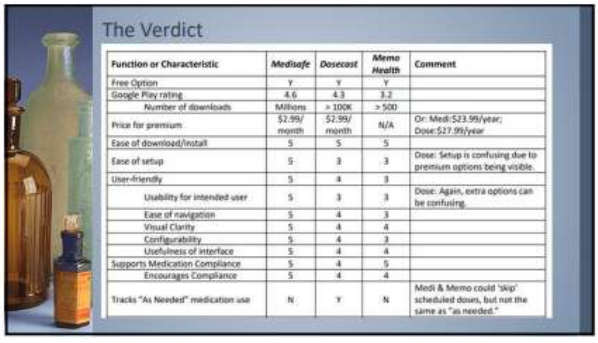

Function or Characteristic	Medisafe	Dosecast	Memo Health	Comment
Free Option	Y	Y	Y	
Google Play rating	4.6	4.3	3.2	
Number of downloads	Millions	> 100K	> 500	
Price for premium	$2.99/ month	$2.99/ month	N/A	Or: Medi:$23.99/year; Dose:$27.99/year
Ease of download/install	5	5	5	
Ease of setup	5	3	3	Dose: Setup is confusing due to premium options being visible.
User-friendly	5	4	3	
Usability for intended user	5	3	3	Dose: Again, extra options can be confusing.
Ease of navigation	5	4	3	
Visual Clarity	5	4	4	
Configurability	5	4	3	
Usefulness of interface	5	4	4	
Supports Medication Compliance	5	4	5	
Encourages Compliance	5	4	4	
Tracks "As Needed" medication use	N	Y	N	Medi & Memo could 'skip' scheduled doses, but not the same as "as needed."

Appendix 3: Med Conformity Presentation. Page 3 of 3.

Download available: http://pi.cs.oswego.edu/~jmiles3/bhi/Miles-Med_Conformity-presentation.pdf