



An assessment instrument for user-centered innovation potential among biomedical engineers

Carolina Vivas-Valencia, Purdue University

Carolina Vivas-Valencia is a Ph.D. student in the Weldon School of Biomedical Engineering at Purdue University, West Lafayette IN. Her research interests focus on simulation modeling and optimization in population health, healthcare data analytics and outcomes research, community-based health operations research, and innovation education in engineering.

Dr. Nan Kong, Purdue University at West Lafayette

Nan Kong is an Associate Professor in the Weldon School of Biomedical Engineering at Purdue University. He received his PhD in Industrial Engineering from the University of Pittsburgh. His research interest includes big-data health analytics. He is actively in collaborating with international partners to enhance American engineering students' global learning.

Mrs. Eunhye Kim, Purdue University at West Lafayette

Eunhye Kim is a Ph.D. student and research assistant in the School of Engineering Education at Purdue University. Her research interests lie in engineering design education, especially for engineering students' entrepreneurial mindsets and multidisciplinary teamwork skills in design and innovation projects. She earned a B.S. in Electronics Engineering and an M.B.A. in South Korea and worked as a hardware development engineer and an IT strategic planner in the industry.

Dr. Senay Purzer, Purdue University-Main Campus, West Lafayette (College of Engineering)

Senay Purzer is an Associate Professor in the School of Engineering Education. She studies design learning in college and pre-college education. She is the editor of the Journal of Pre-College Engineering Education (JPEER) and serves on the editorial board of Science Education.

Dr. LINDSEY B PAYNE, Purdue University-Main Campus, West Lafayette (College of Engineering)

Dr. Lindsey Payne is a Director in the Office of Engagement at Purdue University coordinating service-learning programs and initiatives. She has a courtesy appointment in Environmental and Ecological Engineering where she teaches a service-learning course in which interdisciplinary teams of students collaboratively identify stormwater management problems, co-design solutions, maintain budgets, and evaluate impacts with community partners. Dr. Payne's research sits at the intersection of sustainability, teaching and learning, and engagement focusing on transdisciplinary decision-making frameworks in community-based design projects. She also specializes in the assessment of instructional effectiveness and student learning in active learning environments. She is the recipient of multiple teaching awards, and is the Chair of the Teaching Academy. She has a B.A in Biological Sciences from DePauw University and M.S. and Ph.D. degrees in Ecological Sciences and Engineering from Purdue University. She has also worked professionally in the non-profit and secondary education sectors, and currently serves on multiple community-based environmental boards.

Instrument development for assessing user-centered innovation potential among biomedical engineers: A preliminary study

Abstract

With increasing challenges to health care in the foreseeable future, novel technology solutions are increasingly needed. Meanwhile, biomedical engineers are increasingly asked to develop user-centered solutions (i.e., desired by the end users). Nevertheless, the importance of user-centeredness is often neglected in the innovation process. It remains unclear about the interplay between thinking of solution novelty and desirability in addition to feasibility, and thus it is challenging for biomedical engineering educators to balance the teaching of the above two aspects in a BME design curriculum.

This study aims to develop a preliminary version of a user-centered innovation potential assessment instrument applicable to diverse biomedical engineering design projects. The assessment instrument was adapted from File and Purzer (2014)'s definition of innovation potential (1) feasibility (2) viability (3) desirability and (4) novelty. Among these aspects, we focused on assessing feasibility, desirability and novelty, which can be quantified and assigned to each design idea proposed by the students. As the first attempt, we targeted students' innovation potential in the design prototyping phase.

To validate our preliminary development, we gave an in-class design task for smart pill dispenser to 30+ pairs of senior students enrolled in the BME capstone design course. To assess the design ideas, the instructor and his teaching assistant (two of the authors on the paper) applied a thematic analysis. We first identified patterns from the submitted design ideas by extracting key attributes including dispenser's portability, tracking/reminding capability, safety, and easy to use. We then estimated the frequency and novelty of these key attributes appearing in each design idea and converted each of them to a 5-point scale. Finally, we calculated a composite score for user-centered innovation potential by multiplying the scales on feasibility, desirability and novelty.

We believe this study has added value to improving our understanding of user-centered innovation potential in an undergraduate biomedical engineering curriculum. With further development and scaled-up validation, we may be able to use the instrument to provide insights into developing teaching interventions for stimulating user-centered innovative potentials among biomedical engineers.

Introduction

Innovation has been understood as the implementation of a novel or significantly improved product in a specific work environment [1]. To be considered innovative, a solution must be new and provide benefits in the context where it has been developed [2]. In engineering professional practice, innovation has been defined as the meta-attribute of engineering, and thus it is critical to promote innovative thinking in undergraduate engineering education [3]. Scholars have focused on four areas to assess the innovation abilities of engineering students. These areas include: creative thinking [4], design process [5], problem-solving abilities [6], and entrepreneurial skills [7]. In specific contexts, for example, design of an insulin pump for top

athletes, the innovation potential of a solution should be evaluated beyond its technological feasibility and novelty. Instead, the evaluation should also take into consideration user-centeredness, which has also been labeled as user desirability.

In the area of biomedical engineering (BME), many ideas are indeed dismissed because, despite their novelty and feasibility, considerations on the customer and his/her environment and lifestyle, are not incorporated in the design process. Biomedical engineers have been increasingly asked to develop solutions desired by the end users (often consumers). As such, achieving innovation competency among BME undergraduate students during design learning is of critical importance to addressing the current challenges in balancing the three dimensions of novelty, feasibility, and desirability. Despite a large amount of evidence pointing out the importance, it remains unclear to BME educators how to properly assess the innovation potential in new ideas from design thinking tasks. Subsequently, it remains unclear how to effectively stimulate user-centered innovation potential in an undergraduate BME curriculum.

This study aims to conduct preliminary development of an assessment instrument for user-centered design innovation potential, which is expected to be applicable to diverse Biomedical Engineering design project courses. As a first attempt, our study focused on assessing the innovation potential demonstrated by senior BME students performing design thinking tasks for prototyping in a capstone design course.

Literature Review

Innovation has been broadly studied based on its context and applicability [1], [2]. Researchers have used innovation as a means to explain competencies in individuals, design solutions, and environments that support such solutions [3]. The wide context in which innovation can be used does not necessarily represent a debate on the concept of innovation, rather it calls for further fragmentation of the definition and deeper understanding of the context to which is intended to be applied. Therefore, when developing an assessment instrument for innovation potential, it is necessary to first establish an operational definition for the constructs to be examined. In this study, the construct we focus on is user-centered innovation potential.

During the past years, closing the gap between engineering design and clinical needs that ensure user-centered solutions has been of great interest in the BME undergraduate curriculum for design learning. Researchers have explored new teaching techniques to bridge the gap between two courses at Clemson University, “Clinical Immersion for Engineers” and “Senior Design”, to better translate unmet clinical needs into user-centered design projects [4]. Additionally, the DeFine (Design Fundamental in Needs-Findings Experience) program developed in a partnership between Clemson University and the Greenville Health system, offers clinical and technological immersion experiences to support translating clinical needs into biomedical technologies [5]. Moreover, there have been efforts from BME programs nationwide to immerse their students into clinical settings that would stimulate their user-centered design thinking [6]–[8]. Although many of these studies focused on developing mechanisms to promote user-centered designs in design learning, they do not typically base the promotion on quantitative assessment of user-centered innovation potential among students.

Methods

Existing framework adaptation

User-centered innovation potential is an attribute of a product that is technically feasible, desirable, and novel (see

Figure 1). The user-centered innovation potential can be calculated via a metrics based on Fila & Purzer's (2014) operationalized definition of innovation potential, which is theorized to be a construct with such sub-constructs as (1) feasibility, (2) viability, (3) desirability, and (4) novelty. Guided with the above theoretical framework, we defined feasibility in our context as a metrics to *evaluate whether a proposed solution can be implemented given current conditions*. To measure feasibility, we used a 5-point Likert scale to evaluate specific design requirements described by the end users. More specifically, the feasibility score for each design was given based on the number of functional specifics addressed in the design. We defined novelty in our context as a metrics to *evaluate how different a solution is to other existing ones* [9]. To measure desirability in a classroom setting, we redefined desirability as a metrics to *evaluate whether the designed solution meets the needs of the end-user*. Desirability was assessed by providers and end-users in the area. Viability was excluded from our study because it is expected to *evaluate whether a proposed solution can be easily introduced and maintained*, which focuses on the costs for both implementation and operations. It is not possible to assess given the scope of the design ideation workshop and the educational setting (i.e., a capstone design course) where our proposed assessment instrument was first implemented.

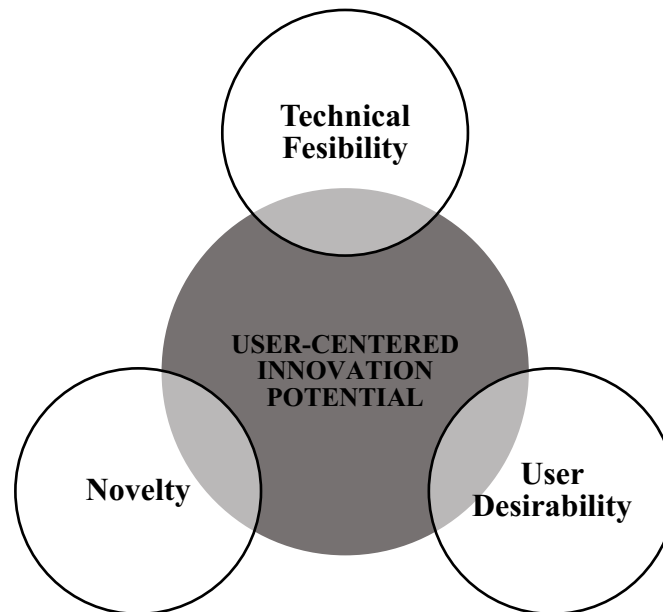


Figure 1 User-centered innovation potential framework

Cohort Study Settings and Participants

Data for our study were collected from a senior capstone design course in BME program of a large research university in the Midwest. Sixty-four students, twenty-nine women and thirty-five men, participated in an in-class design ideation workshop. The students were assigned into

groups of two to perform a design task for smart medication dispenser to improve medication adherence. At the beginning of the workshop, each pair of students received a brochure that contains information about medication adherence such as statistics, facts, and factors that impact medication adherence. The instructor and his research assistant described the purpose of our study. The workshop was then divided into three parts based on the three progressive design scenario we provided. In the first part, the student pairs received a design scenario, description of the target customers, and design specifications. In the second part of the workshop, the student pairs received extra information about additional stakeholders involved in the medication dispensing system, including primary care providers and pharmacists. In the third part of the workshop, the student pairs received further information about the current digital health technology on smart pill bottles and dispensers available on the market, e.g., Pillsy, Vitality GlowCap and Pill.

Regarding the student grouping, it was based on a self-developed empathic design tendency score. Then the grouping was created by selecting a student with a high tendency score to work with a student with the lowest score. This process was repeated until no more students were available on the pool. As a result, the participating students were assigned into 32 groups. For each of the three aforementioned parts of the workshop, we collected a design ideation solution from each pair. Note that one group was deemed invalid entry for not recording participating students' names.

Ideation Task

The ideation task designed for this workshop focused on improving medication adherence for a patient with chronic diseases. The specification of a real-world end-user was intended to provide a realistic scenario so the students could focus their design thinking on meeting the specific end-user needs. A patient's daily activities and medical needs were also included as supplemental information distributed at the beginning of the workshop to promote a sense of empathy among the students. In addition, four user needs were categorically specified to the students 1) portable, 2) enables tracking and reminding, 3) safe, and 4) easy to use.

The target end-user presented was a sixty-year-old salesman who, in the past two years, had been diagnosed with hypertension and arthritis. A specific medication regimen was informed to the students. We specified that the patient takes two types of pills daily to treat hypertension: one taken daily one-hour before breakfast (medication A) and the other taken weekly with food (medication B). We also specified that the treatment for arthritis requires the intake of two pills (medication C), six hours after taking medication A.

Besides providing information about the medication regimen, we also provided information on the patient's lifestyle and other medical conditions. For example, we described that the patient is a salesman, working from Monday to Friday from 9:00 am to 5:00 pm, who in the weekends dedicated his time to volunteer at a community center teaching math. In addition to his routine, we also explained that because of the joint inflammation caused by arthritis, the patient had developed a reduced range of motion that limits some of his daily activities (e.g., opening a jar). The purpose of providing all this information was to stimulate user-centered thinking in the students. Information such as daily activities would suggest to the students that the patient had to walk around the city all day, was busy with constant meetings, and had to take care of many tasks at a time. In such case, the solution had to be incorporated into an already established

routine, suggesting that the design must be portable and should provide reminders of taking medications.

Data Collection

Students completed a solution template where they were asked to sketch their designs and list the design specifications. In their sketches, students included labels, descriptions, and justifications based on the information provided in the design scenario. We selected 28 of the 31 submitted ideas. The three submissions removed did not provide the design and specifications in all three parts (see Appendix A).

Calculation of Novelty

To assess novelty, we first compiled all the ideas generated by each team. Our sample consisted of 28 ideas submitted by 28 teams. The next step was identifying patterns of the design ideas. For this analysis, we examined the student's final solution sketches and written design specifications. Several rounds of reviews resulted in the identification of patterns that allowed us to group the designs ideas based on their usability and product type. Five different categories emerged from this analysis (see **Table 1**). The category of smart pill bottles includes solution ideas that use pill bottles in combination with a display and alarm system, and compatibility with phone apps. The category of programmable pill dispensers includes solution ideas that improve regular pillboxes by adding a programmable dosage panel. The category of wearable pill dispensers includes solution ideas that focus on device portability and accessibility. The category of mHealth devices includes solutions ideas that specify the use of mobile phone-based functionalities in conjunction with pill dispensers. Lastly, the category of alternative devices includes those solutions that did not use a bottle or pill dispenser as part of the design.

Table 1 Type and Frequency of Design Ideas

Frequency of the ideas	
Smart pill bottle	6/28 ideas
Programmable pill dispenser	9/28 ideas
Wearable pill dispenser	3/28 ideas
Alternative devices	2/28 ideas
mHealth solution	8/28 ideas

Table 1 reports the frequency counts of the ideas in each category. The category with the highest frequency was identified to develop a 5-point novelty scale. The highest frequency for an idea was 9 out of 28 ideas, and the lowest score frequency was 2, the novelty score chart was thus created as follows, where the interval is 1.5 ($(9-2)/5=1.4$ (rounded to 1.5) (see **Table 2**).

Table 2 Calculation of Novelty

Novelty Score	5 (highly novel)	4	3	2	1 (not novel)
Frequency of idea (out of 28)	≤ 3	≤ 4.5	≤ 6	≤ 7.5	> 7.5

Calculation of Feasibility

The calculation of feasibility was based on the four design specifications indicated during the workshop. These specifications include 1) portable, 2) enables tracking and reminders, 3) safe, and 4) easy-to-use. We reviewed the design ideas and identified seven key functions associated with these ideas. Similar to the novelty score, a 5-point scale was developed for each design criteria (see **Table 3**)

Table 3 Key functions of ideas

Key functions	Feasibility Score				
	5	4	3	2	1
Portable (patient can take dispenser with them)					
Provides visually or audibly notifications					
Notifications include instructions on the medication					
Pill dispenser or bottle cannot be opened at unspecified times	Meets ≥ 5 functions	Meets 4 functions	Meets 3 functions	Meets 2 functions	Meets 0-1 functions
Includes clock for time-specific medications					
Programmable control panel					
Pill counter					

Calculation of Desirability

The calculation of desirability was made based on expert assessment. Two experts on user-centered design of Biomedical technologies were asked to review the ideas. The experts were asked to assess the effectiveness of the solutions based on the description of the target customers using the Likert scale for effectiveness (see **Table 4**).

Table 4 Calculation of Desirability

	5	4	3	2	1
How effective did you find the idea in improving medication adherence?	Very effective	Effective	Not sure	Somehow effective	Not effective

Evaluation of inter-rater reliability on desirability

Since desirability was the only construct that would be measured subjectively, we proposed to evaluate the inter-rater reliability between the raters to ensure the validity of our assessment on innovation potential. Interrater reliability describes the process where raters assign the same score to the same variable [10]. To test inter-rater reliability, we used kappa statistics (k) to assess the extent to which the data collected during the calculation of desirability is a correct representation of the variable measured. In other words, based on the kappa coefficient, we calculated the probability of agreement based on chance.

To estimate the level of agreement among the two raters, we calculated Cohen's kappa coefficient according to the following formula [11]:

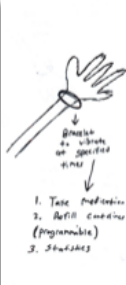
$$k = \frac{\text{Pr}(a) - \text{Pr}(e)}{1 - \text{Pr}(e)},$$

where $\text{Pr}(a)$ represents the actual observed agreement and $\text{Pr}(e)$ represents the chance of an agreement. Cohen suggested that the Kappa result can be interpreted as follows: value ≤ 0 indicates no agreement and 0.01-0.2 as none to slight, 0.21-0.39 as minimal, 0.40-0.59 as weak, 0.60-0.79 as moderate, 0.80-0.90 as strong and ≥ 0.91 as almost perfect [10]. In our study with a probability of observed agreement of 0.71 and a probability agreement 0.26, the Cohen's Kappa coefficient is $k = 0.61$. This suggested that our two raters had a “moderate” level of agreement.

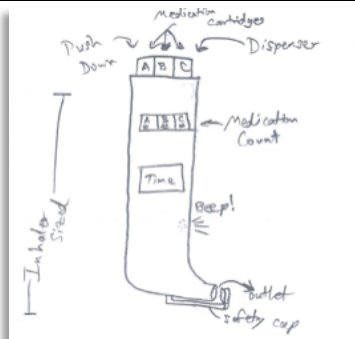
Calculation of Overall Innovation Potential (Novelty x Feasibility x Desirability)

Finally, the overall innovation potential score was calculated by multiplying the feasibility, the desirability, and the novelty scores. Thus, the value of the overall score ranges between 3 and 80 (see **Table 5**).

Table 5 Sample Design Ideas for Reviewer#1

Idea	Novelty Score	Feasibility Score	Desirability Score	Overall Score
 <p>Bracelet to vibrate or provide sound</p> <ol style="list-style-type: none"> 1. Taste medication 2. Audit container (programmable) 3. Shakes 	5	4	4	80

Bracelet with built-in container to hold pills



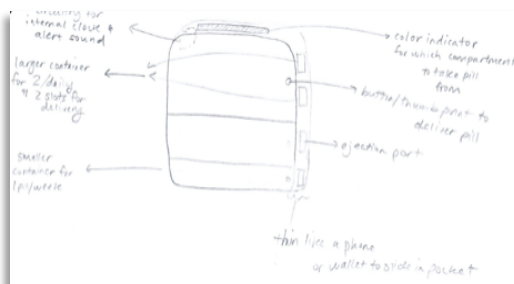
5 3 4 60

Inhaler medication bottle



1 2 2 4

Phone app and pill dispenser



1 1 3 3

Multiple compartment dispenser and phone app

Findings

Summary Statistics on Innovation Potential

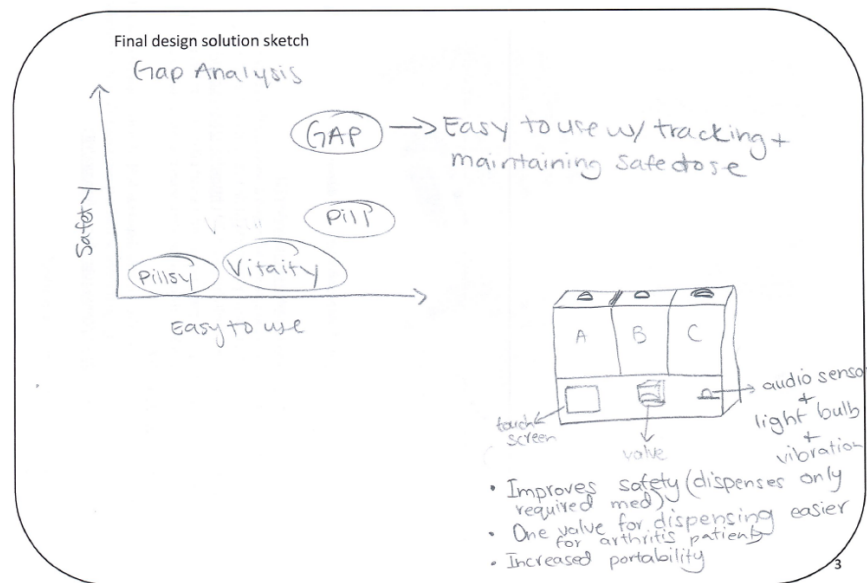
In **Table 6** we provide descriptive statistics on the metrics of novelty, feasibility, desirability, and the overall score for innovation potential. The most common design concept identified by the students was the design of a pill dispenser with a programmable panel and an integrated alarm system that provides notifications at specific times. The most innovative idea identified by both reviewers (with an innovation potential score = 80) was a bracelet, with a built-in system to hold medications. This programmable device would allow users to set up reminders and collect statistics to track medication adherence.

Table 6 Comparison of metric scores

Metric	Mean (N=28)	Median	Max	Min
Novelty	2.07	1	5 out of 5	1 out of 5
Feasibility	3	3	5 out of 5	1 out of 5
Desirability	3.035	3	4 out of 5	1 out of 5
Innovation Potential	18.98	12	80 out of 125	3 out of 125

User-centered Reframing

During the second part of the workshop, eight groups changed and adjusted their ideas based on the additional information provided. Groups that, in the first part, proposed a pill dispenser, adjusted their designs in the second part to include a programmable console generally operated by pharmacist and physician who are in charge of setting the dosages for each medication and filling the dispenser. Other groups adjusted their designs for portability or improved patients' reliability by collecting and sending real-time data of medication intake to the physician. This change was hypothesized to be caused by incorporating the concerns of pharmacists and physicians. During the third part of the workshop, 93% of the groups did not change their ideas, and their responses focused on gap analysis and justification on why their solutions were better than currently available pill bottles and pill dispensers (see **Figure 2**).

Figure 2 Sample of Ideas Generated in Part III of the Workshop

Correlation between Innovation Potential and Empathy Tendency

For each group of two students, we calculated its empathic design tendency score to be the sum of the two students' scores. We analyzed the correlation between the innovation potential score and sum empathic design tendency score. The highest sum empathic score was 6.42 and the lowest 4.58. The team with the most innovative idea (innovation potential score = 80) had a sum score of 6.63. Most of the groups with a desirability score of 4 or more had a sum empathy tendency score above the average (5.74). We furthered the analysis by computing the Pearson

correlation coefficient, which measures the linear correlation among two variables [12]. With a coefficient value of 0.123, our data did not suggest a strong correlation between empathy tendency and innovation solution desirability.

Discussions and Conclusions

In this paper, we describe an initial attempt on developing an instrument for reliably assessing user-centered innovation potentials of undergraduate BME students through in-class design tasks solutions. We considered three constructs for the assessment instrument, namely novelty, feasibility, and desirability. We also proposed to use inter-rater reliability testing in the study protocol to ensure the validity of our assessment instrument on measuring desirability, which is subjectiv by its nature.

Through analyzing the data collected in the study and conducting self-reflection on the workshop, we suggested the following to BME design learning educators. To promote user-centered thinking, information should go beyond the statement of medical needs and include details on the circumstances where the solution would be applied. Instructors thus would be crucial to helping students develop self and social awareness during their design thinking process. This would create an opportunity to improve student skills of thinking broadly about the design context and recognizing their responsibility for promoting better engineering practices.

This initial attempt of the instrument development will pave the way to detailed refinement of the study protocol scaled-up cohort studies on user-centered innovation potential. We expect the assessment instrument will eventually be 1) adapted to assess the innovation potentials of solutions developed by engineering students, and 2) used to highlight the importance of balancing technology novelty and solution desirability along with technical feasibility with an emphasis on user-centered innovation. More importantly, engineering educators can use this tool for formative purposes as they evaluate students' initial design ideas or as a reflective tool that students can use to compare different design solutions based on how they perform in different aspects of user-centered innovation.

Further work is needed to validate how viable this assessment instrument for different types BME design ideation tasks, e.g., clinically driven vs. home-health driven. In addition, there is a need in future work to develop a better cohort study protocol with focus on student grouping and design scenario presentation. There is also a need to further explore the interplay between user-centered innovation potential and empathic design tendency, which provides the intelligence to the educators to apply more targeted teaching innovations in a design class. Finally, other stakeholders such as pharmacists and end-users should be included to evaluate the ideas.

Acknowledgments

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Appendix A

Workshop Part I

Improving Medication Adherence Through Dispensing Design

Design Scenario

Your task is to generate an innovative solution to improve medication adherence. The proposed solution must guarantee the proper dispense of medications in a person with chronic diseases. There are no limits to the number and types of ideas you identify. Any off-the-wall solutions you can think of are welcome. There are no right or wrong answers.

Target customer

- John is a 60 year-old salesman, was diagnosed with hypertension and arthritis, two years ago.
 - The treatment for hypertension requires the intake of two medications (A and B):
 - One pill every day, one hour before breakfast (medication A)
 - One pill every week, must be taken with food (medication B)
 - The treatment for arthritis requires the intake of another medication (C), six hours after taking medication A (two pills of medication C)
- John is a very active person, whose work requires short travels and meetings with clients, from Monday to Friday, from 9:00AM to 5:00PM. During the weekends, John donates his time and volunteers at a community center teaching math.
- Because of the joint inflammation caused by his arthritis, John has developed a reduced range of motion that limits some of his daily activities (e.g. opening a jar, manipulating small objects)

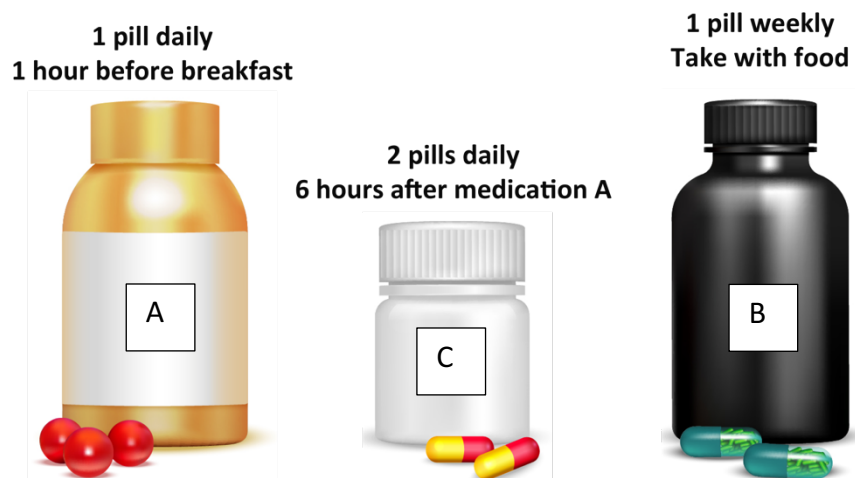


Figure 3 John's medication regimen

Design specifications

Your task is to design a medication dispenser for users such as John. Consider the following design specifications, and use the templates included in the following pages to record your design process.

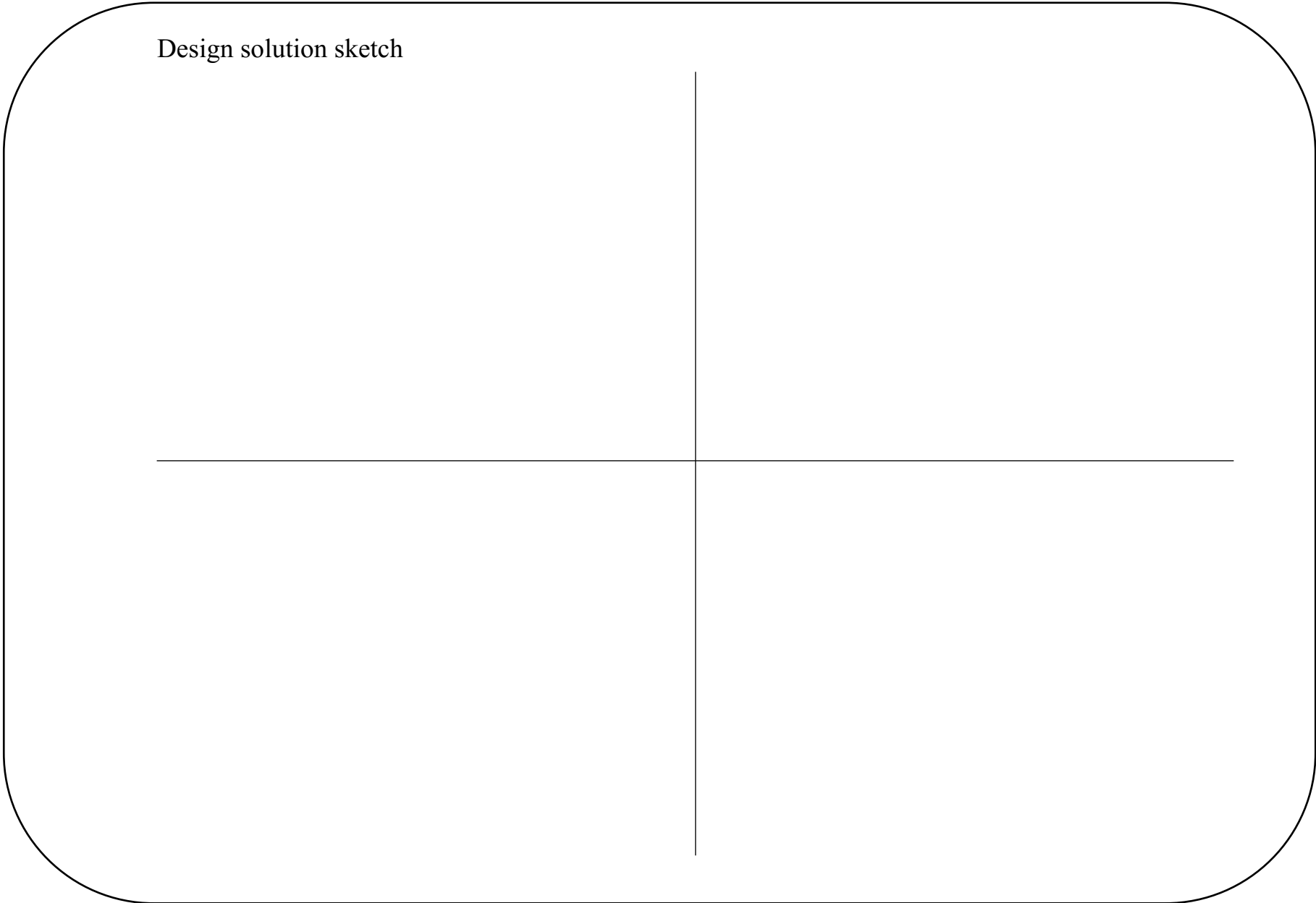
- **Portable**
 - The device must be small, lightweight, and portable so it can be easily transported during the day
- **Enables tracking and reminders**
 - The device should provide reminders to patients to take medication and keep track of the number of medications taken per day and week
- **Safe**
 - The device must dispense the proper medication and dosage at specific times
- **Easy-to use**
 - The device should be easy to use by patients with similar abilities as John

Tips for improving medication adherence

- Provide regular feedback – ideally for every dose
- Combine doses with other existing activities
- Make it easier to take the medication on time
- Consider easy-to-use device

Group member names: _____

Design solution sketch



The sketch area is a large rounded rectangle with a black border. It is divided into four quadrants by a horizontal line and a vertical line that intersect at the center. The text 'Design solution sketch' is located in the top-left quadrant.

Final design solution sketch

- Provide a detailed explanation of the components of your solution, include labels

Design specification: portable

Design specification: enables tracking
and reminders

Design specification: safe

Design specification: easy to use

What is Medication Adherence?

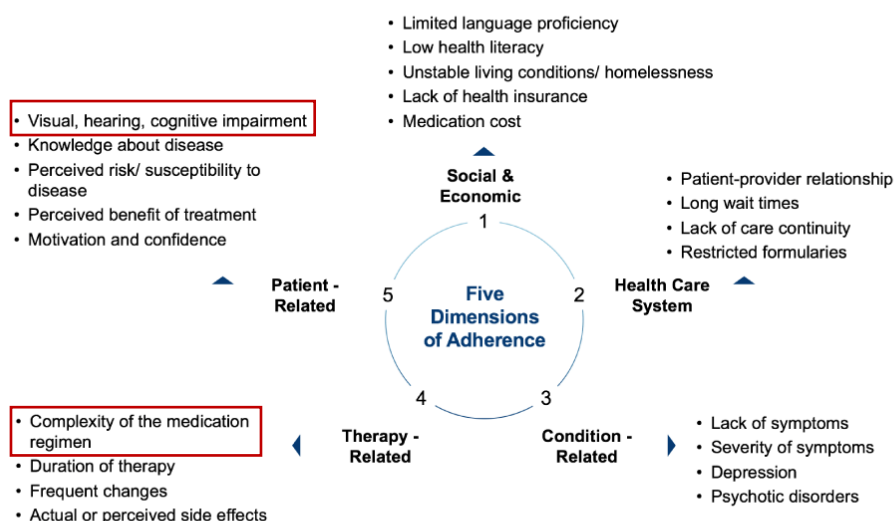
The U.S Food and Drug Administration (FDA) defines medication adherence or taking medications correctly, as the extent to which patients take medication as prescribed by their doctors. This The medication adherence is influenced by involves factors such as getting prescriptions filled in a timely manner, remembering to take medication on time, and understanding the directions [1].



Taking medications is a routine for most Americans; nearly three in five American adults take at least one daily medication. Despite evidence on the effectiveness of medication in combating diseases, their full benefits are often not realized because approximately 50% of patients do not take their medications as prescribed [2]. Medication non-adherence is estimated to incur costs of approximately \$300 billion per year of avoidable healthcare attention [3].

What Factors Impact Medication Adherence?

Medication adherence is influenced by many factors including social and economic factors; the healthcare system in which the person seeks care; the medical conditions being treated; issues related to the specific medication therapy; and the patient's perceptions, motivation, and levels of physical/cognitive impairment (see Figure 1).



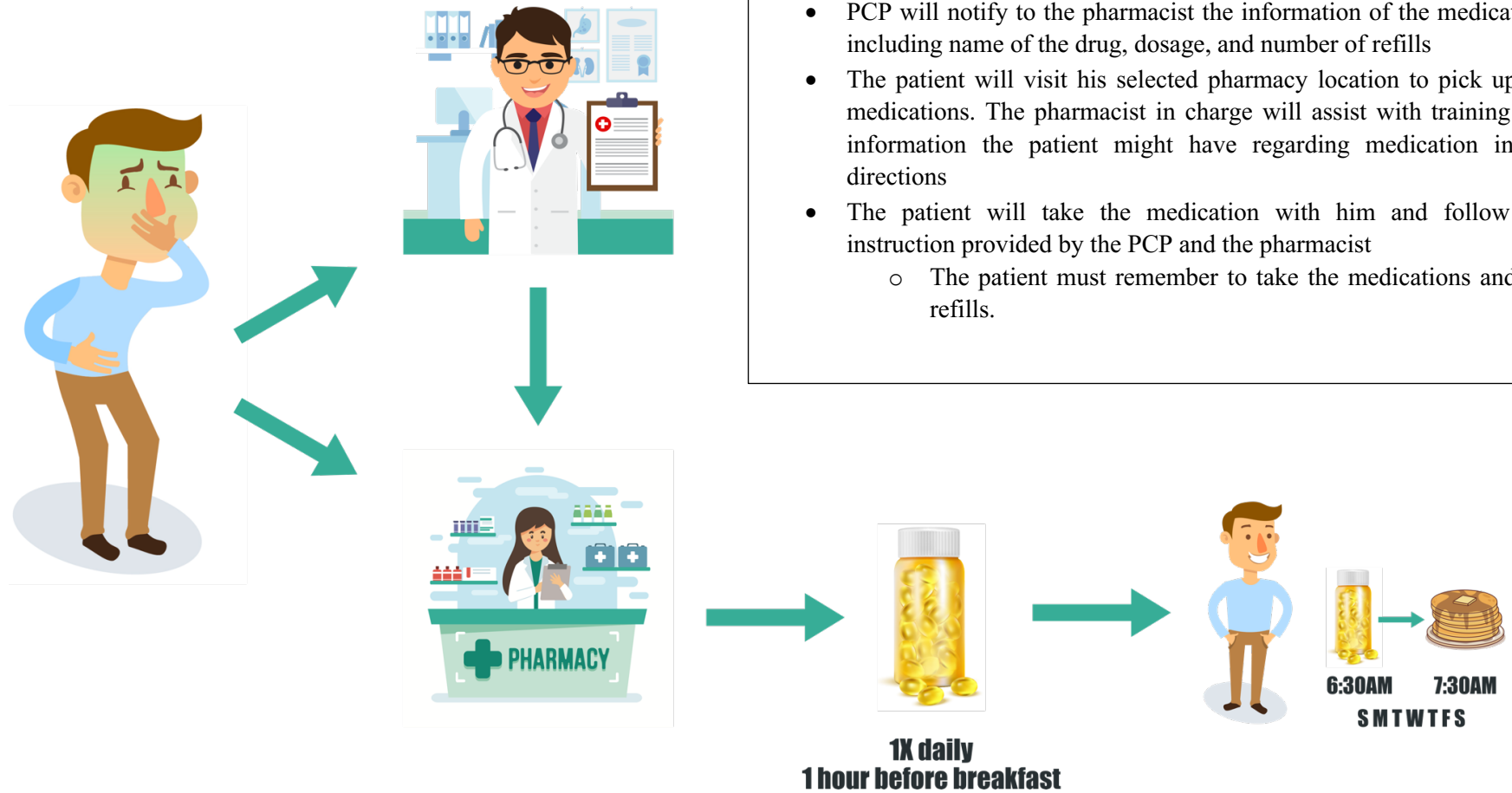
Source: Sabaté, Eduardo. Adherence to long-term therapies: evidence for action. World Health Organization, 2003.
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Figure 1 Diagram outlining the factors related to medication adherence

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Workshop Part II



Solutions for Improving Medication Adherence [1]

Because barriers to medication adherence are complex and varied solutions to improve adherence must be multifactorial. Existing solutions focus on organizing complex drug regimens or reminding users when to take their medications. There are many existing solutions on the market that can be grouped into the following categories. **For this workshop we ask you to focus on the category of Smart Pill Bottles and Dispensers**

- a) **Mobile medical apps:** Mobile medical apps support people in taking their medications on time by sending reminders
 - i) Benefit: Medication-oriented apps, alert patients when to take their medications while allowing them to record their history
 - ii) Benefit: Many apps encourage adherence through the use of gamification and metrics
 - iii) Drawback: Patients who read the alerts may not have necessarily taken their medications, making it difficult to track adherence
- b) **Smart package systems:** smart package devices serve as reminders for patients and provide tracking of dispensed doses
 - i) Benefit: Smart package systems are useful for patients with multiple medications and can integrate with drugs packaged by a pharmacy
 - ii) Drawback: Smart packages can be costly
- c) **Bio-ingestible sensors:** These sensors are embedded onto an oral drug that, when dissolved, sends an alert to a patient's smartphone and later alert a physician via a wearable patch indicating that the patient has taken his or her medication
 - i) Given the novelty of these devices, they are expensive
- d) **Smart pill bottles and dispensers:** Track when a patient takes their medications through sensors in a cap to detect when a bottle is open
 - i) Benefit: Smart pill bottles and dispensers can be used without an app or other technology
 - ii) Benefit: It can be expensive for patients who take multiple medications in a day
 - iii) Drawback: Can track when a pill is removed, but cannot track if the medication was taken

References

[1] R. Marotta, "From Pillboxes to Smart Pills: How Digital Health is Changing Medication Adherence (T. Aungst)," 2018.

Group member names: _____

Final design solution sketch

- Provide a detailed explanation of the components of your solution, include labels

Design specification: portable

Design specification: enables tracking
and reminders

23

23

Design specification: safe

Design specification: easy to use

Workshop Part III

Group member names: _____

Final design solution sketch



Figure 4 Smart pill bottle and dispenser

Smart Pill Bottles and Dispensers Available in the Market [1]

- **Vitality GlowCap:** The GlowCap system works with a smart cap that attaches to a medication bottle and sends alerts to patients when to take their next dose (e.g., audible alert and light alert with a cap lid that changes color) (<https://nanthealth.com/>)
- **Pillsy:** The Pillsy uses a smart pill cap for prescription drugs, and a smart pill cap/bottle for supplements (e.g., vitamins). The cap sends an audible alert when it is time to take a dose (<https://www.pillsy.com/>)
- **Pill:** The Pill is a smart opioid dispenser. The reusable dispenser is filled and dispensed directly from the pharmacy, and has a timer in the device that dispenses each dose in accordance with the prescription (<https://www.robrady.com/venture/Pill>)

References

- [1] T. digital Apothecary, “Smart Pill Bottles.”