UNIVERSITY OF WISCONSIN – MADISON

Personalized Medication Disposal System

Department of Biomedical Engineering
BME 301

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Abstract

An increase in unwanted and unneeded prescription medication is becoming more commonplace since the rise of opioid prescription frequency. Frequently, patients will be prescribed more opioids than they need, and this presents a problem because they are lacking a reasonable way to legally dispose of these medications. This project was started in order to address the current need for a personalized at-home medication disposal system, which will aid in slowing the rising opioid abuse problem in Wisconsin. The proposed system would be easy to use and small enough to fit in an average household without issue. The system would also have to be effective at making the active ingredient of the prescription drug inert and inaccessible.

There are currently products on the market. One is a controlled substances sink that is intended for use in clinical settings. The other is a small baggy filled with activated charcoal that patients can dispose of their meds with. Our design team has worked to improve upon these current methods in terms of increased convenience and environmental friendliness. Our design consists of a modified pill bottle that contains a grinder in the cap to disperse the medication tablets. The pill bottle also comes with a hydrogel powder that aggregates, and solidifies to render the active ingredient inert. These two aspects are expected to be easy enough for the patient, while also reducing risk of these pills polluting the environment. Our group is currently still in the design phase, but plans to fabricate and test this design within this semester's time.

Introduction

Motivation

Federal health officials have starting taking note of a rise in overdose deaths from opioids, including heroin and prescription painkillers that lead to opioid abuse. A recent national report showed that there were 4,397 heroin deaths across the country in 2011, which was a 44% increase from 2010 [1]. This spike in fatalities is accompanied by a persistent upward trend of deaths caused by prescription opioids, which rose 2% that year and accounted for 16,917 lives [1]. Another report found that 71.3% of pharmaceutical overdose deaths in 2013 involved opioid analgesics [2].

The recent national problem with opioid use, both prescription and non-prescription, has been paralleled in Wisconsin, partly because of the abundant supply of such drugs due to an increase in prescriptions. Table 1 demonstrates the frequency of opioid prescription relative to other controlled substances from 1/1/14 - 9/30/14. Hydrocodone/Acetaminophen and Oxycodone HCL combined for 28% of all controlled substances prescribed in the first half of 2014, and 55% of all controlled substance prescriptions were opioids. Since 2000, over 75% of opioid related

Drug Name	Drug Class	Number of Rx	Percent of All Rx
Hydrocodone/Acetaminophen	Opioid	111,831	19.0
Dextroamphetamine/Amphetamine	Stimulant	55,432	9.4
Oxycodone HCL	Opioid	52,888	9.0
Lorazepam	Sedative	45,132	7.7
Clonazepam	Sedative	40,045	6.8
Zolpidem Tartrate	Tranquilizer	32,441	5.5
Alprazolam	Sedative	29,126	4.9
Methylphenidate HCL	Stimulant	27,696	4.7
Oxycodone HCL/Acetaminophen	Opioid	26,305	4.5
Morphine Sulfate	Opioid	21,600	3.7

Table 1: Top Ten Controlled Substances Dispensed in Dane County between 1/1/14 - 9/30/14. A controlled substance is generally a drug or chemical whose manufacture, possession, or use is regulated by the government. Opioids are highlighted red for emphasis. Source: Wisconsin Prescription Drug Monitoring Program (PDMP)

deaths involved prescription drugs as opposed to "street" drugs such as heroin [3]. Heroin death rates have generally been lower, but recently heroin death rates have increased substantially [3]. This increase in death rates can be correlated to the increase in prescription opioid usage. Many people who exhibit opioid dependence report starting their opiate addiction with prescription pain medications [3]. Once the prescriptions run out, many new addicts must find other ways to acquire opioids, and often heroin becomes their drug of last resort. Because most prescription opioids are hard to come by, and heroin is relatively abundant, opioid addiction becomes more affordable when using heroin. An 80 mg OxyContin can cost $60 to $100 a pill. In contrast, heroin costs about $45 to $60 for a multiple-dose supply [4]. For addicts, prescription opioids effectively become gateway drugs to more dangerous substances, and so many believe that the root of the problem comes from the over prescription of opioids as pain killers.

Current Methods

A substantial contribution to the opioid problem in Wisconsin comes from the dilemma around the storage and disposal of medications. Some patients have access to hundreds of pills over the course of a treatment schedule, and many prescriptions go unused [5]. If people throw them in the trash, give them to a friend, or leave them in their medicine cabinet, complications will often arise. The pills may make it to the street for resale, law enforcement may find them, pets and wild animals may ingest the drugs.

The disposal dilemma extends to domains other than the household. Until recently, pharmacists and physicians could not legally take back pain medication due to liabilities [6]. It is environmentally harmful to dispose of pills in the trash or to flush them down a drain. The

impact of birth control flushing on aquatic life has been devastating, and the impact of opioids in waterways is not yet known [7].

There are no official protocols in the U.S. for a safe and environmentally friendly opioid disposal method [8]. Ninety-seven percent of pharmacies have formal procedures in place to dispose of their own unused medication, but only 5% of them offer recommendations on disposal to their customers [8].

According to the World Health Organization, controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. They should either be rendered unusable, by encapsulation or inertization, or then dispersed among the municipal solid waste in a landfill, or incinerated [9].

FDA approved methods of medication disposal include: medicine take-back programs, mixing of medication with unpalatable substances, flushing down a drain (in some cases) [10]. Flushing of potent opioids, such as the extended release hydrocodone tablet Zohydro ER, down a drain is recommended by the FDA because these drugs are considered to be high-risk drugs if unintentionally ingested [11]. The FDA's current stance on opioid disposal is focused on immediate safety of household and community residents, and less focused on environmental effects of disposal, or deactivation of the active ingredient inside the medication.

Statewide disposal methods have also been undertaken. Many police stations now have a medication drop box with which to dispose of unused medication. Once collected, these drugs are then incinerated in a secure location [12]. This method, along with other take-back programs, are inconvenient and cumbersome to many, and virtually unknown to many others.

Figure 1: Medication Drop box. These drop boxes provide a safe and secure method of disposal, but are inconvenient to use. Source: City of Racine homepage

Figure 2: Cactus Smart Sink The Cactus Smart Sink is a specific disposal system for certain medications. Source: Apothecary Products

Figure 3: Medsaway packaging. Medsaway medication disposal system uses activated charcoal to neutralize most medications. However, it has an unknown environmental impact. Source: Apothecary Products

Cactus Smart Sink: The Cactus Smart Sink is designed to dispose of medical wastes in a medical facility safely and easily. The smart sink is designed to dispose of solid medicines,

liquid medicines, and medicinal patches. It disposes of liquids and solids by placing them into a key-locked compartment. Although this product meets many of the criteria needed for an at-home product, as a team, it is has been decided that the Cactus Smart Sink is too expensive and too bulky for an at-home, personal basis [13].

Medsaway: Medsaway is an in-home medication disposal system. The system involves a sealable plastic bag, lined with activated charcoal. When medicines and water are added to the pouch, the activated carbon attaches itself to the medicines, rendering them "inert." Upon further research, no concrete evidence could be found confirming the products viability to inactivate the drugs themselves. The only research performed, has been performed by the company and analyzed by the company [14].

In conclusion, we feel that the all on the market drug disposal systems do not meet criteria set by the client. All systems currently available are too expensive, unreliable, or not available on an at-home basis. From this, we conclude that there is still a need for an at-home medication disposal system.

Problem Statement

The number of prescriptions prescribed to patients continues to increase exponentially with each passing year. Dane county households with an excess of prescription and over the counter drugs have become commonplace, and both unintentional and intentional overdoses are increasing in frequency. Current methods of medication disposal are inconvenient and potentially dangerous, and so stockpiling medication or disposing of it in an environmentally harmful manner are a popular practice in dealing with excess medication.

A personalized medication disposal container has been proposed to physically or chemically deactivate medication through a safe and easy process, which will render it inert and environmentally safe to dispose of. A neutralizing method for opioids such as hydrocodone and oxycodone are of particular interest, as these are the most prescribe and most abuse opiates.

Background

Client Information

Dr. Philip Bain is an internist in Madison, Wisconsin and is affiliated with multiple hospitals in the area. He received his medical degree from University of Wisconsin School of Medicine and Public Health and has been in practice for 29 years, specializing in headaches and other pain management.

Design Specifications

The entire device is to be same size as, or slightly larger than a medication pill bottle. The product must be affordable for practically any working person. The device needs to be very simple to operate. And the device should be able to grind up at least five pills at a time without too much difficulty. It should also be able to store at least an entire prescription worth of opiates to be disposed of. After disposal, the product should be easily washable and reusable for years' worth of prescriptions to come.

The proposed design would be able to withstand multiple uses, and ideally allow the user to keep the same single unit for several years depending on how frequently they use it. The product should cost around $5 to produce a single unit, with the polymer packets being sold separately. Regardless the whole process should have minimal expenses (under $10) as to be as appealing to users as possible. The complete PDS can be found in the Appendix.

Preliminary Designs

Hydrogel Powder

The main idea behind the "hydrogel powder" concept is that the drug tablets would become incorporated into a new compound, and this compound would be rendered inert, effectively trapping the active ingredients inside. The hydrogel powder would contain one or more excipient agents, and one or more desiccating agents that would interact with the opioid in order to facilitate disposal. An excipient is a substance that is incorporated into the active ingredient of a medication. These excipients perform numerous functions, such as binders, disintegrates, and lubricants, which generally work together to facilitate controlled release and solubility of a drug [15]. The excipient will likely take the form of a hydrogel that will incorporate the drug into its matrix. A desiccant is a substance that dries its surrounding environment, commonly by absorbing or adsorbing water. The desiccant will likely take the form of a fast-hardening plaster. These agents would ideally solidify over time to discourage the ingestion of the finished product, to aid in making the finished product inert to the environment, and to increase ease of disposal. The final chemical agent would likely have both hydrophilic and hydrophobic properties. The interaction between these compounds and the active ingredient would ideally be easy for the patient to use, since all they would have to do is pour the powder in with the medication and add water.

Many hydrophilic polymers were considered for the hydrogel. Hydrophilic polymer matrix systems are widely used in oral controlled drug delivery because of their flexibility to

obtain a desirable drug release profile, cost effectiveness, and broad U.S. Food and Drug Administration acceptance [16]. A few of them include:

Poly(acrylic acid) (PAA): Polyacrylic acid contains a carboxyl group pendant chain, and so at non-acidic pH, this pendant chain will ionize. The resulting negative charge, accompanied by the macrostructure of the polymer, allows PAA to trap water at each pendant chain, resulting in swelling of the macromolecule complex. Materials with this property are known as polyelectrolytes. PAA is frequently used as thickening and suspension agents for petroleum recovery, pigment dispersements in paint, ion exchange resins (with cross-linking), and flocculating agents for particles suspended in water, and adhesives [17].

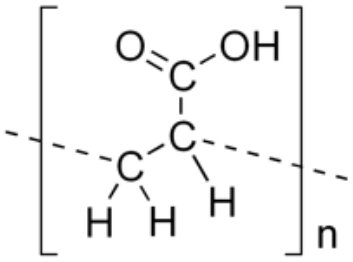


Figure 4: Polyacrylic acid. The carboxyl group gives This polymer its hydrogel Quality. Source: Wikipedia.

Hydroxypropyl methylcellulose (HPMC): HPMC is an inert, non-toxic polymer used as an excipient and controlled delivery component in oral medications. When combined with medication in water, HPMC will aggregate to form a suspended group, called a colloid [16]. Although HPMC is inert, it combusts when reacting with oxidizing agents. HPMC has been widely used to control the administration of a drug by delaying its release. HPMC is also used as a drug binder, which helps to dry and maintain structural support [18].

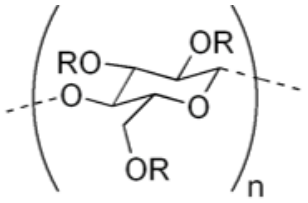


Figure 5: HPMC. A good aggregate, but Possibly dangerous. Source: Wikipedia.

polyethylene glycol (PEG): PEGylation is the act of covalently coupling a PEG structure to another larger molecule, for example, a therapeutic protein, which is then referred to as a PEGylated protein. It is coupled to hydrophobic molecules to produce non-ionic surfactants. When attached to various protein medications, polyethylene glycol allows a slowed clearance of the carried protein from the blood. This makes for a longer-acting medicinal effect and reduces toxicity, and allows longer dosing intervals. This type of material could be useful for the addition of antagonistic substances to the composite.

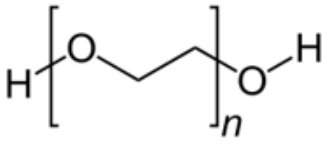


Figure 6: PEG. PEGylation of our target drug May be an applicable design in Terms of aggregation. Source: Wikipedia.

Sodium Starch Glycolate: Sodium Starch Glycolate falls under the category of superdisintigrants. The crosslinked starch glycolate is an anionic polymer that is produced by crosslinking and carboxymethylating potato starch [19]. Sodium Starch glycolate is used as a dissolution excipient for tablets and capsules. Because of its swelling properties in the presence of water, it is used as a disintigrent, suspending agent, and gelling agent [20].

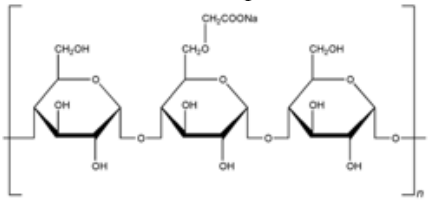


Figure 7: Sodium Starch Glycolate. This polymer is a superdisintigrant and is Anionic, so it may be an ideal hydrogel. Source: Wikipedia.

Sodium Alginate: Alginate is a linear polysaccharide created from algae. Alginate gelling is mild enough to allow encapsulation of large biomaterials such as cells [21]. Mammalian cells do not interact with alginate through receptors, and alginate promotes very little protein adsorption,

and subsequently very little cell adhesion. Alginate also makes a good base material to incorporate specific physical and chemical properties into the excipient substance. Alginate hydrogels are highly porous, allowing molecules to diffuse in and out of the matrix [21].

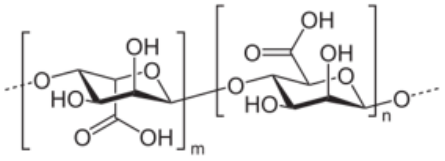


Figure 8: Sodium Alginate.
This polymer is very inert and is most known
Among our team.
Source: Wikipedia.

In addition to hydrogels, numerous desiccants were considered in the design process. Desiccants are widely used in food preservation, and are chemically inert. A few of them include:

Calcium Sulfate: Calcium sulfate is a common lab chemical. In the anhydrous form it is used as a desiccant and coagulant. The hemihydrate and dihydrate form are known as Plaster of Paris and Gypsum respectively, and are used as plasters and thickening agents [22].

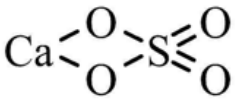


Figure 9: Calclium sulfate Dihydrate.
This desiccant is used as a plaster
And is very common.
Source: Wikipedia.

Cement Plaster: Cement plaster consists of sand, portland cement, and suitable plaster. When combined with water, a smooth paste is created, which hardens quickly. Cement plaster has the advantage of being strong, hard, quick-drying, and durable [23].

The hydrogel powder design also allows for increased flexibility in terms of what is included in the final compound. Specifically, there is a possibility that a substance that works to neutralize, degrade, or antagonize the active ingredient could be included, in order to further discourage ingestion of the finished product. One potentially viable antagonist is:

Naltrexone: Naltrexone is an opioid antagonist used in both opioid and alcohol dependence treatment. It mostly comes in a hydrochloride salt, Naltrexone hydrochloride. Naltrexone blocks opioid euphoric effects, thus helping patients overcome their addiction [24].

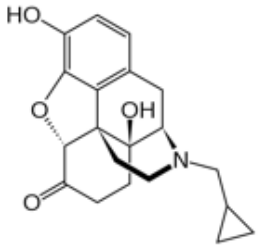


Figure 10: Naltrexone.
Naltrexone can inhibit
Opioids by blocking
Receptors.
Source: Wikipedia.

UV Light

Hydrocodone and other medications are stored in a light resistant containers [25]. This suggests that hydrocodone may undergo some reaction with light. In fact, hydrocodone reacts with light that has a wavelength of less than 290 nm, which would include short length UV light [26]. It is possible that light of certain wavelengths could provide enough energy to allow

electrons to move to a more excited state. Once in this excited state, the chemicals within these pharmaceuticals would more readily react with their environment. And it is due to such reactions that as of 1998, the FDA mandated that all pharmaceuticals must undergo photo stability testing [27]. Given this information a design was postulated that a UV light emitting device could be used to dispose of opiates in an at home setting.

This design was essentially a miniaturized tanning bed. It would be a small cylinder lined with UV light bulbs. The left over opiates could then be dumped into the container, the UV lights would be turned on, the cylinder would be closed, and the opiates would be left to sit. While basking in the UV light, the opiates would ideally lose most of their potency [28]. Then upon completion of the reaction, the drugs could hopefully just be thrown away, as the light should have rendered them fairly inert.

This design had the major advantage of being fairly safe. The only major safety concerns with the design is if someone were to look directly at the UV lights, or there was some kind of electrical short. Also in theory the design would be easy and fairly inexpensive to fabricate. It would simply be a matter of creating the containing and attaching light bulbs in parallel to a switch.

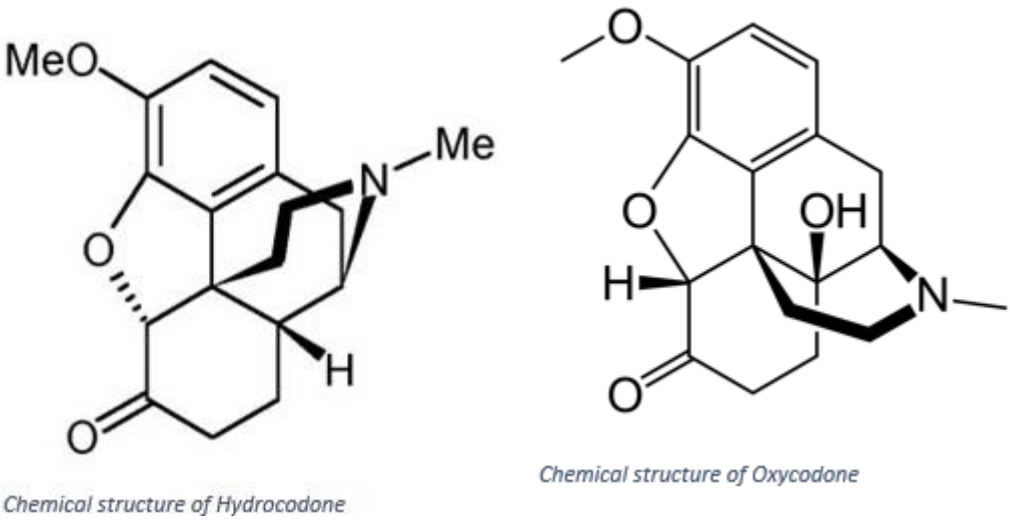
However, this design also has several drawbacks. For starters, each formulation of the opiate may have a different reaction to the light. These reactions could be relatively harmless or they could be fairly active. Likewise the reaction could give off unknown by-products. Furthermore, it is uncertain what the final product will be and how long the reaction will take. If one or more of the bulbs is going out, the reaction could take longer than recommended. Hence, a major issue with this design is a lack of certainty and a lack of control. Additionally finding bulbs that are fairly short, and produce light that has a wavelength of less than 290 nm is not an easy task.

Bond Vibrational Frequency

Chemical bonds between atoms vibrate back and forth at specific frequencies. These specific vibrational frequencies within a molecule can be found [29] using a wave generator. It should be possible to create a bandwidth of frequencies matching those bond frequencies found. Theoretically, if we are able to produce this wave with a large enough amplitude, it should cause the bonds in the molecule to break apart from one another, thus rendering the molecule inert and unable to react with the human body.

Below are the molecular structures of hydrocodone and oxycodone. In order for these molecules to be broken down and activated in the human body, they must first undergo O-demethylation, N-demethylation, and 6-keto reduction. [30] If we are able to remove these groups of molecules, then the molecule will be ineffective in the human body.
The groups we are interested in are the R-OMe, R-C-N, and C=0. These bonds have wavelengths measuring 1210-1320 cm^{-1}, 1000-1250 cm^{-1}, and 1705-1720 cm^{-1} sequentially. Therefore, if we were to produce a wave with a bandwidth of frequencies matching those bond

vibrational frequencies, the bonds should break. [29] Once these bonds are broken, the opiate (hydrocodone or oxycodone) should be rendered inert and unusable.



Chemical structure of Hydrocodone

Chemical structure of Oxycodone

Figure 11: Chemical Structure of common opioids. These opioids have very similar bonds and activate many of the same receptors.

This design would have the benefit of completely destroying the drugs, as the chemical bonds that make the effective would be broken. Once these bonds are broken, the specific medication should lose all of its potency. Thus making it impossible to overdose or abuse this medication.

However, it will involve a very sensitive reaction with an unknown energy release. Breaking bonds releases energy, and as such by breaking the bonds this design could pose a danger to the user. Additionally the creation of a device that could effectively match the wavelengths of a specific chemical bond would be incredibly time consuming and expensive to create. There would also be no guarantee that once the wave generator was removed from the pills that the broken bonds would just reform.

Preliminary Design Evaluation

Design Criteria

An important consideration for this design is how inaccessible the drugs will be after the design has run its course. Inaccessibility could mean that there is simply no way to get at the drugs after implementation of the design, or it could imply that the drugs have been lost their therapeutic effect and no one could overdose off of the final product. This criteria is opposed by safety. As there are many ways to render a drug inaccessible, but not all of them are safe. The

criteria of safety does not just pertain to the safety of the user. While safety of the user is still very important, safety should also consider the environmental impact of the design. A design that has an end product that would negatively affect the water table when thrown out is not a safe design, even if the process to get to the final product was safe and easy for the user.

Another key component to this design, is that is needs to appeal to people. People need to find it convenient to use this device. As such, two additional criteria would be cost and ease of use. People will not use a product that is ridiculously expensive, while their current methods of disposal have minimal fiscal cost. Likewise, if the design is far too complicated to use, then people won't use it.

Finally it is important to consider the marketability and the manufacturability of the design. Ideally this design would go to market, and be used by many consumers. As such, the design cannot be too off-putting. A design such as a household incinerator may seem too dangerous for a user to want to have in their home. Also, in order for this device to go to market it would need to be mass produced. Thus, the method in which the design is manufactured needs to be fairly simple.

Design Matrix

Design Matrix (Weight)	Hydrogel Powder		UV Light		Bond Vibrational Frequency	
Inaccessibility (25)	(4/5)	20	(4/5)	20	**(5/5)**	**25**
Safety (25)	(4/5)	20	**(5/5)**	**25**	(3/5)	15
Cost (20)	**(5/5)**	**20**	(3/5)	12	(2/5)	8
Ease of Use (15)	**(5/5)**	**15**	(4/5)	12	**(5/5)**	**15**
Marketability (10)	**(5/5)**	**10**	(4/5)	8	(4/5)	8
Manufacturability (5)	**(5/5)**	**5**	(4/5)	4	(2/5)	2
Total (100)	**90**		81		73	

Figure 12: The goal of the project is to create device that renders opiates inaccessible and is safe for the user and environment. As such, those two categories had the most weight. Next was cost followed by ease of use. A design that is too expensive or difficult to use will not be used by consumers. This design should be used, as such a design that score well in those categories would encourage people to use it. Lastly, should the design go to market it will need to be marketable and easy to manufacture. Thus those two categories are also included, but are not weighed as heavily as they are not a major concern at this point.

From the design matrix it can be seen that, hydrogel powder won overall and won all the categories except inaccessibility and safety. This is because the hydrogel powder design would be cost-effective, as the individual components are not expensive, as well as easy to use, as it would just be a matter of mixing several packets together. Likewise, mixing to inert compounds

together would not be off-putting for consumers, and the manufacturing process for this design would also be very easy. UV light, only won safety. This is because there are many unknowns that occur with the UV light reaction. However, UV light is fairly safe to use unless someone were to stare at it directly. Bond vibrational frequency won inaccessibility and ease of use. The device would simply obliterate the opiates, such that there was nothing left to access. Likewise it would be very easy to use.

Nonetheless, hydrogel powder won the design matrix. Predominantly because it renders the drugs fairly inaccessible and is fairly safe to use, in addition to meeting all the other criteria.

Proposed Final Design

Since the Hydrogel Powder design ended up scoring the most points in the design matrix, the final design proposed by the team incorporates the method of trapping the active hydrocodone in a gel solution. The proposed final design is a "modified pill bottle" complete with a grinder attachment on the lid and the bottle serving as a reaction compartment for the hydrogel powder to be mixed with the grinded medication and water. The grinder lid is complete with an upper and lower portion, with the upper portion fitting snugly on top of the bottom portion, and the bottom portion screwing on to the bottle attachment to create a tight seal for the reaction. Both portions of the grinder lid have pyramid-shaped spikes evenly distributed around them and spaced far enough apart to allow the average sized hydrocodone or oxycodone pill to fit inside. The bottom portion also has small holes evenly distributed around the bottom surface that will allow the ground medication to sift through into the reaction chamber.

The intended use of this product would have the user place the unused pills evenly spaced in the bottom portion of the grinder, which will be screwed on to the reaction chamber, and place the top portion on top of the bottom portion, and turn the top portion in a circular motion until all the medication is ground into a powder and in the bottom of the reaction chamber. Once the grinding is complete, the user can empty the polymer packet into the reaction chamber, add water, and screw the lid back on to allow the reaction to occur. Once the reaction is complete and the gel has formed around the medication, the user can dispose of the products in the trash. The grinder lid and reaction chamber are intended to be sold together and good for multiple uses, while the polymer packets will be sold separately.

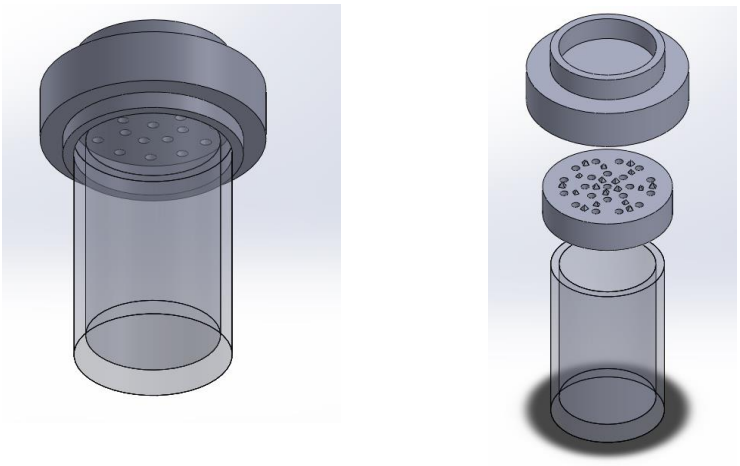


Figure 13: solidworks of final design. The design consists of top and bottom grinder, and pill container.

Future Work

Materials

For the successful completion of this design, we will need to test and evaluate different combinations of compounds that will go in our hydrogel powder. To do this we will need to first decide on a specific combination of materials, and then test these materials under a controlled environment. This means we will need access to both the biochemicals, and a biochemical or organic chemistry lab setting.

Furthermore, we will need to be able to test the composition of our newly created compound after the interaction with the target drug to ensure no adverse reactions took place. This will require access to testing such as Mass Spectrometry or Nuclear Magnetic resonance spectroscopy.

We will also likely have to make the prototype pill bottle out of a plastic. We plan on using the 3D printer for some of this, so the material will likely be made out of what is acceptable for use in the 3D printer.

Proposed Budget

The client did not specify a budget range initially, but given the simplicity of our design and the inexpensive materials and processes needed to complete it, the overall costs for fabrication and testing should total to less than $200. Because the primary goal of this product would be to get people to use it, the team would like the final product to cost around $5 to produce.

Methods

One of the methods we will be using to complete the design prototype will be 3D printing. Since a rough model for the design has been constructed on SolidWorks, the schematic will be able to be used to create a 3D printed copy made of plastic. The team has not yet decided on actual dimensions for the first prototype, but they should be similar to those of the average sized pill bottle.

Another method the team plans to use is a computer-aided mill to create the holes in the bottom portion of the grinder lid. This will be much less time consuming and more accurate than using a mill in the machine shop.

Testing

For testing the functionality of the prototype, the team will need to get access to hydrocodone or oxycodone tablets, which will be possible with the help of a friend of the client. The first step of testing will occur after the prototype is finished being 3-D printed and the computer-aided milling is completed to assess how effectively the grinder lid attachment turns the medication into a powder. The next testing procedure will involve attempting to use the product as described in the Proposed Final Design section above, and ensuring that the polymer reaction is successful, and the ground medication is trapped by the gel and unusable. Other possible testing could involve ensuring that the polymer functions as intended with water separately, but this testing is not necessary unless the reaction with the medication present is unsuccessful.

Conclusions

Because many people aren't properly disposing of their unused medication, the rates for addiction and accidental overdoses on controlled substances such as hydrocodone and oxycodone have greatly increased. To decrease the amount of controlled substances with the potential to be abused, this design allows the user to render their leftover pills unusable by others by grinding them into a powder and trapping the powder in a hydrogel that can be safely disposed of in the trash. The team has concluded this to be the most effective method possible based on research and the results of the design matrix. The next steps for this project involve getting the dimensions and features of the final design set and agreed upon before 3-D printing and computer-aided milling are to begin.

Once the prototype is complete and believed to be ready for testing, the team will carry out tests on how effectively the grinder lid turns the pills into a powder, and how effectively the design grinds the medication and traps it in the hydrogel. Once these tests are complete, any modifications that can be made will be done and tested until a successful final product has been achieved. Once the design is deemed complete, the team may patent the product and look into making it available for consumer use.

References

[1] J. Fauber. (2014), Overdose deaths from opioids, heroin on the rise. *Milwaukee Wisconsin Journal Sentinel*. Available: http://www.jsonline.com/watchdog/watchdogreports/overdose-deaths-from-opioids-heroin-on-the-rise-b99302962z1-265452991.html

[2] (02/10/2015). *Prescription Drug Overdose in the United States: Fact Sheet*. Available: http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html

[3] Bullard-Cawthorne, L., Ndiaye, M. "Snapshot of Opioid Problem in Wisconsin and Dane County 2015." *Public Health: Madison & Dane County.*

[4] D. L. Leger. (2013), OxyContin a gateway to heroin for upper-income addicts. Available: http://www.usatoday.com/story/news/nation/2013/04/15/heroin-crackdown-oxycodone-hydrocodone/1963123/

[5] (2011, 02/20/2015). *Use, Abuse, Misuse & Disposal of Prescription Pain Medication Clinical Reference*. Available: http://www.acpm.org/?UseAbuseRxClinRef

[6] C. S. Louis. (2014), D.E.A. to Allow Return of Unused Pills to Pharmacies. *The New York Times.* Available: http://www.nytimes.com/2014/09/09/health/unused-pills-return-to-pharmacies.html?_r=2#story-continues-3

[7] J. Roach. (2007), Sex-Changing Chemicals Can Wipe Out Fish, Study Shows. Available: http://news.nationalgeographic.com/news/2007/05/070521-sex-fish.html

[8] M. E. Herring, S. K. Shah, S. K. Shah, and A. K. Gupta. (2014). *Current Regulations and Modest Proposals Regarding Disposal of Unused Opioids and Other Controlled Substances*. Available: http://www.jaoa.osteopathic.org.ezproxy.library.wisc.edu/content/108/7/338.full

[9] World Health. (1999). *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies.* [Online] Available: http://apps.who.int/medicinedocs/en/d/Jwhozip51e/5.5.html.

[10] U.S. food and Drug Administration. (2015). *Disposal of Unused Medicines: What You Should Know.* [Online]. Available: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

[11] U.S. food and Drug Administration. (2013). *Medication Disposal: Question and Answers.* [Online]. Available: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm

[12] Safe Communities of Madison-Dane County. (2015). *Safe Communities MedDrop Program.* [Online]. Available: http://www.safercommunity.net/meddrop.php

[13] Cactus, "Cactus Smart Sink," [Online]. Available: http://www.cactusllc.net/. [Accessed 24 February 2015].

[14] Medsaway, "Medsaway," Verde Environmental Technologies Inc., 2014. [Online]. Available: http://www.medsaway.com/. [Accessed 24 February 205].

[15] Lesney, M. S. (2001). *More than just the sugar in the pill.* [Online]. Available: http://pubs.acs.org/subscribe/journals/tcaw/10/i01/html/01lesney.html

[16] Williams, R. O., et al. "Method to recover a lipophilic drug from hydroxypropyl methylcellulose matrix tablets," *AAPs PharmSciTech.* Vol. 2, no. 2, pp 29-37, June 2001. Available: http://link.springer.com.ezproxy.library.wisc.edu/article/10.1208/pt020208

[17] Orwoll, R. A.; Yong, C. S. *Polymer Data Handbook.* "Poly(acrylic acid)". Oxford University Press, Inc, 1999, pp. 252–253. Available: http://www.toarplast.co.il/linkspage/handbook.pdf

[18] Alderman, D. A., Wolford, T. D. „Hydroxypropyl methyl cellulose". US 4678516 A. Jul 7, 1987. Available: https://www-google-com.ezproxy.library.wisc.edu/patents/US4678516

[19] Omidian, H., Park, K. *fundamentals and Applications of Controlled Release Drug Delivery. "*Hydrogels." New York, NY, Spinger, 2012, pp 75-106. Available: http://kinam.com/Articles/Hydrogels%20Papers/Omidian%2012%20Book%20Chapter.pdf

[20] Drugs.com (2015). *Sodium Starch Glycolate.* [Online] Available: http://www.drugs.com/inactive/sodium-starch-glycolate-128.html

[21] University of Wisconsin – Madison Department of Biomedical Engineering. (2015). *Lab 1 – alginate Hydrogels Introduction.* [Online]. Available: https://ay14-15.moodle.wisc.edu/prod/pluginfile.php/152038/mod_resource/content/0/Lab%201%20-%20Alginate%20Mechanical%20Properties.pdf

[22] Gangolli, S. *The Dictionary of Substances and Thier Effects: C.* Great Britain, Royal Society of Chemistry, 1999, pp 71-73. Available: http://books.google.com/books?id=s4YittJrOsAC&pg=PA71#v=onepage&q&f=false

[23] Stucco Guru. (1997). *Portland Cement Plaster*. [Online]. Available: http://www.stuccoguru.com/resources/article.cfm?articleID=A-01050&resourceID=3

[24] Drugs.com. (2015). *Naltrexone.* [Online] Available: http://www.drugs.com/pro/naltrexone.html

[25] (2011, 2/20/2015). *LABEL: HYDROCODONE ACETAMINOPHEN - hydrocodone bitartrate and acetaminophen tablet* Available: http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b165dffd-1550-4d8d-a8ea-fe83512c34e6

[26] PubChem. (2/19/2015). *Dihydrocodeinone*. Available: http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=10224

[27] (2004). *Photostability of Drugs and Drug Formulations (Second ed.)*. Available: https://books-google-com.ezproxy.library.wisc.edu/books?hl=en&lr=&id=AFtAqwtrwucC&oi=fnd&pg=PA1&dq=Photoactivated+drugs+and+drug+formulations&ots=jRkSm-y7Nf&sig=Asu5BrJjuOUCFhRq4SHJ36Vh4uA#v=onepage&q=Photoactivated%20drugs%20and%20drug%20formulations&f=false

[28] H. H. Tønnesen. (2008, Photoreactivity of drugs. *Solar Radiation and Human Health*, 102-112. Available: http://www.dnva.no/geomed/solarpdf/Nr_8_Hjorth_Tonnesen.pdf

[29] W. Reusch, "Infrared Spectroscopy," 5 May 2013. [Online]. Available: http://www2.chemistry.msu.edu/faculty/reusch/VirtTxtJml/Spectrpy/InfraRed/infrared.htm. [Accessed 24 February 2015].

[30] "Hydrocodone," PubChem, [Online]. Available: http://pubchem.ncbi.nlm.nih.gov/compound/hydrocodone#section=Top . [Accessed 24 February 2015].

Appendix

PDS

Personalized Medication Disposal System

Product Design Specifications

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Function: When opiates like morphine or hydrocodone are prescribed to patients, often times they are not taken to completion by the user. If these drugs are not disposed of by the patient, the drugs can often times be stolen, abused, or misused by family and friends. Moreover, if the drugs are disposed of incorrectly, they present a significant threat to the quality of water in the water tables. A personalized medication disposal system to prevent the improper use of opiates is proposed. Currently, there are medication disposal systems available in hospitals and some police stations. There are also at-home, single use drug disposal packets available for purchase. Our goal is to design and develop a re-useable, at-home opiate disposal system that renders these drugs unusable and unrecoverable.

Client Requirements:

1) Render hydrocodone and oxycodone inert
2) Able to use in an "at home" setting
3) As convenient as dumping drugs down toilet/sink
4) Does not produce harmful by-products
5) Eco-friendly
6) Affordable for average person
7) Safe for use by average person

1. Physical and Operational Characteristics:

a. Performance:

- Must completely neutralize/denature medication
- Drugs must be unrecoverable by physical or chemical means
- Drugs must be neutralized within a 48-hour time period

b. Safety:

- Safe for use by average person
- No dangerously high temperatures, pHs, etc.

- Environmentally friendly
- non-toxic
- Children-safe locking cap
- Directions for proper disposal must be included

c. Accuracy and reliability:

- Must be able to able to render drugs inert and in an unrecoverable state

d. Life and service:

- The device needs to be used for years worth of prescriptions without malfunction or failure of the device
- Able to take apart and repair without risk to integrity
- Activated ingredient ought to be made available for purchase in bulk from store locations.

e. Shelf life:

- Should be able to set on the shelf for a few years without breaking down or becoming ineffective

f. Operating environment:

- Homes, pharmacies, portable, etc.
- Able to be used practically anywhere with water access

g. Ergonomics:

- Easy to understand and use
- Sit flat on a level surface
- Not slippery
- Does not get too hot on exterior
- Rotation ought to be smooth

h. Size:

- The entire device should be the same size as, or slightly larger than, a normal medication disposal device.

i. Weight:

- Less than 2.25 kg

j. Materials:

- Powder substance used to transform and render the medicine inert
- Grinder cap where pills will be placed for future grinding
- Pill bottle attachment with holes for medicine powder to fall through
- Measuring Device attached to grinder cap for easy measuring of powder substance
- Containment unit
    - Original or designed plastic medication pill bottle

k. Aesthetics, Appearance, and Finish:

- Not overly complex
- Compact
- Non-intimidating

2. **Production Characteristics**

a. Quantity:

- One, reuseable

Target Product Cost:

- Manufactured for ~$5
- Testing can cost ~$200

Miscellaneous

a. Standards and Specifications:

- Adhere to FDA and Dane County medication disposal regulations
- No illegal products/byproducts
- Federal DEA regulations do not permit controlled substances to be removed for disposal without special approval according to procedures established by regional DEA offices.
- Medical Facilities must submit extensive record keeping for the disposal of controlled substances.
- Controlled substances can never be returned to the pharmacy for re-use.
- Controlled substances are more tightly regulated, and so must often be destroyed by a licensed pharmacist or nurse practitioner with another licensed medical staff person as witness.

- 17 states are silent on the specific process of destruction.

b.*Customer:*

- Usable in residential setting
- Easy enough for use by average person
- No components unsafe for use by average person
- Safe for standard household use

c. Patient-related concerns:

- All parts included must be safe for use by average person
- Must not create harmful products
- Outside does not exceed 37 degrees C or get less than -33 degrees C
- pH of potential chemicals in use/ by products 9-5 to prevent chemical burns

d. Competition:

- Cactus Smart Sink®
- Med Drop boxes at Police Stations
- Other patented personal medication disposal systems (Medsaway)

RESOURCES:

http://www.drugstore.com/medsaway-medication-disposal-system/qxp471622

http://www.cactusllc.net/

http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/LewinGroup.pdf

http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf