My-NR: Coumadin Monitoring and Dosing System

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Executive Summary

Problem: Warfarin levels are monitored either using a point of care device, conducting a PT test at the doctor's office, or scheduling a nurse to make an at-home visit. Many patients taking warfarin are elderly and have difficulty getting to the doctor's office or do not have the money to hire a visiting nurse. INR levels should be measured at least once a week to keep the patient in the therapeutic band (INR of 0.8 to 1.2). Recently, doctors have urged that a patient's INR should be tested more often than once a week because factors such as diet, exercise, metabolic rate, and gender can have a significant effect on how warfarin effects INR.
Solution: Combine an at-home INR meter with a pill dispenser. Both communicate with the doctor which prevents the patient from making frequent trips to the doctor's and ensures that the patient has normal warfarin levels at all times. The doctor will receive the patient's INR results almost instantaneously and can modify the patient's dosage and dispense it at the patient's home.

Clinical Need

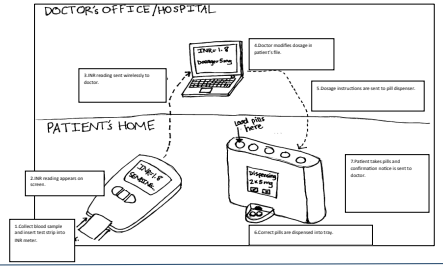
- Approximately **7 million** people in the United States monitor their warfarin levels on a weekly basis.
- **Too much warfarin:** Bruising, hemorrhage, uncontrolled internal bleeding.
- **Too little warfarin:** Clots form that cause stroke or heart attack.
- Warfarin levels should be tested at least once a week.
- Almost half of initial dosages prescribed to patients are inaccurate because the doctor can only make an initial guess at the appropriate dosage.

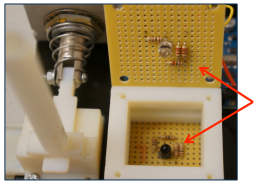
Description of Market

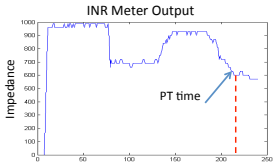
Less than 10 INR meters are currently on the market and only 5% of patients taking warfarin use at-home meters. Some of the companies that make these meters have a system set up where the patient can call a number and report their results to their doctor. However, this may be difficult for elderly patients to do on their own. There are also several automated pill dispensers that exist, but none are specifically for anti-coagulants and none involve wireless communication. Our device will target the 95% of patients who do not use at-home monitoring due to lack of comfort with the technology. The pill dispenser part of our device will also appeal to people who do not have the time or ability to go to the pharmacy.

Description of Design

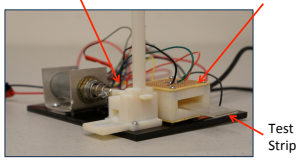
Step 1: Collect blood sample and insert test strip Into meter.
Step 2: INR reading appears on screen.
Step 3: INR reading is sent wirelessly to the doctor.
Step 4: Doctor modifies dosage (if needed) in patient's file.
Step 5: Dosage instructions are sent wirelessly to the pill dispenser.
Step 6: Correct pills are dispensed.
Step 7: Confirmation notice sent to doctor.

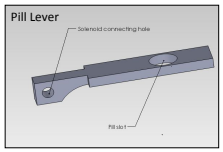


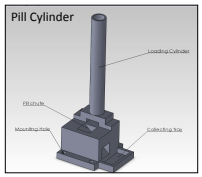




$$INR = (PT_{test}/PT_{normal})^{ISI}$$







Novelty of Concept

- Combination of pill dispenser, INR meter, and wireless communication is what is novel.
- The combination of steps makes monitoring easier for elderly patients and encourages them to check their levels more often.
- There are several INR meters on the market, but none automatically communicate data to the doctor.
- General purpose pill dispensers exist, but doctor can not program them to dispense pills from the office.

Estimation of Product Cost

Part Description	Required Quantity	Quantity Unit	Unit Cost ($)	Total Cost ($)
INR Measurement				
Test Strip	1	each	5	5
Photo-diode	1	each	0.54	0.54
5 mm IR LED (940 nm)	1	each	2.19	2.19
Wire	>1	ft	0.08	0.08
Microcontroller with WiFi	1	each	25	25
Casing	1	each	4.34	4.34
LED Screen	1	each	5	5
Buttons	3	each	1	3
Telecommunication with Doctor				
Open Source Software	1	license	0	0
Software Developer Salary	3	annual	100000	300000
Pill Dispenser (5 Dispenser Columns)				
Loading Pin	0.015	gallon	75	1.125
Pill Cylinder	0.195	gallon	75	14.625
Pill Cylinder Cap	0.0265	gallon	75	1.9875
Pill Cylinder for Gear	0.13	gallon	75	9.75
Pill Gear	0.08	gallon	75	6
Pill Lever	0.055	gallon	75	4.125
Solenoid	1	each	5	5
Microcontroller with WiFi	1	each	25	25
LED Display	1	each	5	5
TOTAL COST PER UNIT				$417.36
START UP COST				$300,000.00

Anticipated Regulatory Pathway

Our device is similar to existing INR meters and automatic pill dispensers. Both of these devices have been approved by the FDA and are Class II devices. We will utilized a 510(k) approval process for My-NR.

Acknowledgements

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