Pack Pal system to help patients with a severe mental illness (SMI) quit smoking – BME Design Excellence Award Executive Summary

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Nicotine dependence is the number one cause of death in people with schizophrenia. The rate of cigarette smoking is much higher among people with schizophrenia (60%;) than that of the general population (20%). Our clients, Dr. Mary Brunnette (MD) and Dr. Joelle Ferron of Dartmouth College, proposed a system to help individuals with SMI quit smoking. This system, known as the Pack Pal, would provide in-the-moment tracking and skills to the patient to support their needs throughout the process of quitting and staying quit. The Pack Pal system is an electronic cigarette case that communicates with a smartphone via bluetooth. This system will perform the following **a.** track when a patient opens the custom cigarette case and cue the user to respond to text, **b.** determine whether they removed a cigarette (or several) and **c.** communicate with the individual to remind them to use coping techniques to cope with cravings and cues to smoke. In addition to patient's interaction with the pack, the system will passively collect data on the patient's cigarette use.

Currently there are no such devices available in the market that interact with smokers with a SMI to encourage them to quit smoking and collect information on their smoking habits. We plan to make six prototypes of the Pack Pal system, which our client plans to implement in a usability trial during the summer of 2013.

The Pack Pal system consists of the integration of the following three parts: 1. The custom designed physical cigarette case, 2. Printed circuit boards consisting of two sensor boards and one master control board per case and 3. The custom software application written on the Android platform.

Custom physical cigarette case – We designed and tested the mechanical case using SolidWorks and fabricated the first prototype using Delrin plastic. This case holds all the electronics, rechargeable battery and power indicators.

Sensor boards and master control board –The electronics consist of multiple sensor boards, to detect the state of the cigarette case (either open or closed) and the number of cigarettes present in the case. The Master control board has a mbed NXP LPC11U24 microcontroller. In addition, the master board contains supporting circuitry to implement Bluetooth communication (v4.0) with the smartphone application. Upon the removal of a cigarette from the case the associated sensors are activated. The activation of the sensors is managed by the mbed. The mbed also coordinates the Bluetooth module to send ASCII characters to the Android phone corresponding to the number of cigarettes taken and the state of the case. Each time the user accesses the case; the smartphone application will take the data sent from the case and format it appropriately. Power management circuitry is also included in the system which will provide indication to the user when the device is low of power and needs to be recharged via a microUSB. We designed all the necessary printed circuit board electronics using a software called Altium and tested individual circuit components on a breadboard.

Custom software application on an android platform – We built custom application on the Android platform using Java and xml layouts. This application collects data received via Bluetooth, does necessary analysis and wirelessly reports a copy of the formatted data on a weekly basis to the patient's healthcare professional. Data will also be available through the smartphone application in an easily accessible and understandable manner for the users so that they can monitor their own progress throughout the quitting therapy process. Overtime, the users will gain knowledge about their smoking habits and will be able to hold themselves accountable for their cigarette use. The application also offers alternatives to smoking such as playing a video game, listening to music or engaging in another related activity. Overtime, the users will gain knowledge about their own use and will then be able to use skills (aquired via the application) to cope with not having a cigarette.

We plan to complete one fully functional prototype of the Pack Pal by first week on May. Since this design satisfies all our clients' requirements, we plan to build the remaining five prototypes by May 15. We will travel to Dartmouth College on May 18 to meet with our client, install our prototype for clinical studies at the clinic and provide any necessary hardware and software support. The usability trial will involve researchers rigorously testing the Pack Pal System in the field with participants diagnosed with schizophrenia and who also smoke to assess usability, usefulness and acceptability. We believe our innovate design and product will serve as a useful tool to patients with schizophrenia and aid in their efforts to quit smoking.

Please see if the Executive Summary addresses all the below Guidelines. Guidelines for:

B. BME Design Excellence Award

This award is focused on critical-path research or specialized one-of-a kind devices. It does not require the team to perform market analysis, but instead should highlight how thoroughly the engineered solution addresses the client's problem through rigorous design, construction, testing and validation. Criteria for assessment are:

How well did the team:

- 1. Characterize the problem by explaining the client's biomedical or scientific need.
- 2. Concisely define the BME design problem.
- 3. Identify and review any competing devices and/or existing intellectual property.
- 4. Completely address the entire problem statement and client's needs.
- 5. Briefly describe the resulting design and prototype.
- 6. Succinctly describe the design validation process and the completeness of this testing.
- 7. Summarize how well the design meets the client's operational requirements.
 - 8. Describe the impact of their design with respect to the client/user.