A User-Centric Redesigned CPAP Framework to Improve Patient Compliance

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September 18, 2016

Sleep apea affects millions of individuals world wide. Herein a solution framework is proposed consisting of two independent but complimentary subsolutions: a redesigned CPAP device enclosure using a football helmet to create a more familiar device that is self-contained (*i.e.* wireless and hoseless), and a user-centric designed smartphone app that incorporates a reward-based system for compliant behaviour and a cloud-based machine learning model to help patients engage and track their health condition in a personalized manner. Together, this framework aims to lessens the alienation of the medical device, promote engagement for treatment and familiarity with their personal condition, and increase use of the device with the reduction of stigmas associated to the use of CPAP. A synergistic effect may manifest in the implementation of this framework to increase patient compliance with their CPAP treatment.

1 Introduction

Over 42 million American adults have sleep-disordered breathing (SBD) [16] of which 20% have mild obstructive sleep apnea (OSA) and approximately 7% have severe OSA [17], a prevalence comparable to asthma and diabetes in the US population[10].

Since adherence to OSA treatment via a CPAP device will occur in the first month of use, it is crucial that the first experience with the device is positive, informative, and reinforces a patient's likelihood for continual and correct use. Any health condition requiring regular and personalized monitoring by healthcare professionals will continue to burden the medical system with each new diagnosis; an effect amplified by the aging "baby boomer" population [7]. Increasingly the demand on centralized health care institutions is saturating, requiring that the demand instead become decentralized and be offset to the individual patients themselves in the form of self-care.

Familiarization with any new technology requires a patient's motivation and regular engagement to become technically informed and competent in the use of the device to optimize its effectiveness for self-care. Mobile health applications ("apps") have proven to be an effective solution when paired with devices for self-treatment [4, 9]. User-centric design additionally supports an individual's engagement with the treatment, facilitating their interactions with the foreign device. A CPAP device is considered a Class II medical device by the Health Canada Guidance on the Risk-based Classification System for Non In-Vitro Diagnostic Devices [11], and like most medical devices can appear as an alien and unintuitive technology to the majority of the populations necessitating its use. The general population has the capacity to adopt innovative and unique technologies, however those devices that trespass into the intimate, personal space of the bedroom might only be a adopted reluctantly, setting an initial stigma despite the promised benefits. The initial experiences with these devices must therefore be positive and supportive to promote long-term compliance. The introduction of the CPAP into intimate space is abrupt: from wearing no disruptive device previously to requiring the regular use of an invasive breathing apparatus thereafter.

Herein is proposed a two part solution with the goal of increasing patient adherence to CPAP therapy, increase the motivation to use CPAP, and increase knowledge of how to adjust or troubleshoot CPAP. This solution framework aims to primarily improve compliance among OSA patients familiar with the game and culture of football, although can also extend into the general population. With the appropriately matured design and implementation of this solution, an increase in sleep quality and comfort with use of CPAP may additionally be achieved, addressing each of the Solution Requirements outlined by the Seeker, The Football Players Health Study at Harvard University.

2 Proposed Solution

Solution Overview

The solution framework herein proposed contains two independent, but complimentary, subsolutions. Each addressing a different subset of the Solution Requirements outlined by the Seeker. Implemented together, this solution framework could have a consequential effect for successfully increasing patient compliance. The solution framework consists of:

1. **Redesigned CPAP Device Enclosure:** Housing all components within the shell of a football helmet, modifying the football madible/facemask to channel airflow, and mount the CPAP facemask to the helmet mandible, creating a self-contained (*i.e.* wireless and hose-less) CPAP unit.

2. **User-Centric Designed Smartphone App:** A supporting smartphone app to track sleeping variables/patterns from helmet sensors to engage and inform users about trends in their personal condition to increase long-term compliance. A cloud-based machine learning model can be used to identify 'abnormalities' in a patient's sleeping patterns to help correct behaviours.

Redesigned CPAP Device Enclosure

Figure 1 highlights the general components required in a CPAP device. Given the prevalence of sleep apnea among football players, this solution framework

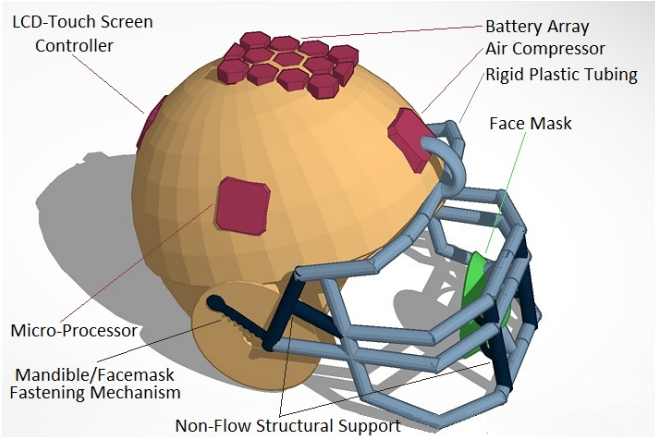


Figure 1: ***Overview of the Redesigned CPAP Device Enclosure using a Football Helmet.*** *Housing the components of the CPAP device in the shell of a traditional football helmet. Elements in red represent components that would lie within the helmet shell, or protrude slightly depending on dimensions; their positions are approximated ergonomically around the helmet to distribute the weight. Electrical connections between the components would also be housed within. The light blue mandible represents hollow plastic tubing to channel air from the compressor. Dark blue represents non-hollow tubing to structurally support the hollow-tubing. The green face mask approximately represents the traditional face mask of a CPAP system, mounted onto the structural supporting tubing.*

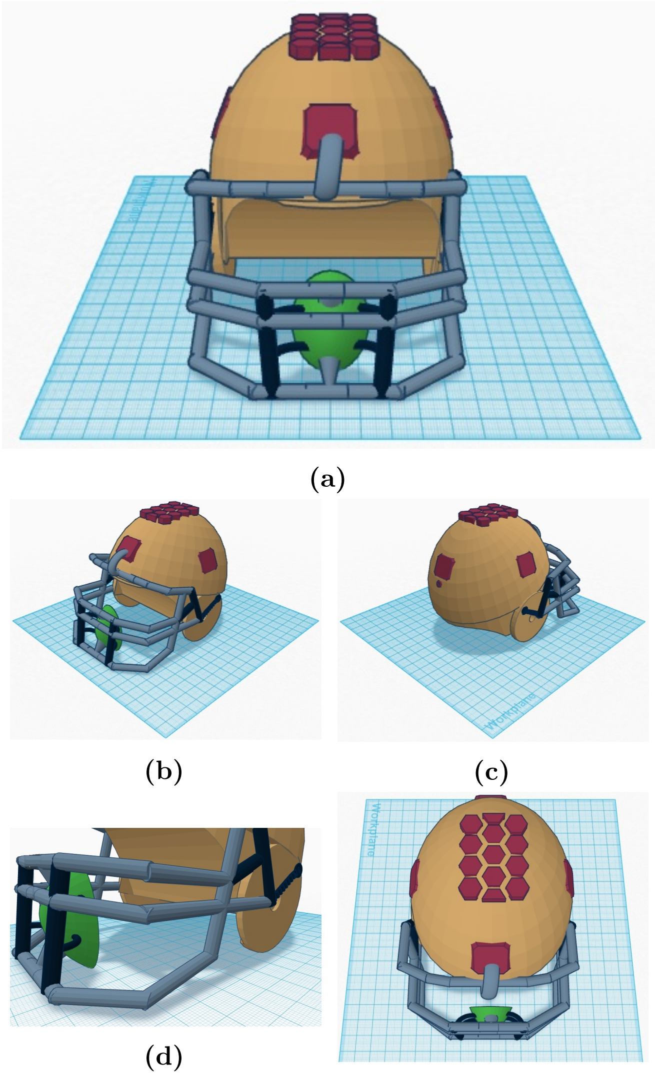
primarily targets patients previously acquainted with football. However, any individual bearing stigmas towards a traditional CPAP device might also find this redesigned solution more desirable. The novelty in housing the components within a more familiar and aesthetically appealing wearable need not be limited to football helmets, inviting similar solutions in similar objects (*e.g.* hockey helmet, Darth Vader mask, motorcycle helmets, etc.). Though to produce the appropriate face mask contact with the patient, a mandible/facemask fastening mechanism is preferred as it permits simple and intuitive engagement and release of the pressure required to maintain the face mask contact with the patient's mouth/nose, minimizing the complexity of using the mask.

A properly fitted helmet will naturally move with the patient's head motions. The chances that the face mask loses its contact with the patients mouth/nose throughout the night is therefore minimized. Any unintentional motions that might knock off the mask or push it aside resulting in air leakages is less likely due to the protective nature of the football mandible.

Re-purposing the mandible framework, originally consisting of a metallic protective guard [14], into a conduit for the air from the compressor maintains the aesthetic appeal of the device without compromising functionality. The appropriate gauge for the rigid plastic tubing can be customized depending on the flow requirements of the patient. Given the modularity of this design, components can be easily exchanged given a patient's requirements (*i.e.* flow and pressure) or preference (*i.e.* colour and style).

Volumetrically, the components required of a traditional CPAP device can be accommodated within the space originally occupied by the protective materials within the helmet. Helmet customizations can be accommodated for any individual with helmets ranging from traditional sizes small, medium, large. The only component requiring access through the exterior shell is the LCD-touchscreen for device configuration which could be accommodated with a hinged flap for access to the internally mounted component and to prevent any involuntary contact.This would provide patients with two mechanisms to configure the parameters of their CPAP device: the first through the proposed smartphone app and the second through this touch screen mechanism.

Figure 2 shows various angle views of the three-dimensional model illustrating the proposed design. The red embedded components are positioned in such a way to illustrate where they could be embedded within the concave shell of the helmet, or protrude through the shell in order to accommodate the component size. Electronic wiring between components would also reside within the concave portion of the shell. Layering removable padded helmet material over the components will provide easy access for any maintenance or replacement without compromising on comfort. Customized padding for individuals could be designed such that the experience of wearing the helmet might not impede traditional sleeping comfort. Padding extending from the back base of the helmet down the nape of a user's neck and around their shoulders, functioning as pillow, could achieve this (not visually represented in this document).



(a) (b) (c) (d) (e)

Figure 2: ***Face, Angle and Top Views of the Three-Dimensional Model of the Proposed CPAP Device.*** *Integrating all CPAP components into a football helmet, functioning as device housing, and mounting the face mask onto the helmet mandible, the CPAP device becomes fully contained in a more familiar object. Workplane not to scale.*

User-Centric Designed Smartphone App

Complimentary to any device is its User Manual, detailing the appropriate use and configuration of one's device for optimal function. Often in the form of a static technical document, a more user-friendly and dynamic format is necessary to modify human behaviour. The use of smartphone apps to fulfill this need has resulted in some success [9, 4]. While the application marketplace already hosts an ensemble of sleep apnea-specific apps (ApneaApp, Home Sleep Apnea A-Z, Sleep Assess, Sleep Apnea Monitor, Sleep Connect), none have adopted a user-centric design approach which adapts itself to its user through the various stages experienced by patients by means of a machine learning classification model to highlight patterns of interest. Research also suggests that the incorporation of "Gamification", wherein users are rewarded in-app 'badges' or awards has also proven effective in modifying health-related behaviours (*e.g.* fitness routines) [8, 12]. While additional clinical research is necessary to establish conclusive influence of "gamification" in mobile health apps for patients with chronic illnesses (*e.g.* diabetes), evidence suggests positive results from the use of an in-app reward system for treatment compliance [2].

As the solution framework primarily addresses CPAP treatment compliance among patients familiar with the game of football, it is assumed that these patients are naturally competitive. Incorporating a reward-based system which allots a certain virtual point value for every night of compliance to CPAP treatment could reinforce a patient's motivation to engage with the therapy. Enforcing penalties for occasions of non-compliance could also promote renewed effort. By incorporating a social platform where "friends" undergoing the same treatment can compare their successes to others can generate a positive community of healthy competition. Understandably an individual might not wish to be reminded about their chronic condition, however encompassing this individual in a supportive community might improve their outlook on their therapy.The spouse of an OSA patient is also directly implicated by this technology. Should the reward-based system also allot rewards for spousal support in the treatment, the couple might come to consider compliance to the therapy as something to be achieved together. This support may also produce synergistic results through the various stages of treatment. Defining 'Spousal Support' is not included in this document.

An example of the gamification reward algorithms can be seen in Figure 3. Here a night of compliance results in the steady increase in scores during consecutive nights of CPAP treatment. On a night of non-compliance, the score is reduced proportional to their previous score. Given the Penalty Multiplier, penalties in the initial days and weeks will not severely impact a user's scores and they will be recoverable through 2-3 nights of renewed compliance. However as the scores increase, the Penalty Multiplier is such that a night of non-compliance may severely reduce one's score. This should reinforce the motivation of individuals with established CPAP therapy habits and thereby reduce the likelihood of non-compliance out of fear of regenerating their score.

There is an opportunity to create a multi-stage platform to engage patients throughout their treatment. Early on (*e.g.* first month) the application would focus on addressing any questions patient's may have and to troubleshoot any problems that arise as well as establishing a baseline for sleeping patterns (see Figure 4). Once comfortable and habituated to the treatment, the app would revert to a monitoring and gamification phase, recording and

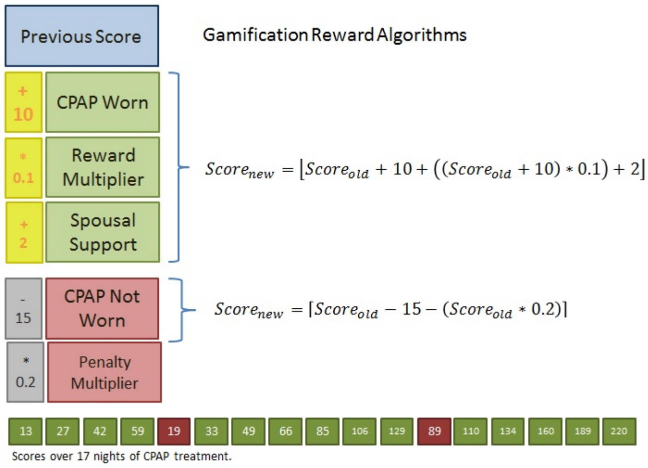


Figure 3: *Gamification Reward Algorithms and 17 Night Example.* *The scores for nights of compliance will gradually increase the user's scores with every successive use. Taking the floor of their score slightly biases scores so as not to inflate. However, on a night of non-compliance, scores are severely diminished, proportional to the scale of the score. The example assumes 'Spousal Support' for every instance.*

visualizing certain sleep-specific information (see Figure 5). The ability to integrate a number of sensors into the helmet and a wireless communication module would provide added-value to the solution framework. This information might easily be reported to physicians tracking the patient, though automation would be needed to characterize what is 'abnormal'. The definition of 'normal' versus 'abnormal' patterns will require sensor data from a number of validation trials using a prototyped helmet.

A machine learning classification model will be required to analyze and evaluate the sleep signals. Creating a model with high accuracy and low false-alarm rate would be robust to characterize the sleeping patterns of individuals being treated and highlight regions within their sleeping patterns that can be classified as 'abnormal'. The definition of an 'abnormality' loosely refers to a sleeping event(*e.g.* air leak, excessive movement) and/or a critical health signal (*e.g.* prolonged period without breath, cardiovascular health biomarker). This monitoring can be achieved in real-time or computed at given intervals depending on the complexity of the signals received from the sensors. From a research perspective, the centralization of large amounts of sleep data from diagnosed patients could significantly improve the classification model with time. The database would also require a large dataset from individuals not diagnosed with OSA.

Developing an app that is intuitive and complimentary to the specific device used by the patient is key to promoting positive engagement with the treatment. Motivating compliance in the form of reward-based cometition will also engage patient's and their spouses. Combined with a user-friendly device, the solution framework has an increased opportunity for success. The opportunity to add sensors for sleep monitoring and a cloud-based machine learning classification model would provide added value and enable users and physicians to receive quality data through the evolution of a patient's therapy.

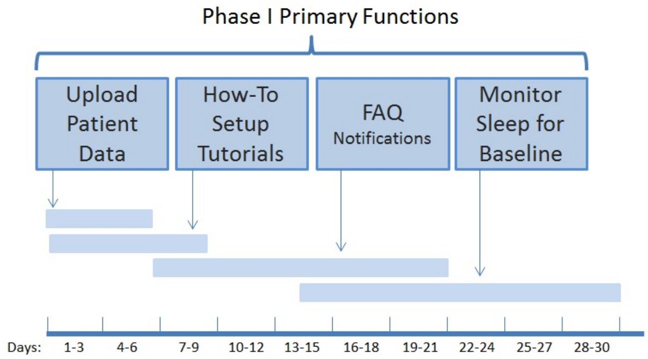


Figure 4: ***Primary function of the sleep apnea smartphone app during the first month of sleep apnea therapy. The monitoring function only begins after two weeks of adaptation to the therapy.***

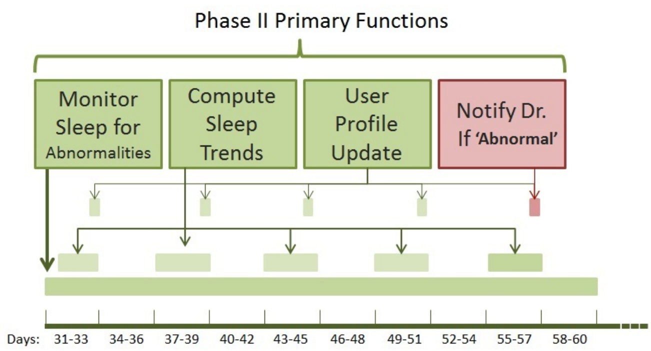


Figure 5: ***Primary function of the sleep apnea smartphone app during the following months of sleep apnea therapy. Should an event of medical relevance be triggered by the machine learning model, a notification could be sent to the primary physician treating the patient.***

3 Solution Design & Implementation

A general CPAP device design is outlined in a Maxim Integrated Inc. tutorial written by John Gosson [6]. The specifications of each component outlined in this design would cumulatively fit easily within the volumetric space within the inner shell of the helmet; a space normally occupied by impact-absorbing materials. Considering the hardware implementation proposed in the tutorial, a prototype helmet could be created.

The helmet itself could either modify pre-existing football helmets, or be newly designed and fabricated with the intention of resembling existing helmets. The structural design might be based on pre-existing football helmets and assemblies for which exists numerous prior art [3, 5, 14] with substantial modification to the mandible. The protective function of the helmet may be heavily relaxed given the low impact environment for which they will be used and component mounting points could be incorporated in their stead. The mandible will instead consist of rigid tubing to channel the air generated by the compressor. Parallelizing the mandible tubing increases the cross-section of airflow, and various designs might be produced to achieve different flow rates. The general shape of the mandible can be adapted from existing styles. Designed to be modular and detachable from both the helmet and facemask, a patient could interchange this piece based on either need or preference.

With the flexibility to design cushioning to provide a more comfortable user-experience, the helmets could be worn with the same or increased comfort when compared to the traditional football helmet. Padding material could also be modular enabling an individual to change the ergonomic support. The distribution of components within the shell of the helmet should be such that the weight is balanced. Wiring between components need not be limited to a compact design. A greater number of small components would layer themselves more easily throughout the shell. Mounting points for each components could be used to easily assemble the device and to replace any components as necessary.

Further customization of the helmet could be achieved by painting the helmet or representing various football team logos. For football players requiring this treatment, a renewed sense of masculinity might be achieved through this design. This is a key point to the solution framework as patient's should not be intimidated by a medical technology, but rather feel comfortable using it.

Initially, the smartphone application should provide the user with information to troubleshoot problems that may arise and incorporate helpful videos illustrating its use. Keeping the interface simple and easily navigable at the onset will ensure individuals are not overwhelmed. As the first days and weeks progress, the interface should change such that it incorporates a display indicating the monitoring progress, visualizing variables such as breathing rate, breathing depth, head movement, and others. Individuals should at this point be adapting to the device and showing the trends in their sleep patterns will further engage them. An indicator highlighting regions of interest (*e.g.* small mask air leakage) could be implemented to help individuals adjust their behaviours to return to normal limits (partially determined during the "baseline monitoring" phase and partially from validation trials during prototyping).

The machine learning model proposed should be implemented as a cloud-based model. Uploaded data could be processed on a dedicated cluster and returned to the individual's application. Given the helmet volume available to integrate the electronic components, several gigabytes of memory could be incorporated to store signal data. Data could be exchanged via Bluetooth with the patient's smartphone device and transmitted to the cloud where it is then analyzed and returned.

Several machine learning frameworks and classifiers are available for scaling such an implementation. The literature consists primarily of classification studies on electroencephalograms, electrocardiograms, and saturation of peripheral oxygen signals [15, 13, 1]. As the data will be collected from the specific implementation of sensors, generating the proposed model will require a large database of sensor data and annotations of sleeping events to signal segments. Once prototyped, validation studies could be performed to generate the model and optimize it. This smartphone application classification feature is added-value to the application and therefore not necessary. It is proposed here given that the solution framework would support it and the treatment personalization it would offer.

The solution framework influence is summarized in Table 1 where arrows indicate whether a certain outcome variable is likely to increase (*i.e.* $\uparrow$), decrease (*i.e.* $\downarrow$), or outcome is uncertain (*i.e.* $\updownarrow$). These outcomes are hypothetical and rationalized from a subjective evaluation of existing CPAP technologies.

Table 1: *Rationalizing Solution Framework with Expected Outcomes on Influence Variables*

Solution	Proposed Influence	Expected Outcome
Redesiged CPAP Device	Number of Face Mask Dislodgement Events	$\downarrow$
	Contact with Patient's Face	$\uparrow$
	Air Loss via Leakage	$\downarrow$
	Comfort of Treatment	$\updownarrow$
	Feeling of Claustrophobia	$\updownarrow$
	Aesthetic Appeal of CPAP Device	$\uparrow$
	Motivation to Use CPAP Device	$\uparrow$
	Familiarity with the Medical Device	$\uparrow$
	Simplicity to Engage/ Disengage Face Mask	$\uparrow$
	Stigma Towards CPAP Treatment	$\downarrow$
	Device Customization	$\uparrow$
	Sense of Masculinity	$\uparrow$
	Device Marketability	$\uparrow$
	Patient Compliance to CPAP Treatment	$\uparrow$
User-Centric Designed Smartphone App	Patient Knowledge of Sleep Apnea and Treatment	$\uparrow$
	Patient Engagement and Interest in CPAP Therapy	$\uparrow$
	Patient's Ability to Track Changes/Trends of their Sleep Behaviours	$\uparrow$
	Patient's Ability to Receive Recommendations Based on Recent Sleep Trends	$\uparrow$
	Patient Self-Care	$\uparrow$
	Burden on the Medical System	$\downarrow$
	Patient's Ability to Troubleshoot their CPAP	$\uparrow$

Hypothetically determined when compared to traditional, existing CPAP treatments.

Conclusion

A solution framework consisting of two independent but complimentary subsolutions are proposed to increase patient compliance to CPAP treatment: a redesigned CPAP device enclosure using a football helmet to create a more familiar device that is also self-contained, and a user-centric designed smartphone app that incorporates a reward-based system for compliant behaviour and a cloud-based machine learning framework to help patients engage and track their health condition in a personalized manner. Together, this framework aims to lessens the alienation of the medical device, promote user engagement in their treatment, and increase use of the device with the reduction of stigmas associated to the use of CPAP. Together a synergistic effect may manifest in the implementation of this framework to increase patient compliance with their CPAP treatment.

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