UBC LIFE SCIENCES STARTUP COMPETITION 2017

MIT Healthcare

MIT (Medical Information Technology) Healthcare develops point of care diagnostics using multi parametric measures and focuses on simple, reliable, accessible and easy-to-use portable devices that offer better quality of care at a reduced cost.

Team members

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Mentor

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1. Executive Summary

MIT Healthcare is a digital health company, based in Vancouver British Columbia, that focuses on building simple, reliable, accessible and easy-to-use point-of-care devices (POC) for Coronary Artery Disease (CAD) monitoring and heart attack diagnostics. Our POC medical device offers better quality of care at a reduced cost. Through the use of intelligent algorithms and machine learning principles, biomedical signals produced by the body are harnessed and analyzed to help the end user make clinical decisions using a multi-parametric model. Heart disease is prevalent in North American, accounting for 1 in 4 deaths annually, thus demonstrating the need for a device to help with disease prevention, prediction, management and treatment. MIT Healthcare is targeting CAD prevention through early diagnosis and behavior intervention and monitoring. Hospitals, medical centers, primary care practitioners are turning towards POC device solutions to predict, monitor, and treat CAD diseases of interest, and to affordably expand their service delivery.

MIT Healthcare aims to accomplish the following short and long-term goals:

- Conduct big-data analysis on currently available CAD data sets to mine for disease trends
- Develop and test algorithms on device for performance determination
- Apply for patent protection (USPTO)
- Implement algorithms on diagnostic device that is portable, intuitive to use, robust, and scalable
- Seek regulatory approval (US FDA) approval to allow market access
- Establish partnerships portable diagnostic developers and manufacturers such as Omron Health Care (https://omronhealthcare.com) or Intricon (http://www.intricon.com/) for product development, distribution and/or acquisition

2. Market Analysis

2.1. Problem

Coronary Artery Disease is the most common type of heart disease, killing over 370,000 people annually [1]. For some patients, the first sign of CAD is a heart attack which can often be debilitating, if not fatal [2]. Heart attack prediction related to CAD is currently performed by physicians through an extensive and relatively subjective process. Medical information from a patient's chart (which includes multiple tests of varying measures), subjective information provided by the patient, and generic risk calculators are used to calculate a final risk score. Prediction requires synthesizing large amounts of information which is time consuming and error-prone. Additionally, the prediction timeframe is limited and typically only predicts months to years ahead. An automated, objective, efficient and robust diagnostic device for heart attack prediction that can narrow the window of prediction (weeks and days vs. months and years) is needed to help identify risk early on so patients can receive early preventative treatment to reduce the risk of a heart attack, consequently avoiding CAD and heart attack related hospitalization and death.

2.2. Market Need

The disease impacts patients, families and health care organizations on multiple personal, financial and systemic levels. Primary customers include: family physicians (for prevention and monitoring of patients) and hospitals and acute care centers (for diagnostics and treatment).

2.3. Market Size

USA - Hospitals and Community Health: 5,564, Cardiologists: 23,000, Family Physicians: 115,900, CAD Patients: 15,800,000. Heart disease is the leading cause of death for both men and women, and direct and indirect costs total more than $320.1 billion a year [1]. The number of people diagnosed with heart failure is expected to increase from about 5.7 million today to nearly 8 million by 2030, according to the American Heart Association [3].

3. Competition

3.1. How are Customer Needs Addressed Today

Currently, CAD monitoring is performed by a physician through routine tests (e.g. physical exams and blood tests) and others diagnostic tests such as an Electrocardiogram (ECG). An ECG test is carried by attaching a Holter device to the patient's body, who must then wear the device for 24 to 48 hours [4]. Results are processed 3-5 weeks later by a Cardiologist, creating a delay in the prediction and diagnosis process [4]. Moreover, overall predictions are given without narrowing the expected attack to a window of time, such as months or weeks (e.g. 10-year risk calculator predicts disease trends over 10 years without giving approximate date) [5]. Thus, there is a large unmet need in terms of a device that is automated, timely, efficient and accurate in disease monitoring and prediction.

3.2. Environmental Scan (main competitors)

AliveCor Heart Monitor is the first main competitor. The company applied for FDA approval five times for different aspects of their device. On 01/27/2015 they were approved by the FDA as a *Substantially Equivalent* common collection device of ECG signals for cardiovascular. The product has multiple patents. Currently, the company claims that the device can detect atrial fibrillation, however, there is no report on the detection accuracy in terms sensitivity and specificity. The company is collecting data in collaboration with The Chinese University of Hong Kong. The company started in 2012 and raised $10.5 million in Series B venture financing.

Masimo Corporation is the second main competitor. The company applied for FDA approval on carbon monoxide measurement. On the 12/28/2016 they were approved by the FDA to be a *Substantially Equivalent* to the common calculation of cardiac output for cardiovascular. In 2009, they raised a total of $55.9 million in gross proceeds from the IPO.

3.3. Competitive Advantage

Through advanced machine learning involving the integration of multiple diagnostic parameters, a more accurate detection and prediction model will be achieved that is low cost and easy to use. More than one biosignal will be harnessed from the body to improve screening and prediction by the creation of an app that integrates the predictive and diagnostic models. Extensive research in this area has already been done by the Dr. Elgendi, and our product will build on his expansive knowledge, facilitating fast execution of the product. Anticipated development of product is approximately 1 year, in addition to another year of going through regulatory requirements of the FDA . The added value of this multi-parametric device will be significant as there is no other diagnostic device that aims to combine multiple biosignals for increased prediction accuracy of CAD and heart attacks. This approach also opens the door to other disease diagnosis and prediction given the multiple biosignals used. Our device also combines monitoring with prediction, in contrast to our current competition who does not integrate these two features.

Commercialization Plan

4.1. Science / Technology Overview

Through the use of intelligent algorithms and machine learning principles, biomedical signals produced by the body are harnessed and analyzed to detect unique and informative biological patterns. These patterns are then translated into a more accurate prediction models that helps the end user make clinical decisions.

4.2. Growth Strategy

IP: a patent will be applied for once the algorithms are developed. The product will be rigorously tested against current models and on current patient data sets (from openly available sources). Mobile software will be developed on already existing hardware (e.g. mobile phones). Consumable items include the sensor/probe used to collect the biosignals.

Partners: Once the prototype is tested and validated, the FDA approval process will begin. Health authorities in the areas for standards of care will also be approached and consulted during the development process to ensure current standards of care are met, if not exceeded. Omron Health Care (https://omronhealthcare.com) or Intricon (http://www.intricon.com/ licensing), or others will be approached for further product development, distribution, and marketing.

4.3. Milestones

Product Development: Data mining, 3 months (already ongoing, target completion April 2017), Algorithm Development (2 months, target completion June 2017), Algorithm testing and validation on device (5 months, target completion November 2017). Deliverable = prototype readiness for proof of concept testing. Cost = In-kind time from Dr. Elgendi + prototype equipment cost (approx.$20,000 including computer, mobile device, software developer).

IP and Regulatory Approval: Subsequent to POC testing, submission for IP protection US provision followed by PCT (approval once prototype delivered). Initial cost = approx. $15,000 (patent lawyer, application fee, etc.) dependent on the jurisdictions to be pursued.

Market Entry and Exit Strategy: 3 years for first exit opportunity to occur, subsequent to the completion of multi-center trials to demonstrate predictive capacity. Note: significant hurdle will be to establish prediction validity, which is feasible for our product given Dr. Elgendi's expertise and connections in the medical community. Cost = approx. 2 million

5.1. Financial Needs and Justification

We will apply for different grants that encourage commercialization and that help in the scientific evaluation of our proof-of-concept device. For example, we will apply for Bill and Melinda Gates Foundation Stars in Global Health, NSERC, and Mitacs Accelerate, and Mitacs Elevate. The first year we will attract postgraduate students to work with us via the application to Mitac Accelerate and Mitacs Elevate. The second year we will continue our first year efforts and will start approaching NSERC for an industrial scholarship to attract talented postdoctoral fellows and apply for global heath funding agencies such as Bill and Melinda Gates Foundation and Stars in Global Health. The third year we will start approaching health care companies with a more validated prototype.

5.2. Fundraising plan

The market opportunity requires significant financing starting with seed and possibly venture capital to commercialize. Non-dilutive funding sources will be sought in parallel. We intend to seek approximately 2 million to facilitate our exist strategy, some of which will be equity financing.

5.3. Exit

Exit strategy is to be acquired by a larger company (Omron Health Care, Intricon, or others for acquisition). Investors will get their money back through a lump-sum payment.

5.3. Business Model

MIT Healthcare has three revenue streams: 1) Selling the device for approximately $150 to health care facilities and and primary care physicians (calculated based on estimated labor, materials, overhead, and marginal profit to put the device below current competitors cost which is approximately $200. 2) Selling consumable CAD-based sensors such as the ECG, pulse oximeter, and digital stethoscopes biosensors ranging from $50 to $80. Current competitors do not sell replacement sensors, rather the customer must buy an entirely new device. Sensors will be purchased by the patient who will take the device on loan from the health care provider. 3) App usage charge: Once the primary care physician/health facility purchases the device and the patient uses it for monitoring, prediction and diagnosis, the patient will be charged a fee ($2.50) each time a significant predictive or diagnostic feature is activated(e.g. patient activates a feature for cholesterol forecasting based on current collected biological parameters, and offers tips and information on how to prevent disease risk and escalation). Health care practitioners will recover half the cost of the device once 60 activated features are logged by the patient (60 X 2.50 = $150, half of this will be returned to healthcare facility).

Team

CTO (Chief Technology Officer): Dr. Moe Elgendi is an intuitive biomedical engineer whose creativity and knack for posing pertinent research questions led to this startup. His vast technical knowledge and intelligence related to bio-applications will yield results that stand up against rigorous empirical validation in the engineering and medical communities. He is responsible for aspects related to R&D, technology, data, privacy and research. **COO/CEO (Chief Operations Officer/Chief Executive Officer):** Ms. Halla Elmobayad is a seasoned business executive specializing in operations, contract negotiations, stakeholder engagement, communications, protocol and policy development, fundraising/partnership to exit development, and board governance. She will be responsible for items related to the day-to-day smooth operations of the company. **Advisory Committee:** The advisory committee will be responsible for providing guidance related to device usability and uptake, in addition to providing guidance for items related to regulation and current standard of care models, and how our device will integrate into these pieces. Advisors will include: 2 Cardiologists: Dr. Ian Adatia University of Alberta, Dr. Ian Norton (World Health Organization), and a Family Physician (TBA). **Consultants:** Responsible for aspects of product development, regulatory checks, marketing, etc. Current consultant, Dr. Ritch Fletcher, Massachusetts Institute of Technology.

References

1. Centers for Disease Control and Prevention and National Center for Health Statistics (2015) Underlying Cause of Death 1999-2013 on CDC WONDER online database (Data are from the Multiple Cause of Death Files, 1999-2013, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program).

2. (2017) Heart Disease and Stroke Statistics – At-a-Glance. American Heart Association.

3. (2017) Heart failure deaths rising after decade-long decline. American Heart Association.

4. (2017) Holter Monitor, American Heart Association.

5. (2017) Risk assessment calculator accurately predicts heart attacks, strokes. American Heart Association.