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BM2210 - Biomedical Device Design

Investigation Report
by
Group D

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1. INTRODUCTION

We are a dedicated group of Biomedical Engineering students who are committed to transforming the healthcare industry by utilizing cutting-edge technology and medical knowledge. We are dedicated to turning health issues into success stories that benefit people and communities around the world because we think that every health crisis offers an opportunity for innovation.

This investigation report is to find a strategic focus to initiate a new project (i.e a problem in the healthcare sector to solve) which meets our acceptance criteria.

2. STRATEGIC FOCUS

A strategic focus refers to a clearly defined and prioritized direction that directs all project planning, execution, and results.

Developing a strategic focus is a dynamic process which encompasses multiple explorative steps.

- Determining a mission
- Identifying personal strengths and weaknesses of group members through conducting a personal inventory
- Defining an Acceptance Criteria
- Evaluating opportunities, we have against the acceptance criteria.

We successfully set the essential prerequisites after completing these procedures.

2.1 Our Mission

Our mission is to create a healthier, more promising future for people and communities all across the world. Our work is inspired by the idea that every health problem offers a blank canvas for innovation.

2.2 Our Strength and Weaknesses

As a team of 2nd year undergraduates in the field of biomedical engineering, our expertise has been refined in a particular area in the field of bioelectronics, our focus which is medical electronic equipment. Our core competency thrives in the field of bioelectronics, yet our skill does extend somewhat to biomechanical designs. But as passionate and enthusiastic innovators we would see the world in a fresh perspective so we can address the problems we face and develop novel solutions.

2.3 Acceptance Criteria



2.3.1 Compatibility with mission and values

Our goal is to transform healthcare with cutting-edge technologies. This is a wonderful fit with the emphasis we've selected, ensuring that the work we do directly advances the goals of our startup. Our efforts will have a meaningful impact and connect with stakeholders who hold similar beliefs if we remain true to our values.

2.3.2 Market opportunities and demand

We understand how critical it is to address the healthcare issues of the real world as second-year biomedical undergraduates. We guarantee that our efforts have relevance and the possibility for favorable market reception by choosing a focus that has clear market demand and presents growth chances.

2.3.3 Resources required.

Our resources are constrained because there are limitations to electronic components these days. And also we only have about three months to complete the project. So, the time resource is also a constraint. As a result, our strategic priorities must be in line with our current capacities and availability of resources. By doing this, we can perform efficiently without exhausting ourselves.

2.3.4 Sustainability

As second-year undergraduates, we are laying the groundwork for the success of our startup. We ensure that our efforts continue to have an impact after we graduate by choosing a sustainable focus, leaving a legacy of significant accomplishments.

2.3.5 Matching with the strengths of our team

Our area of specialization is electronics, with some background in biomechanical designs. By concentrating on these advantages, we can make the most of our distinctive skill set and guarantee the production of high-caliber results that demonstrate our competence.

2.3.6 Affordability

Financial restrictions are a serious constraint for us as undergraduates. We ensure that our efforts are financially cautious and won't interfere with our capacity to complete the project successfully by selecting a focus that is in line with our budget.

3. NEED FINDING

3.1 Problem: Monitoring and measuring the saline flow rate.

Source: Nurse in Colombo National Hospital - 24th August 2023

Saline injection intravenous or topically has several uses in hospitals. It helps with rehydration, electrolyte balance maintenance, and medicine administration. Medical professionals carefully choose the right saline concentration and administration method to treat a variety of medical conditions.

3.1.1 Need statement

- **Problem** - Need to monitor the saline pumping to the patient and measure the saline flow rate constantly in a centralized manner.
- **Population** - Nurses who are in charge of monitoring the patients.
- **Outcome** - Automate the monitoring saline flow rate process and design a system to automatically control the flow rate and centralized control system can help nurses to observe all the saline levels in wards from a computer.

“A way to address the constant need to monitor the saline pumping to the patient and measuring the saline flow rate in nurses who are in charge of monitoring patients in wards that automating monitoring and measuring process.”

3.1.2 Disease state fundamentals

Delivering intravenous saline solutions in hospitals, saline infusion pumps are essential for patient treatment. During the process, an IV line is set up to enable for the regulated delivery of saline for fluid balance, drug administration, and hydration. Veins and the circulatory system are part of normal anatomy. Pain and inflammation can be brought on by abnormalities such as infiltration or phlebitis. Inadequate setup can result in air embolisms and infections, while incorrect flow rates might cause discomfort and consequences. Different healthcare facilities experience these problems at different rates. Poor pump usage results in high healthcare expenses, including extended hospital stays and hampered workflows caused by manual monitoring. Modern pumps are equipped with cutting-edge technologies that improve patient care, reduce interruptions, and maximize healthcare efficiency, underscoring their critical role in enhancing healthcare outcomes.

3.1.3 Existing solutions

Without automated infusion pumps, Sri Lanka's healthcare system uses a notification-based alert system. All prospective solutions are still in the research stage, according to an analysis of global offerings, and there are no products on the market right now.



Figure 1: Infusion pump currently using to pump saline

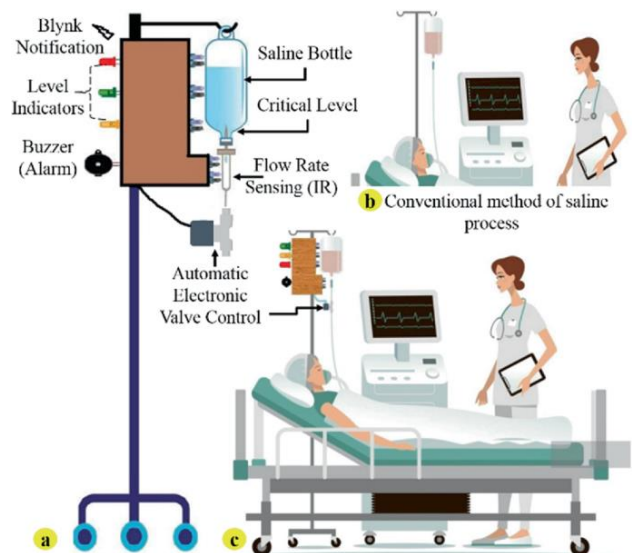


Figure 2: Smart Saline monitoring system.

3.1.4 Stakeholder analysis

- **Patients:** Patients are at the center of healthcare, and it is the main priority to ensure their well-being. An automated saline infusion pump allows for precise and reliable fluid supply for patients, resulting in a safer and more efficient course of therapy.
- **Medical professionals:** By eliminating the need for manual adjustments, automated pumps can simplify their work and free them up to concentrate on other important responsibilities and deliver more individualized patient care. Also, the number of personal needed for the wards will be less as the monitoring will be done in a centralized point.

- **Manufacturers and Developers:** who oversee creating, producing, and advancing smart saline monitoring systems. They guarantee the system's excellence, precision, and technical advancement.
- **Healthcare Institutions:** Hospitals, clinics, and other medical facilities play a key role in the development of smart saline monitoring systems because they use them to carefully monitor and regulate the delivery of fluids, thereby improving patient safety.

3.1.5 Market Analysis

Since there are no products currently available in the market, it is difficult to predict the market for the smart saline monitoring system.

3.2 Problem: Control the pain for identified issues (Chronic Pain Management)

Source: Physical Therapist - 25th August 2023

Pain is the unpleasant sensation caused by illness or injury. It is also a warning mechanism which helps to detect harmful stimuli. Once the cause is identified, pain is just a disturbance for a normal way of living. Although drugs can be used for relieving pain, they come with many side-effects.

3.2.1 Need statement

- **Problem** - Need to control and relieve pain for identified stimuli.
- **Population** - Patients who are suffering from pain due to identified stimuli.
Ex: chronic pain, migraine
- **Outcome** - Reduce their pain to a considerable level.

“A way to reduce pain in patients who are suffering from pain due to identifies stimuli that reduce their pain with continuous monitoring and auto personalized parameters in patients with minimum side effects.”

3.2.2 Disease state fundamentals

An indication that anything is wrong is pain. Pain, also known as chronic pain, can, however, potentially develop into a serious concern when it lasts past the normal healing process or happens without tissue damage. People who are afflicted by such ailments find it difficult to live a calm life due to pain. Typically, on such occasions, medication is given to them in order to lessen their perception of pain. Drugs have several negative effects, despite the fact that they help reduce pain. To alleviate chronic pain, several medical practises, such as nerve ablation, have emerged. To stop pain impulses, this treatment involves deliberately harming some nerves. This procedure's root cause is the targeting of pain-transmitting nerve circuits that are malfunctioning. Understanding the distribution of nerves is part of

normal anatomy as it relates to nerve ablation. Inadequate pain treatment or unintentional nerve injury may result in abnormalities. Post-procedure symptoms and indicators may include transient discomfort, altered feeling, or lingering pain. There is a sizable population of persons who struggle with chronic pain, necessitating such therapies. Due to the costs associated with the treatment, follow-up care, and resolving any problems, the cost to the healthcare industry is substantial.

3.2.3 Existing solutions

The main existing solution for minimizing pain is drugs. Although those drugs minimize the pain, they come with various side effects such as kidney diseases. Transcutaneous Electrical Nerve Stimulation (TENS) devices are also common in foreign markets as well as in the Sri Lankan market. The problem associated with those devices is that they are manually customizable. As parameters such as frequency and intensity of electrical impulse given by TENS could vary from person to person, tolerance can be built on the person for that treatment reducing trust from users for the device. Also, it is unsafe to use that device continuously for a long time without monitoring and using customizable parameters which can later come up with some side-effects.

To enable patients to self-administer TENS instead of needing to attend clinics, infrastructure and resources are required is a problem associated with TENS.

3.2.4 Stakeholder analysis

- Patients: Quality of life of the patients increases as no need to suffer from pain for identified issues and no need to take drugs with the risk of side effects.
- Doctors: No need to frequently monitor the conditions of the patient for the same issue and adjust parameters of medication when conditions change.

3.2.5 Market Analysis

From 2022 to 2030, the transcutaneous electrical nerve stimulation (TENS) market is expected to increase at a CAGR of 3.84%, reaching a market value of USD 300 million in 2021. This rise is being fueled by the rising demand for TENS devices to treat musculoskeletal injuries and chronic pain, especially in the elderly. TENS devices became more crucial in the post-COVID-19 patient rehabilitation process after the COVID-19 pandemic, which originally had an impact on the market due to disruptions in healthcare services. The market is now dominated by North America, but due to rising health awareness and the number of sports injuries, the Asia Pacific region is expected to develop at the fastest rate. OMRON Corporation, Zynex Medical, NeuroMetrix, and DJO Global are significant market participants.

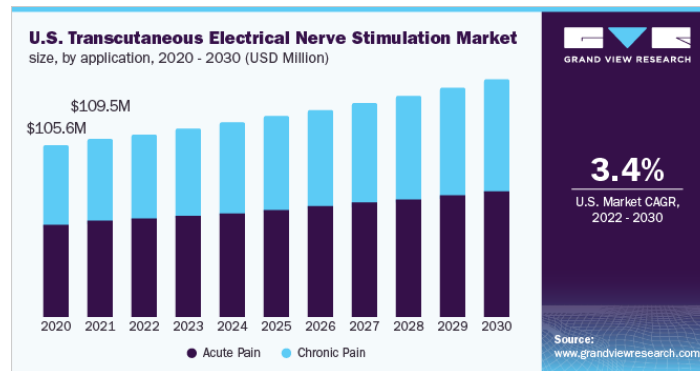


Figure 3: USA TENS Market from 2020 to 2030

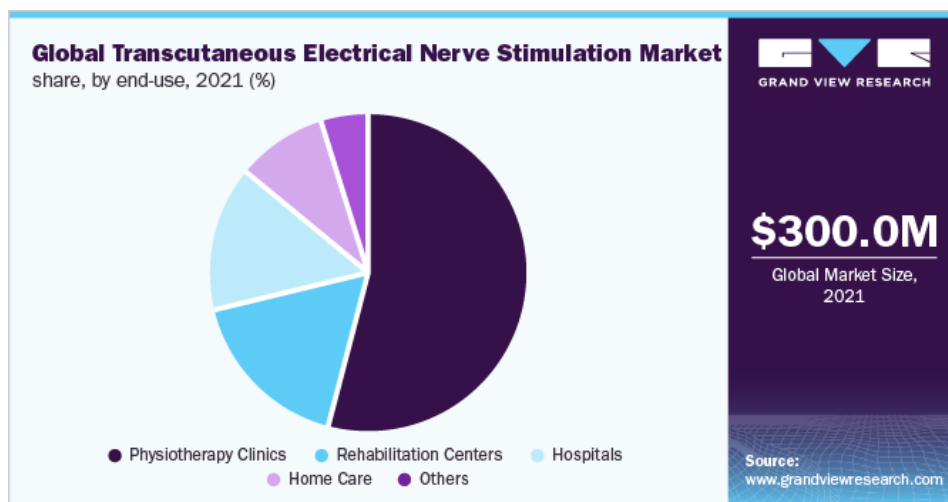


Figure 4: USA TENS Market

3.3 Problem: Noninvasive method to detect CKD in early states.

Source: Urologist in Army Hospital - 26th August 2023

Early and precise identification of chronic kidney disease (CKD) holds immense significance due to the potential health risks it poses. As CKD often develops silently without noticeable symptoms, its timely detection is essential, allowing for appropriate interventions. Advanced diagnostic methods, including blood tests and imaging techniques like ultrasounds, play a crucial role in diagnosing CKD's stages and severity. Once diagnosed, a collaborative healthcare approach involving nephrologists, dietitians, and other specialists becomes crucial for devising personalized treatment plans to manage the disease effectively, ensuring improved patient outcomes and reduced healthcare burdens.

3.3.1 Need statement

- **Problem** - Early Detection of Chronic Kidney Disease (CKD)
- **Population** - Individuals at risk of CKD due to factors like age, diabetes, and hypertension.
- **Outcome** - Timely identification of CKD's onset for effective management and intervention.

“A way to address Chronic Kidney Disease (CKD) in people at risk of CKD that identifying CKD in the early stages.”

3.3.2 Disease state fundamentals

A steady decline in kidney function over time, known as chronic kidney disease (CKD), frequently results in significant problems. Early on, CKD may not show any symptoms, which contributes to its quiet progression. In order to diagnose kidney disease (CKD), blood tests are used to evaluate creatinine levels and calculate glomerular filtration rate (eGFR). Diabetes, hypertension, and particular hereditary disorders are just a few of the underlying illnesses that might contribute to CKD. In accordance with their normal anatomy, the kidneys filter waste and extra fluid from the blood while also preserving electrolyte balance and blood pressure. Anemia, electrolyte imbalances, and proteinuria are abnormalities brought on by CKD. Fatigue, edema, and alterations in urine patterns are signs of advanced CKD. Millions of individuals worldwide are impacted by CKD, which affects a large number of people. Due to the high costs of diagnostics, treatments like dialysis or transplantation, and treating related consequences, the healthcare industry is under tremendous financial strain, which emphasizes the importance of early identification and intervention.

3.3.3 Existing solutions

Traditional diagnosis involves invasive blood tests to measure serum creatinine levels and estimate glomerular filtration rate (eGFR). However, this method may not capture early-stage CKD, and the disease might remain undetected until advanced stages.

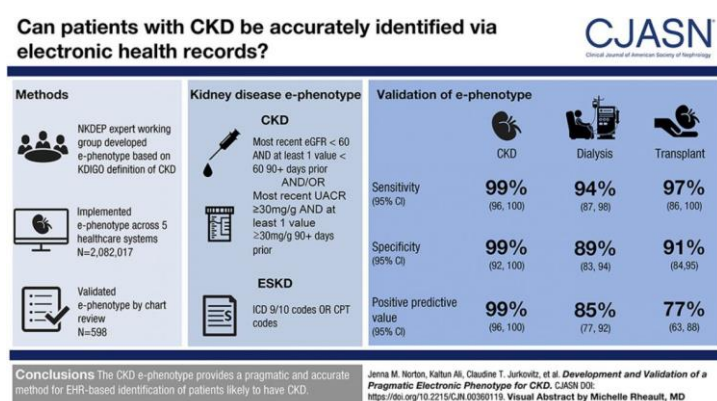


Figure 6: Tests for CKD

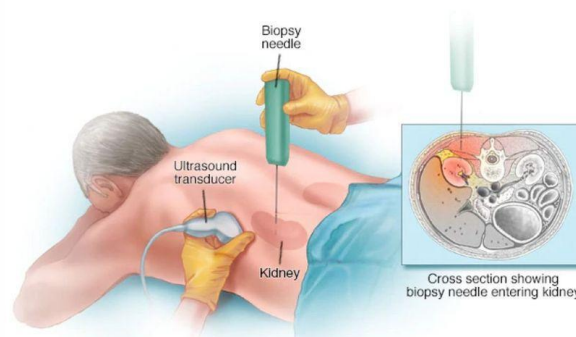


Figure 7: Invasive Biopsy needle

3.3.4 Stakeholder analysis

- Patients: Primary stakeholders at risk for CKD due to age, diabetes, or hypertension. Early detection through a proposed non-invasive tool empowers proactive health management and improved quality of life.
- Doctors: Can make informed decisions and provide timely interventions based on accurate diagnostic results.
- The public: Gains from enhanced healthcare practices focusing on early CKD detection. Accurate, non-invasive diagnostic tools boosts confidence, health literacy, and proactive health engagement.

3.3.5 Market Analysis

The global market for innovative diagnostic tools catering to chronic kidney disease (CKD) detection is poised for substantial growth. With a projected CAGR of 6.3%, reaching USD 1.2 billion by 2025, the market is driven by the increasing prevalence of CKD, the need for early detection, and advancements in medical technology. Key segments include technology, end-users, and application. Factors like the aging population, preventive healthcare, and personalized medicine contribute to growth. Challenges include cost-effectiveness and access, while collaborations drive innovation and partnerships.

4. NEED SELECTION

We evaluated our five problems, scored them based on our analysis, and opted for the best one.

Criteria	Estimated Market	Patient Impact	Providers Impact	Feasibility Index	Co-owners Preferences			Total	Rank
					I	II	III		
Need	Out of 5	Out of 3	Out of 5	Out of 5	Out of 2 for each			Out of 24	
Monitoring and measuring the saline flow rate	4	2	4	5	2	2	2	21	1
Control the pain for identified issues	4	3	3	3	1	2	2	18	3
Noninvasive method to detect CKD in early states	4	3	4	3	2	2	2	20	2

5. CONCLUSION

In conclusion, after careful consideration, we have identified the pressing need for addressing the challenge of monitoring and measuring the saline flow rate. This shift in focus is rooted in its significance and viability. Our intent is to develop a method that accurately caters to intelligent monitoring and measuring the saline flow rate and connecting it into a centralized system, aligning with the crucial demands of the medical domain.

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