A Consumer Device for Detecting Gastrointestinal Disorders

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Abstract—This paper presents a new consumer product that allows a consumer to detect gastrointestinal disorders, such as colorectal cancer and others, using new technology and artificial intelligence. We review the concept, compare the product to existing market technologies, and show the significant opportunities for this consumer product to inform clinical decisions for clinicians.

I. INTRODUCTION
Most medical conditions have an inverse correlation between the time to discovery and the cost to treat and its success rate. 8.8 million people die globally every year due to cancer, and late detection is a significant factor. As cancer progresses undetected to an advanced stage, the likelihood of a successful treatment and survival decreases while the cost of treatment increases. [1]. Ideally, every individual would visit the doctor and run multiple tests regularly, which would greatly increase the opportunity for early detection and successful treatment of medical disorders. Unfortunately, this is not practical. People often don’t seek testing services in the absence of symptoms, and this further contributes to delayed detection rates. However, there are practical consumer products than can provide an accurate level of symptom analysis and opportunity for early treatment by medical professionals. This is the mission of ClinicAI and its products.

More than 80% of all deaths in the US are due to diseases that could have been avoided with early detection followed by a lifestyle modification [2]. However, people generally lack the proper tools to help them monitor and maintain their health on a regular basis and technology that can provide them with useful actionable data. There is a golden opportunity for the consumer products area if new diagnostics devices can be creative, affordable, and accurate. However, accuracy presents a challenge as characterized by a recent Spectrum article describing "Digital Snake Oil": products that make greater claims than then deliver [3]. This has been true for many alternative medicine products including teas, herbs, acupuncture, etc.

There is a tremendous opportunity to lower the number of deaths due to chronic conditions. Moreover, there is an opportunity to decrease spending associated with these conditions which are costing the United States about 75 percent of the nation's aggregate health care spending [4]. One way to lower the expenditure is by tracking gut health for potential changes associated with inflammation, including chronic inflammation. Most gut disorders lead to changes in bowel movements, stool consistency and other changes that, if tracked on a continuous basis, could give us a wealth of information on gut health and gut disorders [5].

This paper starts with an overview of some gastrointestinal disorders and a description of ClinicAI’s toilet monitor consumer product. This is followed by a description of the steps used by the system to scan, safely communicate with the cloud based Artificial Intelligence Engine, and identify potential gastrointestinal disorders. Later, we talk about user notifications, if there is risk, and the corresponding information that can be transmitted to the user’s supporting medical facility for confirmation and treatment recommendations. We characterize the accuracy of the system and compare that to other consumer products and medical procedures. In summary, we establish a non-invasive, accurate technology to potentially identify multiple gastrointestinal disorders.

II. GASTROINTESTINAL DISORDERS
Almost 60 to 70 million people in the US alone are affected by one or more digestive disorders, resulting in more than 245,000 deaths each year [6]. The financial burden of digestive conditions amounted to almost $140 billion in 2015 and continues to increase [7].

A. Inflammatory Bowel Disorder
Inflammatory bowel disorder, or IBD, which includes Crohn’s disease and ulcerative colitis, affected 3 million people in the US in 2015. The number of hospitalizations due to IBD is increasing each year [8]. Symptoms of IBD include severe diarrhea, abdominal pain, fatigue and weight loss [9]. Challenges with IBD care include: determining what biologic medication should be used for which patients, characterizing patient response to medication, and determining if the patient has achieved complete mucosal healing. Monitoring includes a stool test for fecal calprotectin, a serum test for C-reactive protein and ESR (erythrocyte sedimentation rate), and colonoscopy to evaluate mucosal healing. However, more comfortable and affordable tools for continuous monitoring are needed.

B. Colorectal Cancer
Colorectal cancer (CRC), is on the rise among younger people, including millennials [10]. While the exact reason for this trend is still being researched, possible causes include sedentary lifestyle, obesity, and microbiome changes. The biggest issue that contributes to late detection is the lack of symptoms in earlier stages. Moreover, it can take some time for people to recognize certain symptoms as related to colorectal cancer [11]. Patients seek testing only when they exhibit certain symptoms during later stages, such as blood in the stool. Unfortunately, survival rates drop from 94% at earlier stages to 11% at Stage IV [12]. Moreover, according to Medicare, the expenditure in the first year after diagnosis for a patient at stage I is less than $50,000 while it is almost $100,000 at stage IV [13]. By detecting this cancer early, a
family saves money, improves health, quality of life, and longevity.

III. SMART TOILET MONITOR

A. Initial Product

ClinicAI’s first consumer product is an at-home smart toilet monitoring device that can be attached to any toilet. The device is portable and convenient and offers passive tracking that doesn’t require daily user input. It remotely and regularly scans human waste via optical and additional sensors. Once users’ daily toilet activities are scanned, the information is encrypted and securely uploaded to the ClinicAI cloud, followed by a machine learning algorithm-based analysis. The results are returned to the user. If positive, the user can be referred to their doctor for additional screening. To make our device more impactful and engaging, we are planning studies on additional disorders that can be tracked through the same device. Moreover, we are building a friendly and entertaining mobile application that will give users regular summaries on their gut health.

Consumer product pricing will be primarily based on manufacturing costs and will be competitive with alternative colorectal cancer detection products. In the future, reimbursement will be sought through insurance companies. There will be an upfront hardware fee, that can have a higher down payment and lower monthly fees, or a lower down payment and higher monthly fees. Moreover, there is an additional fee for data analytics and user summaries, which will be charged monthly through ClinicAI’s mobile application. There will be no need to purchase several devices per household: one device can be used by multiple people through phone pairing. The monitor will not be activated and will assume a “guest” mode if the user is not detected and is unknown.

ClinicAI will offer frequent and accurate reports while eliminating the risks of sample loss and contamination during collection and shipping.

B. Core Technology: Hyperspectral Imaging

Some high-level discussion on hyperspectral imaging.

- Hyperspectral imaging captures and processes an image at a very large number of wavelengths. Whereas multispectral imaging might evaluate an image in three or four colors (red, green, blue and near-infrared (NIR), for example), hyperspectral imaging breaks the image down into tens or hundreds of colors.
- Samples are illuminated by a light source in real-time while a photo-sensor quantifies reflectance. Our analysis to date indicates that reflectance will vary depending on stool texture, color, and consistency in addition to changes in gut microbiome.

C. Core Technology: Machine Learning

The smart toilet monitor scans waste and packages the scanning information together with symptom and user identification data.

System assumes a smart edge device, such as a smartphone, with an internet connection. This device pairs and encrypts user associated sample information with symptoms. For now, we assume the communication between the toilet monitor and edge device is secure.

In an office environment the monitor can have additional security features. Here, security can be applied within the monitor system and communicate with an office gateway, such as an HR system, to the ClinicAI machine learning engine for analysis. The technology is nearly identical for an office environment, but many things need to differ for security. As an example, the toilet monitor may be notified of user identity by a “badge” entry into the toilet stall. While the data flow process will be the same for home and office use, here we focus on the consumer product that is used at home. Office use will require consideration of additional complexities such as user identification and security between monitor and edge.

IV. IMPACT OF EARLY DETECTION

Early detection with the implementation of our product could increase the rate of early detection, which is associated with greater treatment success, an almost 100% 5-year survival rate, and decreased treatment cost as shown in figure 1 [13].

![Figure 1: Colorectal Cancer Survival vs. Cost](image)

Treatment and survival success rapidly decline as the time to discovery and treatment increases. Also, over time, the cost of treatment moves from a few thousand to hundreds of thousands. Of course, if it is discovered before or at stage I, which could be done with our device in the future, the treatment success nears 100%, the 5-year survival rate is maximal, and the cost of treatment is minimized.

V. OPERATION AND DATA FLOW

The data flow as shown in Figure 1.

1. The smart toilet monitor activation
2. Phone pairing for user identification
3. The optical sensor performs scan
4. The information is packaged, encrypted and sent to the edge with scan and known identity
5. The edge packages and secure the data
6. This is sent to the ClinicAI cloud for analysis with machine learning algorithm.
7. The analysis is returned to the edge and system “owner”.
8. Optionally, results are sent to an assigned physician if there is an indication of a possible disorder.

VI. **OTHER COLORECTAL CANCER DETECTION METHODS**

Many existing tools for colorectal cancer detection are either invasive, inconvenient, or both. At-home stool screening kits, such as Fecal Occult Blood Test (FOBT) and Cologuard, are both approved by the FDA, currently available and are covered by insurance. An at-home stool kit is sent to the individual and shipped back with a stool sample for laboratory analysis. It is time consuming, tedious, requires effort, and only provides a one-time measurement. Accuracy of the FIT is 75%, while Cologuard’s is 92% [14,15]. Moreover, most of the kits currently in the market mainly detect blood, which is not an accurate indicator and limited to certain symptoms or to later stages. These tests are sometimes performed only in the presence of certain symptoms, that tend to appear in later stages.

Colonoscopy, another detection tool, is expensive, uncomfortable, and is a risky procedure that can lead to gut perforations and associated death. It is performed by a doctor and uses a colonoscope to visualize the colon. There is a preparation required for this procedure that can include eliminating solid food or a laxative. Accuracy highly depends on the expertise of the performing physician [16]. A table comparing Cologuard, or stool DNA, colonoscopy and ClinicAI is below:

<table>
<thead>
<tr>
<th></th>
<th>CLINICAI</th>
<th>Stool DNA</th>
<th>Colonoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process</strong></td>
<td>At home</td>
<td>User collects a stool sample</td>
<td>Performed by a doctor</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>Daily</td>
<td>Every 3 years</td>
<td>Every 10 years</td>
</tr>
<tr>
<td><strong>Preparation</strong></td>
<td>None</td>
<td>None</td>
<td>Fasting, colon cleansing</td>
</tr>
<tr>
<td><strong>Type</strong></td>
<td>Noninvasive</td>
<td>Noninvasive</td>
<td>Invasive</td>
</tr>
</tbody>
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Figure 3: Alternative methods of CRC detection vs ClinicAI

VII. **METHODS AND CURRENT RESULTS**

We have been testing our device using samples to both train the AI engine and evaluate its effectiveness. As with many biomedical projects we initially started with mice studies, but the current results are based on human samples. Samples were obtained from a clinical site. Patients supplying samples either had a diagnosed gastrointestinal condition (e.g. colorectal cancer) or served as a control. Samples came from patients with no previous history of cancer or any type. Stool samples were collected using a plastic collection spoon provided in the cap of the collection container and frozen within 2 hours of collection and stored at -80°C. Thawed stool samples were analyzed using an optical sensor. Intensity versus wavelength data was collected and used for training machine learning algorithms. The best performing algorithms...
resulted in a sensitivity of 77.78% and specificity of 100%. With increased sample size, we expect to reach better results.

VIII. PLAN AND EVOLUTION

Basic product currently under limited testing (being scheduled at the time of this writing). Manufacturing for broader usage in the next several years, endorsements and FDA clearance expected following extensive tests and results.

IX. SUMMARY

We have defined a consumer-oriented product that works with data analytics from a cloud service and detects potential gastrointestinal disorders, such as colorectal cancer. The accuracy is expected to be stronger than existing consumer products, with incomparable convenience and ease of use. As a consumer device, ClinicAI’s smart toilet monitor offers an opportunity to cover multiple disorders leading to situations where the consumer can take over-the-counter treatments and have more control over their health. Our system also provides medical experts with continuous health-monitoring data, serving as valuable supplementary information to hospital testing results for doctors to early detect gastrointestinal disorders and evaluate treatment options. The key is the inverse curves between early detection and cost of treatments. Our strategy is to capitalize on the inverse relationship between time of detection, and treatment cost and success. This technology has the ability to scale beyond the home and office space, potentially extending to health tracking in space and other isolated environments. This sets the future for consumer health monitoring and early detection of gastrointestinal disorders.

REFERENCES