RESEARCH ARTICLE

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Utilizing an Artificial Intelligence and Machine Learning Model to Predict Colorectal Cancer Risk in American Samoa: A Pilot Study

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Abstract

Objective: This pilot study aimed to assess the feasibility of using an artificial Intelligence and machine learning (AI/ML) model to predict colorectal cancer (CRC) risk in American Samoa, where resource limitations and cultural barriers significantly hinder screening efforts. **Methods:** The AI/ML model used complete blood count (CBC) results, along with age and gender, to predict CRC risk. A retrospective analysis was conducted on data from 6,025 individuals aged 50 and above from the Lyndon Baines Johnson Tropical Medical Center's electronic health records. Of these, 62 participants were identified as high-risk for CRC based on the AI/ML model. The study also incorporated the methylated Septin 9 (mSept9) biomarker as an alternative, less invasive screening method for CRC detection. Participants were contacted for follow-up CRC screening, which included colonoscopy, fecal immunochemical testing (FIT), or mSEPT9 blood testing. **Results:** The AI/ML model identified 62 high-risk participants. However, only four participants returned for further testing, and just one agreed to a colonoscopy. The colonoscopy result revealed a benign polyp and low hemoglobin levels in the participant with the highest risk score. mSEPT9 levels were elevated in this participant, indicating the potential utility of this biomarker for early CRC detection. Despite promising results, the model's validation was limited due to low participation in follow-up screening. **Conclusion:** This study demonstrates the potential of AI/ML models for predicting CRC risk in resource-limited and culturally diverse populations like American Samoa. However, significant barriers, including cultural, financial, and logistical factors, limit patient follow-up and the broader implementation of these technologies. Future research should focus on addressing these barriers, enhancing community engagement, and integrating culturally appropriate interventions to improve CRC screening and outcomes in underserved populations.

Keywords: American Samoa- Colorectal Cancer- Artificial Intelligence- machine learning- Screening Barriers

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Introduction

Colorectal cancer (CRC) is the third leading cause of cancer deaths in men, and fourth in women [1]. Healthy People 2030 has designated a national screening goal of 68.3% of eligible adults [2], yet Native Hawaiian and Pacific Islander (NHPI) populations face persistent disparities due to resource limitations and social determinants of health [3]. In American Samoa (AS), CRC is the third most prevalent cancer, with 80% cases diagnosed at stage 3 or higher [4], and only 13% of eligible adults reporting CRC screening [5].

AS, the only U.S. territory south of the equator, had a population of 49,710 in 2020, with 22.1% aged 50 and older [6]. The territory operates within a hybrid governance system of Samoan cultural traditions, U.S. policies, and global influences, which, along with geographic isolation, exacerbates health disparities. Access to cancer treatment requires a five-and-a-half-hour flight to Hawai'i, available only twice weekly.

Social determinants of health significantly impact CRC disparities in AS. The poverty rate stands at 57.8%, the highest among U.S. states and territories [6]. Educational attainment is also low, with only 13.3% of adults holding a bachelor's degree compared to 37.5% nationally [7]. These factors contribute to high rates of obesity (93.5% of adults vs. 74% in the U.S.), diabetes (34% vs. 15%), and other non-communicable diseases [5, 8, 9]. These behavioral risk factors and health outcomes are commonly shared with other culturally diverse and geographically

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dispersed NHPI [10–12].

Despite resource limitations, AS is culturally rich in Fa'aSamoa (the Samoan way), which emphasizes collective well-being. The traditional governance system, Fa'amatai, led by the Ali'i (chiefs), fosters community mobilization. This cultural framework has successfully improved breast cancer screening rates [13] and could be leveraged for CRC interventions [14].

Colonoscopy is considered the gold standard for CRC screening [15, 16]. However, its invasiveness has been a reported barrier in low colonoscopy uptake in Indigenous populations, including NHPI, due to cultural barriers [17, 18]. Alternative methods include the fecal immunochemical test (FIT) which detects hemoglobin in stool [19, 20], and the Methylated Septin 9 (mSEPT9) blood test, a promising biomarker with high sensitivity for CRC detection [21]. The CBC test is a routine blood test that can flag anemia, a potential CRC indicator [22].

CRC screening services in AS are limited. The American Samoa Community Cancer Coalition (ASCCC) implements cancer control programs and provides financial support for CRC patients. The Lyndon Baines Johnson Tropical Medical Center (LBJ TMC), the only acute care facility, has one general surgeon and a single colonoscope, restricting screening colonoscopies to three per week. The Tafuna Family Health Center, the sole Federally Qualified Health Center, screened only 0.61% of adults for CRC in 2023 using guiac Fecal Occult Blood Test [23].

Artificial intelligence and machine learning (AI/ML) are advancing CRC detection, improving early diagnosis and reducing disparities [24]. AI-driven models analyze medical history, imaging, and biomarkers to detect adenomas and malignancies [25–27]. However, AI/ML models risk bias due to incomplete and non-representative datasets, disproportionately affecting marginalized populations [28, 29]. The LGI Flag™ algorithm, developed using decision trees and cross-validation, identifies individuals at high CRC risk based on age, sex, and CBC results [25, 30]. The model was validated using retrospective electronic health records (EHR) data from over 600,00 patients in Israel, the U.K., and the U.S., patients in the top 1% were 20 times more likely to have CRC [25, 26, 30]. This demonstrated a strong predictive performance in identifying individuals with lower gastrointestinal cancers using CBC test results and other clinical parameters, confirming its utility across diverse populations and healthcare settings. Evaluating this algorithm in AS could improve early detection and reduce CRC mortality in this underserved population.

Materials and Methods

This research aimed to pilot test the use of an AI/ML model that uses CBC test results, age, and gender in AS to address cultural barriers to CRC screening through the adoption of less invasive techniques. The efficacy of the algorithm would be determined by using a combination of colonoscopy, FIT, and mSept9 results to calculate specificity and sensitivity.

This was a retrospective study supported by a multisector partnership between the ASCCC, LBJ TMC, Medial EarlySign, University of Hawai'i's Cancer Center, and the central hub of the Artificial Intelligence/ Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD). The ASCCC administered the study and coordinated amongst the partners.

Study Sample

The LBJ TMC assigned two representatives who were approved to review patient health records to assist the study staff. Patient records were included in the data set if they had CBC results from January 1, 2020, through December 31, 2022, and were age 50 or older at that time. Those excluded were those who had active cancer for whom further evaluation may not be recommended, patients under active gastrointestinal surveillance or with scheduled appointment, and those who were up to date with their recommended CRC screening.

Using the inclusion and exclusion criteria, LBJ TMC representatives ran a query of the electronic health record. The resulting data were de-identified by the LBJ TMC's representative who replaced the medical record number (MRN) with a randomized Universal Identification (UIE) number specifically for the study. The LBJ TMC representatives were the only ones to have access to both the MRN and UIE securing patient confidentiality from the study staff.

Piloting the Algorithm and Patient CRC Screening: LGI Flag™

The final patient dataset was reformatted from an Excel spreadsheet into an input file acceptable to test the algorithm. A representative at Medial EarlySign placed the data into a secure Amazon Web Service 3 bucket which processed the data through the algorithm and provided an output file which was returned to the study staff for interpretation. Each patient received a CRC risk score ranging from 0.0 (low) to 1.0 (high). The output file sorted the patients from highest to lowest CRC risk score. Concurrent to the sharing of the output file, the original de-identified patient dataset was deleted.

Patients who scored in the top 1% of the total sample were then contacted by LBJ TMC staff to return for either a colonoscopy or FIT at the LBJ TMC surgical ward. Deidentified results were shared with the study staff. As an alternative, participants were also offered an opportunity to provide a blood sample taken at the LBJ TMC laboratory to assess mSept-9 levels to confirm CRC diagnosis.

For those selecting the blood test, a trained phlebotomist collected 10 uL of blood in an ethylenediamine tetra-acetic acid (EDTA) tube. The tube was labelled only with the study UIE and was retrieved by the study staff. The EDTA tube was placed into a centrifuge and spun at a rate of 1,600 g force for 10 minutes. Using a disposable pipette, plasma was aliquoted into 0.5 mL cryovials. The buffy coat was also collected and stored in 0.5 mL cryovials to analyze white and red blood counts. All cryovials were stored in a -80 Celsius degree freezer and shipped via air cargo on dry ice to the University of Hawai'i's Cancer Center for analysis. Two PyroMark mSept9 DNA

methylation assays were custom designed to cover two nearby regions within the Septin 9 gene (intron). Both assays cover multiple CpG sti. A normal and positive control from a previous study were added to the analysis.

The use of colonoscopy and FIT results was modeled after Ayling et al. [31]. However, this was the first study to include mSept9 biomarkers to assess the efficacy of the algorithm and within the AS population. Efficacy would be analyzed using sensitivity, defined as the model's ability to identify actual CRC cases and specificity, the ability to identify actual negative cases [32].

Results

The LBJ TMC dataset revealed 6,776 patients that met the inclusion criteria. After removal of incomplete data and those excluded, there were 6,025 eligible participants. Of those participants, 62 fell within the top 1%. Of those 62, four returned for a blood draw, and one completed a colonoscopy during the study period See Figure 1.

Results of the Model

Median age of the 6,025 patients was 60 years old (SD 7.0; min 50 y.o.; max 75 y.o), 52.9% were male, and 47.1% female. The CRC score range for the top 1% (n=62) was from 0.231 to 0.7843 (Table 1). The 62 individuals were contacted via telephone to return for recommended screening by LBJ TMC staff. Only four (3 males; 1 female) returned to LBJ TMC for recommended screening (e.g. colonoscopy, FIT, mSEPT 9). Due to the low number, efficacy of the algorithm could not be assessed through specificity and sensitivity analysis. However, Table 2 presents the algorithm CRC risk score, CBC red blood cell indices of the four patients who returned for further testing, normal values, and the mean values of the patients with scores at 2% and higher (n=5963) as case presentations to inform future testing of AI/ML models predicting CRC among AS people.

The four patients are ranked from highest to lowest CRC risk score. Patient four had the lowest CRC risk score but was 440% higher than the mean score of the patient sample greater than 1%. Patients one and two had the highest CRC risk scores and the most below normal values in the red blood cell indices. Only patient one received a colonoscopy. Results found a benign polyp and gastritis. A diagnostic CBC found low hemoglobin levels. Patients two, three, and four did not have a medical history of anemia or reports of blood in the stool. The

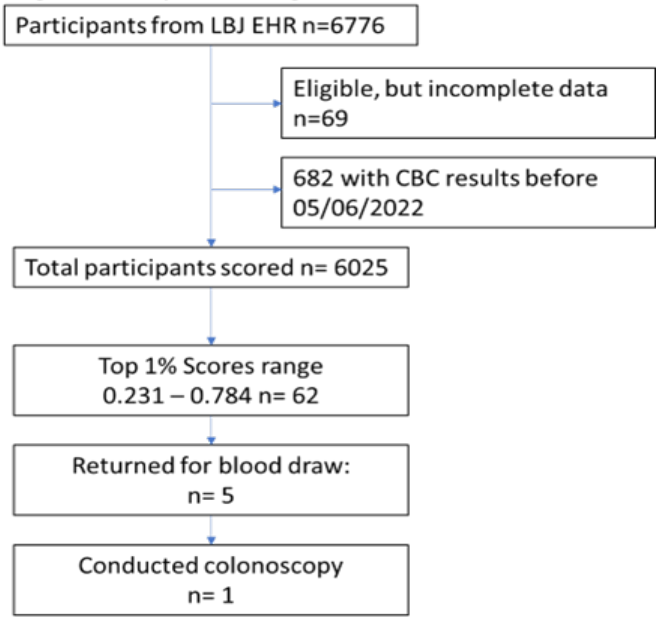

Figure 1.Sample Tree Diagram

Table 1. Patient Methylated Septin 9 Levels of Four Patients (PyroMark Assay 1)

CpG Positions:	1	2	3	4	5	6	7	Mean
Controls								
UnDNA	2.1	1.7	4.8	1	2.4	1	0.8	2.0
MeDNA	100.0	99.5	89.6	87.6	98	83.9	85.4	92.0
Patient 1	1.1	3.0*	4.5	2.6*	1.5	1.6*	3.1*	2.5
Patient 2	1.1	0.5	2.2	0.7	1.5	0	4.3*	1.5
Patient 3	0.9	0.9	4.4	0.9	1.7	0.8	-	1.6
Patient 4	1	1	2.1	1	1.5	0.7	1.8*	1.3
cfDNA_TXL	18.1*	17.2*	17.3*	15.9*	17.3*	11.8*	5.3*	14.7

* Denotes above the negative control (unmethylated DNA); cfDNA_TXL, Additional positive control from cancer patient cDNA sample from another study; UnDNA, Negative control (unmethylated DNA); MeDNA, Positive control ("100% methylated DNA)

Table 2. Colorectal Cancer (Risk Score, Demographics, and Complete Blood Count Results of Four Patients

	Normal Values	Patient 1	Patient 2	Patient 3	Patient 4	>1%
LGI Score		0.78	0.32	0.27	0.27	0.05
Gender		Male	Male	Female	Male	
Age		68	60	72	61	61
RBC (Mean)	4.0-5.4 µL	3.9 (-)	3.6 (-)	4.4	5.6 (+)	4.7
HGB (Mean)	11.5-15.5 g/dl	8.3 (-)	9.0 (-)	11.4 (-)	14.0	13.5
HCT (Mean)	36% - 48%	29.2 (-)	28.1 (_0	37.4	45.7	41.3
MCV (Mean)	80 – 100 fL	74.2 (-)	77.7 (-)	84.9	81.8	88.9
MCH (Mean)	27 – 31 pg	21.1 (-)	25.0 (-)	25.8 (-)	25.0 (-)	29
MCHC (Mean)	32 – 36 g/dL	28.4 (-)	32.1	30.4 (-)	30.5 (-)	32.6

(+), Higher than normal value; (-), Lower than normal value; RBC, Red blood count; HGB, Hemoglobin; HCT, Hematocrit; MCV, Mean corpuscular volume; MCH, MCHC, Mean corpuscular hemoglobin concentration; µL, Microliters; g/dl, Grams per deciliter; fL, Femtoliters; pg, Picograms

Table 3. Patient Methylated Septin 9 levels of four patients (PyroMark Assay 5)

CpG Positions:	18	19	20	21	22	23	24	25	26	Mean
Controls										
UnDNA	4.3	5	1.1	2.3	1	1.9	4.4	1.6	1.3	1.94
MeDNA	98.9	87.3	81.4	91.8	83.1	95.6	85.4	98.0	97.3	90.39
Patient 1	1.8	5.3*	1.3*	2.9*	1.7*	2.1*	6.0*	3.2*	3.4*	2.95
Patient 2	0.8	2.5	1	1.8	0.7	1.8	2.5	1.5	0.9	1.44
Patient 3	0.8	2.8	2.2*	1.6	0.6	2.4*	2.5	2.1*	1	1.77
Patient 4	0.6	1.3	1.9*	1	0.6	1.5	4.5*	1.2	0.7	1.62
cfDNA_TXL	12.8*	19.0*	15.1*	18.4*	17.9*	19.4*	20.0*	19.5*	18.8*	18.44

"* Denotes above the negative control (unmethylated DNA); cfDNA_TXL, Additional positive control from cancer patient cDNA sample from another study; UnDNA, Negative control (unmethylated DNA); MeDNA, Positive control ("100% methylated DNA)

LBJ TMC representatives were to continue follow-up with these patients.

mSept9

The mSept9 results from the four patients who returned for recommended screening utilizing PyroMark Assay 1 (Table 1) and PyroMark Assay 5 (Table 3) are presented. The "UnDNA" represents unmethylated DNA and the negative control, whereas "MeDNA" represents methylated DNA and the positive control. The methylation levels were low in all four patients when compared to the positive control sample (cfDNA_TXL) from a previous study and could not be used to determine statistical significance. However, the positive results occurred more frequently in Patient #1 who also had the highest CRC risk score among the total sample.

Discussion

This study assessed the use of an AI/ML model to predict CRC risk using complete CBC test results, age, and gender in AS adults ages 50 and older. The following describes both the feasibility and challenges of deploying AI/ML models in marginalized populations with limited resources.

The return of only four participants to obtain recommended screening underscores the challenges in patient follow up for CRC screening. Cultural factors, financial constraints, limited healthcare infrastructure, fear of invasive procedures and lack of trust in health care systems are significant barriers [18]. These must be addressed to effectively implement AI/ML and to improve both CRC screening and health outcomes within this population.

The use of mSept9 as an alternative, less invasive biomarker to detect CRC presents a promising avenue for early detection. Although the number of patients who provided samples for mSept9 analysis was small, results from the highest-risk patient (CRC score: 0.7843) showed elevated methylation levels, indicating the potential utility of mSept9 in detecting polyps or early-stage malignancies. While this finding aligns with emerging evidence regarding mSept9's potential value in CRC screening, the result must be interpreted with caution due to the limited sample size. Larger, well-powered studies are necessary to substantiate its utility in the American Samoan population. However, a future study with larger sample sizes of control and CRC positive patients is needed to fully assess its applicability in the AS population.

A retrospective design relied solely on the staff of the LBJ TMC to gather data from the EHR and recruit the 62 high risk participants for recommended screening. Furthermore, time limitations did not allow the study staff to utilize known behavioral health models to address education and awareness gaps that may have hindered recruitment. A future prospective study design that incorporates known models (e.g. health belief model, transtheoretical model) can help to increase recruitment

for recommended screening to statistically evaluate the utility of the AI/ML model.

This was the first study to utilize an AI/ML model to predict CRC risk in AS adults. The LGI Flag™ model was selected primarily because of its emphasis on clinical indicators instead of demographics and social determinants of health that can create bias especially in marginalized populations that lack rich data like AS. Future studies should consider developing AI/ML models that incorporate this data to build the contextually rich datasets recommended to eliminate biases.

The LBJ TMC is the only setting that performs CBC for both screening and diagnostic in AS. CBC's taken for diagnostic purposes are usually due to illness/under medical observation and do not reflect normal observation. We were not able to confirm the setting in which the results were gathered.

This study underscores the importance of tailoring AI/ML models to fit the healthcare context of resource-limited populations like AS. By utilizing widely available and less invasive tools such as CBC results and mSept9 testing, we can develop culturally appropriate and accessible screening protocols. However, overcoming the cultural and logistical barriers to healthcare access remains crucial. A key next step is to collaborate with local health organizations to improve CRC screening rates and promote community engagement in health research.

Furthermore, addressing data quality and representation in AI/ML models is vital for ensuring the benefits of predictive technology are extended to marginalized populations. Incorporating local datasets and enhancing health literacy in the community will contribute to building more inclusive and accurate models.

In conclusion, while this pilot study has provided valuable insights into the application of AI/ML for CRC risk prediction in AS, the challenges highlighted call for a concerted effort to improve healthcare access, community engagement, and data representation in future research.

Author Contribution Statement

All authors contributed equally in this study.

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Ethical considerations

Ethical considerations were provided by the Western Copernicus Group Institutional Review Board who determined the study exempt from human subjects research (WCG IRB WO#1-1701067-1; IRB Tracking #20242454). This study was not registered in a clinical trials registry, as it was not a clinical trial nor did it fall under categories requiring registration (e.g., systematic review, meta-analysis, or guideline development). There are no conflicts of interest to disclose. All authors contributed substantially to the study design, data collection, analysis, interpretation of findings, and manuscript preparation. De-identified datasets generated during the study will be made available through the American Samoa Community Cancer Coalition (ASCCC) website: www.asccancercoalition.org.

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