

West Virginia Oral Health Technology Initiative

Utilizing Health and Wellness Findings and Data to Improve Oral Health



Introduction

The West Virginia Oral Health Coalition (WV-OHC), the Institute for Technology in Healthcare (ITHC), Avësis, LLC, and Harmony Health (HH) are united in their mission to drive positive change in underserved communities through innovative technologies. Our primary focus is on promoting general health and wellness in these communities by utilizing low-risk, cutting-edge tools. The technologies deployed in this program are not designed to diagnose or treat specific diseases but rather to support licensed healthcare providers in their efforts to improve health outcomes. These tools provide non-diagnostic health insights that encourage proactive wellness management, while licensed providers make formal diagnoses and develop comprehensive, holistic plans to enhance oral health. We remain committed to advancing health equity, empowering communities, and using innovation to improve oral health and overall well-being. This report outlines our latest initiative: a pilot program that uses point-of-care salivary testing and mHealth (smartphone) apps to improve oral healthcare access for rural West Virginians.

The Impact of New Technologies on Rural Oral Health

Innovative wellness-focused technologies have the potential to greatly enhance oral health awareness, particularly in rural communities facing barriers to accessing care (Weinstein et al, 2014; Boynes et al, 2018). These technologies empower patients with actionable insights into their health, enabling them to take proactive measures for maintaining overall wellness. (Guo & Li, 2018)

- **Point-of-Care Testing:** The salivary testing device provides rapid on-site wellness insights that support preventive health measures. These insights are intended to guide general wellness interventions and should not be interpreted as diagnostic results for specific conditions. These insights are essential for early identification of health trends and promoting behaviors that support overall wellness, without functioning as a diagnostic tool for specific diseases. (Pretty, 2006; Zhang et al, 2009; Nayak et al, 2017; Liu et al, 2019; Pittman et al, 2023)
- **mHealth Applications:** The mHealth application used in the pilot program features both patient-facing and provider-facing interfaces. In this pilot, the app was primarily provider-facing, with patients accessing their profiles either through the app or via a printout provided by the provider. Integrated into the app were risk assessment surveys, such as the America Dental Association Risk Assessment Survey, which evaluates a patient's risk for developing cavities, and the American Diabetes Association Diabetes Risk Assessment Survey, which assesses an individual's likelihood of developing diabetes based on factors such as age, weight, and family history. These surveys were incorporated into the wellness reports generated by the app, providing a comprehensive health profile that combined risk factors with biomarker levels obtained through salivary testing. The resulting wellness reports were used chairside to educate patients and assist providers in their traditional differential diagnosis process, while reinforcing the device's role as a health and wellness tool. These risk assessments, along with biomarker data, are integrated into wellness reports to support patients in making health-conscious decisions, without serving as diagnostic tools. The insights provided by these assessments are designed to encourage preventive care and lifestyle improvements, empowering patients and providers within a wellness framework. By pairing risk assessments with biomarker data, these reports supported proactive health management, serving as an assistive tool for providers to improve the well-being of their patients. The technologies also allow for timely results at the point of care, remote consultations, reduced travel needs, real-time health monitoring, patient education, and personalized care plans—making healthcare more accessible in underserved areas (Maxim et al, 2014; Liu et al, 2019; Mustafa, 2021; Sharma, 2023; Boynes et al, 2024).

Health and wellness data, including metrics such as salivary pH, buffering capacity, and glucose levels, etc., contribute significantly to value-based care. By analyzing these biomarkers, care teams can personalize health interventions and provide tailored health education, empowering patients to engage in preventive care that reduces the risk of oral health issues.

The Pilot Program

In line with our mission to improve access to care through technology, we launched a pilot program in rural West Virginia. Through collaboration with various community partners and continuous evaluation, we strive to create

sustainable, scalable solutions for oral health equity. This goal of this program is to:

- **Enhance Access to Quality Care:** The pilot program leverages point-of-care salivary tests and mHealth applications to address significant barriers to care, such as the lack of dental providers in underserved communities. (Wong, 2006; Arunkumar, 2014; Harpaldas et al, 2021) By enabling on-site or point-of-care oral health evaluation and the capability of remote consultations, these technologies reduce the need for travel, thereby improving access to timely and quality care for populations that traditionally face challenges in accessing oral health services. (von Lode, 2005; Yoshizawa et al, 2013; Liu et al, 2017)
 - The salivary testing and mHealth technologies utilized in this program are designed to enhance overall health and wellness by enabling early detection of wellness trends that can prompt lifestyle changes. These technologies do not replace clinical diagnosis but empower both patients and providers to engage in preventive health practices.
- **Increase Patient Engage Patients:** The use of personalized health insights and tailored recommendations through these tools enhances patient engagement and encourages active participation in preventive care. (Korte, 2014; By empowering patients with easily accessible health information, the program promotes better adherence to care plans and overall health outcomes. (Náfrádi et al, 2017; Lee et al, 2018)
- **Evaluate the Implementation of New Technologies:** This pilot program systematically assesses the operationalization of point-of-care testing and mHealth applications in clinics serving underserved populations. By collecting and analyzing data on the integration of these technologies, we aim to identify best practices for replicating and scaling successful models. This approach not only addresses access issues but also drives systemic improvements in healthcare delivery, ensuring that high-quality care is more broadly available. (Maxim et al, 2014; Vernazza et al, 2021; Liao et al, 2023)
- **Address Barriers to Care:** By implementing these innovative technologies, the program tackles common barriers to care such as geographic isolation, provider shortages, and limited resources. The use of these tools enhances the ability to deliver quality care directly within communities, thereby improving health outcomes for underserved populations. (Liu et al, 2017; Nasseh et al, 2014; Nasseh & Vujicic, 2014; Boynes et al, 2018)

Selecting Salivary Testing and Smartphone Applications

To address the challenges in rural healthcare delivery, we implemented a novel integration of salivary testing with a smartphone-based mHealth app aimed at improving access and outcomes. Salivary testing offers a non-invasive and convenient method to monitor health and wellness trends by assessing biomarkers that may provide early wellness indicators. (Ligtenberg et al, 2014; Kawabata et al, 2017; Ilea et al, 2019; Buzalaf et al, 2020; Cirillo, 2024) This approach not only enhances early detection and preventive care but also presents an opportunity to personalize treatment plans by correlating test results with practitioner data, ultimately improving patient outcomes. (Chiappin, 2007; Lee & Wong, 2009; Dawes & Wong, 2019) The process is straightforward and non-invasive: saliva is collected using a specialized foam swab that filters and purifies the sample. The saliva is then dispensed onto a test card containing a colorimetric lateral flow assay. A smartphone app captures an image of the test card, and advanced software analyzes the results. These results are transmitted to the mHealth app, where they are presented as a comprehensive wellness report. This report provides valuable insights into both oral and systemic health, enabling early detection and timely interventions. By combining salivary wellness testing with smartphone technology, patients are empowered to monitor their health, receive educational resources, and maintain ongoing communication with healthcare providers. This integrated approach is particularly beneficial in underserved rural settings, where access to care is often limited. Further details on the piloting process are available in Appendix A.

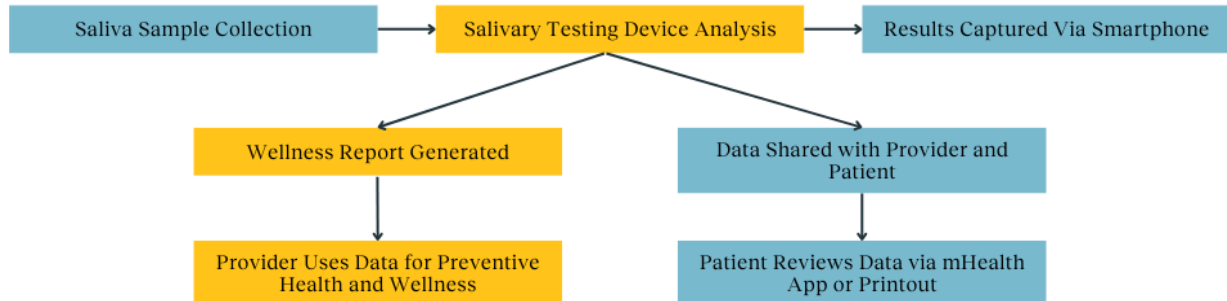
The salivary testing device used in this study adheres to the FDA's general wellness device guidelines. As per FDA's guidance on general wellness products, this device is intended to support general health and wellness by providing users with health insights that promote proactive health management, rather than serving as a diagnostic tool for specific diseases. The device is designed to offer information on biomarkers linked to overall oral health, such as pH, glucose levels, and nitric oxide, encouraging users to maintain a healthy lifestyle that supports oral health.

mHealth apps are mobile health applications that enable patients and healthcare providers to monitor, manage, and improve health through digital tools like smartphones and tablets. These apps can enhance healthcare access by providing remote monitoring, personalized care, and real-time communication, making it easier for patients to engage with their health and for providers to deliver timely and efficient care, particularly in underserved areas. (Underwood et al, 2015; WHO, 2021; Mustafa et al, 2022) Within this pilot program, the mHealth app is utilized by providers and care teams during chairside examinations to enhance clinical decision-making. The app provides immediate access to the patient's personalized wellness report, generated from salivary test results, offering detailed information on oral and systemic health markers. Providers can review these results in real-time to identify relevant biomarkers, such as those associated with periodontal disease or systemic conditions. The app also allows for efficient data entry and

updates, with all information securely synchronized with the patient's electronic health record (EHR). This integration supports streamlined documentation and coordination across the care team. By using the app during examinations, providers can deliver evidence-based care, tailor treatment plans according to individual patient data, and ensure consistent follow-up and monitoring.

Clinical Pilot Program

Flowchart of the Salivary Testing Process



Key findings from the pilot include:

- **Sites:** Three sites participated in the piloting:
 - Site 1-Health Department
 - Site 2-Community Health Center
 - Site 3-Free Mobile Clinic
- **Participants:** 79 underserved adults from rural areas.
- **Testing:** The device measured biomarkers including:
 - Glucose (saliva and blood) levels are commonly used to assess diabetes risk and control.
 - Buffering Capacity assesses how well saliva neutralizes acids in the oral cavity.
 - Salivary pH influences the balance between demineralization and remineralization of tooth enamel.
 - Nitric Oxide plays a key role in maintaining vascular health and regulating blood flow, while also contributing to the defense against oral pathogens.
 - MMP-8 and P. gingivalis levels help identify, stage and monitor periodontal diseases, as well as assess risk for inflammatory disorders and disease states.
 - Additional information on the biomarkers testing and their correlation to disease states is available in Appendix B.
- **Results:**
 - Sensitivity: 89.7%
 - Specificity: 95%

Pilot Findings: Performance and Scalability

- **Performance:** The device demonstrated high precision in providing wellness data, with a sensitivity of 89.7% and specificity of 95%. While these metrics reflect the reliability of the wellness insights provided, it is important to emphasize that the device is not designed to treat diseases but to encourage health-promoting behaviors. (FDA, 2007; Swift et al, 2020; Bastos et al, 2021; Simon et al, 2022d; Sharma, 2023)
- **Impact on Rural Underserved Communities:** Enhancing care for rural underserved communities through non-invasive, cost-effective prevention, maintenance, and detection tools in oral healthcare is a necessary mechanism of health equity and impacting barriers to care access. (Boynes et al, 2018; Henderson-Frost & Deutchman, 2022) The point-of-care salivary testing approach utilizes a correlation of biomarker counts or results as a proxy for detecting periodontal diseases and caries. These findings are compared with the clinical diagnoses made by the care teams, and the pilot team is asked to document how closely the salivary test results align with those diagnoses. This innovative approach has the potential to improve access to essential healthcare services, facilitate early detection and management of oral diseases, and ultimately lead to better health outcomes for individuals in these communities.
- **Scalability:** The salivary testing device offers a low-cost, scalable solution for supporting wellness initiatives in underserved populations by providing health insights that encourage preventive care and lifestyle adjustments. The device plays a role in promoting overall health and wellness by encouraging preventive care and healthy behaviors, rather than diagnosing or managing specific diseases.

Cost Effectiveness

Economic Benefits

The economic evaluation of the pilot program reveals significant cost savings potential:

- **Reduced Treatment Costs:** Cost savings are derived from early wellness insights that encourage preventive actions, which may help reduce the risk of more serious health conditions. These insights are intended to support health-conscious behaviors, not to diagnose or treat diseases (Karter, 2003; Casamassimo et al, 2009; Hirsch et al, 2012; CareQuest Institute, 2024).
- **Lower Healthcare Utilization:** By facilitating preventive care and early intervention, these technologies reduce the frequency of dental visits and associated healthcare costs. (Curb et al, 2009; Lee, 2013; Edelstein & Ng 2015; Oneill et al, 2017)
- **Increased Productivity:** Healthier populations contribute to increased productivity and reduced absenteeism, benefiting both individuals and the broader economy. (Edelstein & Frosh, 2012; Boynes et al, 2017)

Summary of Cost Savings Projections

This analysis is grounded in a detailed evaluation of cost savings derived from early detection and intervention across multiple conditions, including caries, periodontal disease, and diabetes. The findings, expanded upon in Appendix C, are briefly summarized here to ensure clarity in the main body. Early detection and management of oral diseases can prevent the progression to more severe conditions, reducing the need for costly treatments and interventions. (Casamassimo et al, 2009; Edelstein & Frosh, 2012; Merglova & Polenik, 2016) Cost savings result from leveraging early wellness insights that promote preventive measures, potentially lowering the likelihood of developing more severe health issues. These insights are designed to foster health-focused habits and behaviors, rather than being used for diagnosing or treating medical conditions. By facilitating preventive care and early intervention, these technologies help lower healthcare utilization, decreasing the frequency of dental visits and associated healthcare costs. Additionally, healthier populations contribute to increased productivity and reduced absenteeism, benefiting both individuals and the broader economy. Cost savings from oral health are crucial because they not only reduce healthcare expenses but also enhance overall health and quality of life. (Petersen et al, 2005; Sischo & Broder, 2011) By focusing on prevention, early wellness monitoring, and purposeful maintenance, significant savings can be achieved across various conditions. (WHO, 2005; Boynes et al, 2018; Nguyen et al, 2023)

- **Caries Prevention:** Early wellness monitoring and addressing wellness indicators can save approximately \$500 per patient annually. The pilot revealed 20 cases of wellness report and clinical diagnosis alignment, leading to total savings of \$10,000.
- **Periodontal Disease:** Prevention and disease mitigation strategies can save up to \$1,200 per patient annually. With 15 cases of wellness report and clinical diagnosis alignment in the pilot, the total savings amount to \$18,000.
- **Diabetes Management:** Early monitoring and management can save an estimated \$9,000 per patient annually in healthcare costs. The pilot identified 10 wellness report and clinical diagnosis alignment cases, resulting in total savings of \$90,000.

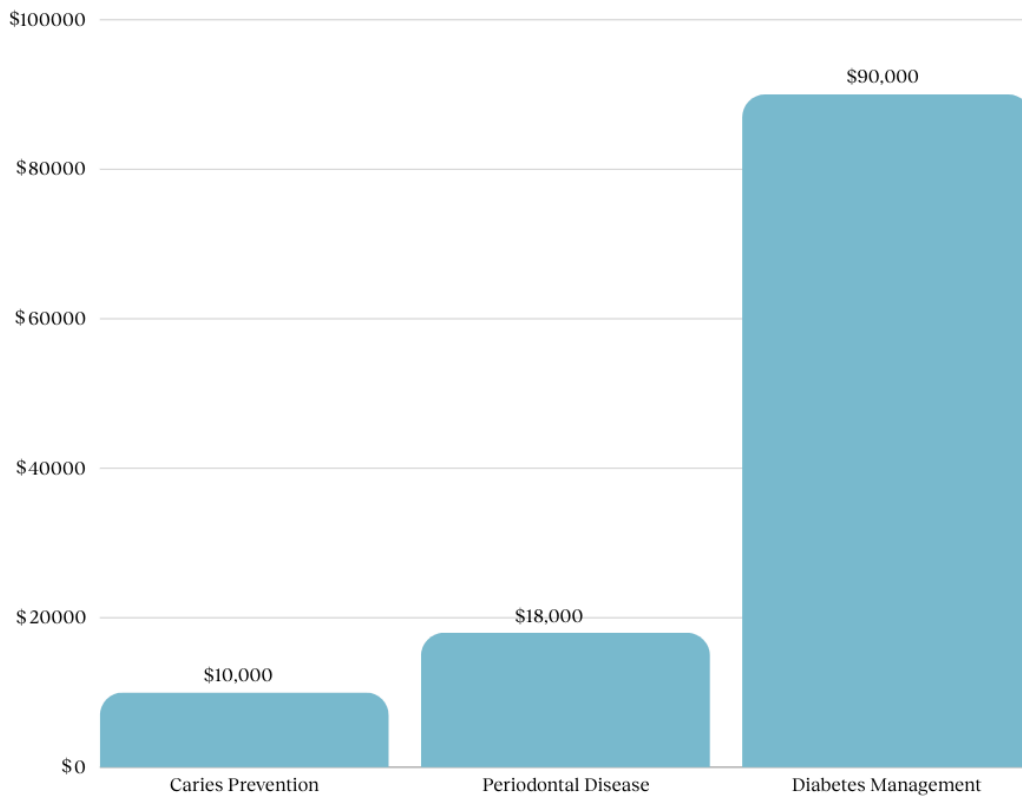
Overall, these preventive measures achieved a total cost savings of \$118,000 during the pilot.

Methods of Analysis:

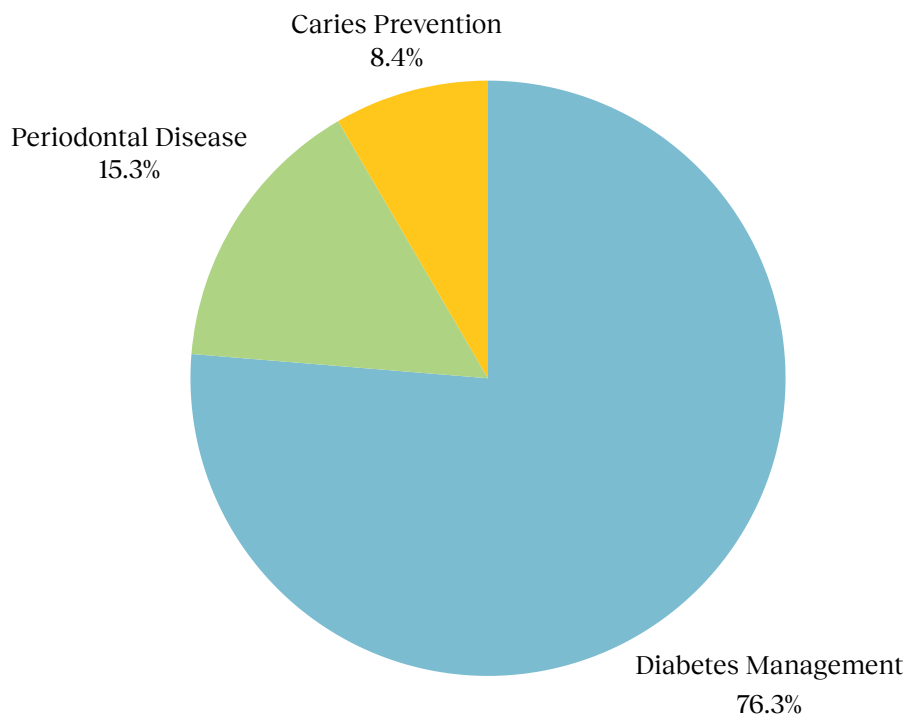
To support these findings, various statistical analyses were performed:

1. **Descriptive Statistics:** Summarized demographic characteristics and test results.
2. **T-Tests:** Compared the means of cost savings between groups with and without early wellness indicators.
3. **Chi-Square Tests:** Analyzed the association between the presence of wellness indicators and test outcomes.
4. **Linear Regression:** Assessing the relationship between salivary glucose wellness levels and projection of finding risk for undiagnosed diabetes.

Cost Savings Per Condition



Overall Cost Savings \$118,000



Wellness Scores by Site

To ensure a comprehensive evaluation of oral health status, the point-of-care salivary testing results are systematically correlated with practitioner-collected data, including clinical indices such as visual examinations, radiographs, bleeding on probing (BOP), and the incidence of cavities detected during routine cleanings and oral examinations. This correlation not only enhances the validity of the salivary biomarkers used but also provides a holistic view of each patient's oral health. The selection of biomarkers, including glucose, buffering capacity, pH, nitric oxide, *P. gingivalis*, and MMP-8, was meticulously guided by their critical roles in oral and systemic health. For example, *P. gingivalis* and MMP-8 are strongly associated with periodontal disease, salivary pH and buffering capacity provide insights on the environment for caries development, and glucose levels and nitric oxide provide insights into inflammatory systemic conditions like diabetes and cardiovascular health. (Loo et al, 2010; Maldupa et al, 2011; Rathnayake, 2013; Gupta et al, 2017; Mtheny et al, 2017; Ilea et al, 2019; Luchian et al, 2022; Shamsi-Basha et al, 2024) By correlating these biomarkers with practitioner data, we can more accurately assess disease risk and tailor interventions accordingly. Detailed correlations and further analysis are available in Appendix B, which includes a comprehensive matrix linking salivary biomarkers to clinical findings and disease risk scores.

Biomarker Analysis and Average Wellness Score

Site	Mean Glucose (mg/dL)	Mean Buffering Capacity (PPM)	Mean pH	Mean Nitric Oxide (µM)	Mean <i>P. gingivalis</i> (CFU/mL)	Mean MMP-8 (ng/mL)	Mean Wellness Score
Site 1 Health Department	2.3 Normal	190 Moderate	7.8 Normal to Basic	220 Optimal	150,000 Normal	50 Optimal	4.2
Site 2 Community Health Center	4.5 High	85 Poor	6.4 Acidic	100 Poor	800,000 Poor to Extremely Poor	220 Poor	7.5
Site 3 Mobile Free Clinic	3.1 Normal	175 Moderate	7.2 Normal to Acidic	210 Optimal	400,000 Poor	150 Poor	5.3

Key Findings and Epidemiological Sites

The integration of biomarker data such as pH, glucose, and nitric oxide allows for a comprehensive view of a patient's general wellness. These biomarkers provide insights into trends that can guide lifestyle modifications to maintain oral health, fitting within the framework of wellness promotion rather than disease diagnosis. The selection of biomarkers for this study was strategically guided by their established relevance to both oral and systemic health outcomes. Key biomarkers, such as Matrix Metalloproteinase-8 (MMP-8) and *Porphyromonas gingivalis* (*P. gingivalis*), were chosen for their association with periodontal disease and their broader implications in conditions like cardiovascular disease and diabetes. This selection process was based on a rigorous review of current evidence. Additional information is provided within *Appendix B*.

1. **Higher Disease Burden in Site 2:**

- Site 2 consistently shows higher risk scores across all health conditions compared to Site 1 and Site 3. This indicates a higher disease burden in Site 2, suggesting a need for more intensive interventions.

2. **Biomarker Correlations:**

- High levels of MMP-8 and *P. gingivalis* correlate strongly with higher risk scores for periodontal disease and overall disease risk with cardiovascular disease and diabetes [See *Appendix B* for the biomarker and risk correlation matrix and additional biomarker analysis].

3. **Demographic Factors:**

- *Medicaid Status:* The majority of participants in all sites are Medicaid recipients, indicating a low-income population. This demographic factor is crucial as it often correlates with limited access to healthcare resources and higher disease prevalence. (Joynt-Maddox et al., 2018)
- *Gender Distribution:* Females were found to have slightly lower glucose levels and buffering capacity compared to males, with similar pH levels between genders. Males exhibited higher average levels of nitric oxide, MMP-8, and *P. gingivalis*, indicating a higher risk for periodontal disease. Additionally, males had higher global risk scores, suggesting an overall greater health risk.

Actionable Steps by Site Based on Clinical Findings and Wellness Assessments

Based on the salivary and risk assessment results, interventions were developed at the site level to address the primary health risks identified across the population served by each location. These site-specific strategies are designed to optimize oral health outcomes by targeting the most prevalent biomarkers and risk factors within the community. While the care teams implement these generalized recommendations across the site, they also personalize care plans for individual patients based on their unique needs. This approach ensures that the interventions are both scientifically grounded and effectively tailored to improve overall community health while addressing individual patient concerns.

By analyzing health trends and data across patient populations, these technologies can help identify individuals who may benefit from wellness interventions aimed at promoting oral health and preventing lifestyle-related risks.

Site 1: Health Department with Mobile Dental Care

Interventions: Maintain current health practices, regular monitoring, and routine dental check-ups. Focus on preventive care to sustain low-risk levels.

Recommendations:

- *pH and Buffering Capacity:* Educate on the importance of maintaining a neutral to high oral pH and optimal buffering capacity to prevent enamel demineralization. Additionally, highlight how frequent acid attacks from dietary choices can lower oral pH, increasing the risk of caries. Emphasize the role of regular monitoring and dietary management in minimizing these acid challenges to protect tooth enamel.
- *Fluoride Treatments:* Continue with fluoride varnish treatments (based on risk level) to strengthen enamel and prevent caries, consider up to 4x per year for those at high risk.
- *Silver Diamine Fluoride (SDF):* Introduce SDF applications for individuals at high risk of caries, particularly for those with limited access to routine dental care. SDF can arrest active decay and prevent its progression, providing a non-invasive, cost-effective solution. Additionally, consider using SDF with potassium iodide (KI), which has a higher acceptance rate due to minimal staining, especially when treating anterior teeth.
- *Remineralization Strategies:* Recommend the use of nano-hydroxyapatite toothpaste, which can penetrate the enamel surface to rebuild and restore tooth structure that has been demineralized by acidic conditions. Additionally, consider incorporating biomimetic technologies such as self-assembling peptide technology. This innovative approach works by mimicking natural enamel formation, where peptides organize themselves into a structure that promotes the deposition of calcium and phosphate, effectively re-mineralizing and strengthening teeth. Combining these strategies with fluoride offers a comprehensive approach to enamel repair and protection.
- *Oral Hygiene Practices:* Continue promoting regular brushing, flossing, and interdental care, emphasizing the use of toothpaste with both fluoride and hydroxyapatite to enhance remineralization. Consider promoting the use of electric toothbrushing or connected toothbrushes to improve frequency, duration, and coverage of home oral hygiene care.

Site 2: Rural Community Health Center

Interventions: Implement intensive interventions to reduce glucose levels and improve buffering capacity. Enhance education on oral hygiene and dietary practices. Increase frequency of dental check-ups and professional cleanings.

Recommendations:

- *Dietary Counseling:* Provide targeted dietary counseling to reduce glucose intake, which directly influences the oral microbiome and buffering capacity. Reducing sugar intake helps lower the risk of caries and periodontal disease.
- *Fluoride Treatments:* Continue with fluoride varnish treatments (based on risk level) to strengthen enamel and prevent caries, consider up to 4x per year for those at high risk.

- *Silver Diamine Fluoride (SDF)*: Introduce SDF applications for individuals at high risk of caries, particularly for those with limited access to routine dental care. SDF can arrest active decay and prevent its progression, providing a non-invasive, cost-effective solution. Additionally, consider using SDF with potassium iodide (KI), which has a higher acceptance rate due to minimal staining, especially when treating anterior teeth.
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- *Periodontal Health*: Encourage the use of arginine-based toothpaste for patients at risk of periodontal disease. Arginine helps neutralize acids produced by bacteria and promotes the growth of beneficial oral bacteria, reducing the risk of periodontal inflammation and improving overall gum health. Additionally, consider the application or use of iodine rinse as part of the periodontal care routine. Iodine has antimicrobial properties that can help reduce harmful bacteria in the mouth, particularly those associated with periodontal disease. Regular use of iodine rinses can aid in controlling plaque levels and support the maintenance of healthy gums. Tobacco and nicotine use are also associated with poor periodontal outcomes and incorporating tobacco and nicotine cessation strategies would assist in improving the oral health of the population. (Ye et al, 2020)

Site 3: Free Mobile Dental Clinic

Interventions: Improve buffering capacity and pH levels through dietary adjustments and fluoride treatments. Provide additional support for periodontal health, including antimicrobial treatments and evaluation of toothpaste usage to include arginine dentifrice. Monitor and manage glucose levels to prevent systemic health issues.

Recommendations:

- *pH and Buffering Capacity*: Educate on the importance of maintaining a neutral to high oral pH and optimal buffering capacity to prevent enamel demineralization. Additionally, highlight how frequent acid attacks from dietary choices can lower oral pH, increasing the risk of caries. Emphasize the role of regular monitoring and dietary management in minimizing these acid challenges to protect tooth enamel.
- *Fluoride Treatments*: Continue with fluoride varnish treatments (based on risk level) to strengthen enamel and prevent caries, consider up to 4x per year for those at high risk.
- *Silver Diamine Fluoride (SDF)*: Introduce SDF applications for individuals at high risk of caries, particularly for those with limited access to routine dental care. SDF can arrest active decay and prevent its progression, providing a non-invasive, cost-effective solution. Additionally, consider using SDF with potassium iodide (KI), which has a higher acceptance rate due to minimal staining, especially when treating anterior teeth.
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- *Portable Oral Hygiene Kits*: Provide portable oral hygiene kits that include fluoride and arginine toothpaste, floss, and instructions for maintaining oral health while on the go.
- *Follow-Up Care*: Ensure regular follow-ups to monitor progress and adjust care plans as needed, with an emphasis on tracking changes in salivary biomarkers and pH levels to optimize intervention effectiveness.

Usability and Satisfaction of mHealth Applications via Smartphone for Clinics

Enhancing Prevention and Diagnostic Understanding

The integration of mobile health (mHealth) applications in clinical settings has shown significant promise in enhancing prevention, disease monitoring, and management of various health conditions. mHealth applications

leverage smartphone technology to provide real-time health monitoring, patient education, and remote consultation capabilities, which are particularly beneficial in rural and underserved areas.

Benefits of mHealth Applications

- **Improved Access to Care:** mHealth apps facilitate remote consultations and follow-ups, reducing the need for physical visits and making healthcare more accessible for patients in remote areas.
- **Enhanced Patient Engagement:** These apps empower patients to take an active role in their health management by providing educational resources and personalized health monitoring tools.
- **Data Collection and Analysis:** mHealth apps enable continuous data collection, which can be analyzed to identify health trends, predict disease outbreaks, and tailor interventions to individual needs.

Evaluation of Validate Survey Tool Responses: Usability and Satisfaction

The usability and satisfaction of the mHealth application were evaluated using two validated survey tools: the mHealth App Usability Questionnaire (MAUQ) and the Physician Satisfaction Survey Ease of Implementation Subscale. Both surveys were completed at the end of the pilot program by care team leadership and required only those that participated in the clinical administration of the device and mHealth app. The MAUQ survey utilizes a seven-point Likert scale to assess various aspects of mHealth app usability. (Zhou et al, 2019; Mustafa et al, 2021) The PSS survey employs a five-point Likert scale with specific descriptors to align answers to the questions asked.(Wolosin et al, 2006) The Physician Satisfaction Survey was initially designed with physicians in mind, ensuring it addresses their experiences and needs. However, its versatile structure has allowed it to be effectively adapted for use across various healthcare professions and non-physician roles. These tools provided comprehensive insights into the application's ease of use, functionality, and overall satisfaction among the pilot participants. The table below provides the average scores by pilot site.

Combined Usability and Satisfaction Survey Results

Survey Tool	Site 1	Site 2	Site 3	Overall Average
MAUQ Average Mean Score	4.5	6.2	5.8	5.5
Physician Satisfaction Survey	3.8	4.2	4.2	4.1

The usability and satisfaction results indicate that the mHealth application was generally well-received by both patients and physicians, with high scores for ease of use, learnability, and overall satisfaction. The moderate scores for navigation and error recovery suggest areas for improvement in the app's interface design. Physicians appreciated the ease of implementation and overall satisfaction with the app, though they indicated a need for further improvement in clinical efficiency. These insights highlight the importance of continuous refinement and user feedback in developing effective mHealth applications. [Additional information and details on the usability and satisfaction results are available in Appendix D]

The high satisfaction scores for ease of use and learnability emphasize the critical role that wellness tools can play in enhancing patient engagement. By providing real-time access to health insights through an easy-to-use interface, the salivary testing device and mHealth app empower patients to take an active role in their health maintenance, improving adherence to preventive care strategies. This level of engagement is essential in promoting general wellness and preventing more serious health conditions from developing.

mHealth App Usability Questionnaire (MAUQ)

Key Findings:

- **Overall:** The average total score for the MAUQ across all sites was 5.5, indicating a generally positive user experience.
- **Ease of Use:** The app was generally easy to use, with a score of 5.3 on average across sites.
- **Learnability:** Users found it easy to learn how to use the app, with a high score of 6.

- **Navigation:** Navigation consistency was rated slightly lower, with an average score of 5.
- **Functionality:** Users felt the app's interface allowed them to utilize all functions effectively, scoring 5.7.
- **Error Recovery:** The ability to recover from mistakes was also highly rated at 5.7.
- **Satisfaction:** Overall satisfaction with the app was high, with an average score of 6.

Physician Satisfaction Survey Ease of Implementation Subscale

Key Findings:

- **Overall Satisfaction:** Physicians were generally satisfied with the salivary testing kit and mHealth application, with an average score of 4.3.
- **Ease of Implementation:** The ease of integrating the app into daily operations was rated at 4.
- **Improvement in Clinical Efficiency:** The perceived improvement in clinical efficiency was rated at 3.3, indicating room for improvement.
- **Alignment with Clinical Care:** The alignment of the app's process and results with clinical care was rated at 4.

Overall, the pilot study demonstrated the potential of mHealth applications to enhance healthcare delivery in rural and underserved areas. With strategic enhancements based on user feedback, these technologies can significantly improve access to care, patient engagement, and clinical outcomes.

mHealth Application: Challenges and Lessons from the Pilot Study

In the pilot study conducted in rural West Virginia, several challenges related to the use of mHealth applications were identified, which are common in real-world implementations:

- **Technology Issues:**
 - *Login Issues:* Early participants experienced difficulties with social media logins, which affected their ability to access the app consistently. Initially, the pilot team attempted to isolate the study by using a TestFlight app; however, they found it more effective to utilize the production app available in the app store. By tagging participants through test card numbers within the production app, the team streamlined the app download process and mitigated login issues, allowing for a more seamless experience. Simplifying the login process and providing alternative login options further mitigated this problem early, enabling a smoother user experience after the first round of use.
 - *Reliable Wi-Fi:* The lack of reliable internet connectivity in rural areas posed a challenge more for mobile clinic operations than other types of care delivery. Ensuring offline functionality or minimal data requirements can help improve usability in such settings. Additionally, developing a robust data caching system can ensure that critical information is accessible even when connectivity is temporarily lost.
- **Training and Support:**
 - *Training Needs:* Initial synchronous or asynchronous training sessions were essential not only to ensure adherence to IRB protocols for the pilot study but also to equip users with the necessary skills and knowledge for successful implementation in any setting. These trainings are crucial for maintaining the integrity of the process and ensuring that users can effectively operate the device and application. Beyond the pilot, providing comprehensive user manuals and video tutorials can further support diverse learning preferences and enhance overall user competency, making the technology accessible and effective for broader use.
 - *Ongoing Troubleshooting:* Continuous technical support was essential during the beta phase testing to address app functionality issues and ensure smooth piloting. To support long-term success beyond the study, establishing a dedicated support team and creating comprehensive troubleshooting guides will be crucial. This ongoing support will provide timely assistance to users and maintain app performance, ensuring sustained effectiveness and user satisfaction as the technology is scaled and integrated into broader healthcare settings.
 - *Educational Development:* There is a pressing need for enhanced education and curriculum development in educational institutions to better prepare the future workforce. Integrating training on newer technology applications into healthcare education programs will equip future professionals with the knowledge and skills required to effectively utilize these technologies. Additionally, offering Continuing Medical Education (CME) and Continuing Dental Education (CDE) opportunities for existing workforce members will encourage the adoption of these new technologies, ensuring that current professionals remain proficient and adaptable. This dual approach will foster a more skilled and responsive healthcare workforce, capable of meeting evolving industry demands.
- **User Engagement:**
 - *Engaging Users:* Personalized content, regular updates, and interactive features are essential for maintaining user interest and engagement. This can be achieved through personalized health insights, gamification elements, and regular notifications. Additionally, incorporating user feedback mechanisms, such as surveys or in-app rating systems, can help continuously improve the app based on user preferences and needs.
 - *Improving Provider & Care Team Satisfaction:* To further streamline the integration process, it is essential to develop a more intuitive onboarding procedure and provide detailed step-by-step guides tailored specifically

for healthcare providers. Simplifying the setup process can significantly reduce the initial learning curve. Additionally, developing customizable features that allow providers to tailor the app to their specific clinical practices can improve alignment with day-to-day operations. Regular updates based on clinical feedback should be implemented to ensure the app evolves in line with providers' needs.

- *Enhancing Information Sharing and Accessibility:* To address challenges related to sharing information from the app, it is important to streamline the process of sending data directly from the app to patients or care teams. Simplifying the steps needed to download, share, or print reports directly from a smartphone can enhance user experience. Ensuring compatibility with various communication platforms and integrating easy-to-use sharing options will reduce friction in utilizing the app's features, thereby improving both patient satisfaction and provider efficiency.

Conclusion

The integration of salivary testing and mHealth apps in this program adheres to FDA guidelines for general wellness devices. By focusing on the role of these technologies in promoting general health and wellness, the program underscores the potential to enhance patient outcomes without making claims about specific disease diagnoses. This adherence ensures the safety and regulatory compliance of the technologies used while advancing public health goals.

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APPENDIX A: Piloting Processes

The pilot program conducted under the West Virginia Oral Health Technology Initiative focused on utilizing innovative tools to improve oral health in underserved rural communities. This initiative integrated point-of-care salivary testing with a smartphone-based mHealth app to assess and manage oral health risks. The salivary testing device used in the pilot was from Oral Genome, Corp (Carlsbad, CA), while the mHealth app was provided by Harmony Health (Weirton, WV), utilizing Apple and Google Test Flight platforms and app version 1.0.1. The study aimed to enhance access to care, increase patient engagement, and evaluate the effectiveness of new technologies in a rural healthcare setting.

Agreement with Clinical Findings

An essential component of the West Virginia Oral Health Technology Initiative is the integration of clinical diagnosis logs from the pilot sites. These logs will play a pivotal role in capturing and comparing the clinical findings and diagnoses of dental professionals with the results provided by the Novel salivary point-of-care, multiple assay test salivary testing device. This comparison aims to validate the accuracy and reliability of the salivary test in a real-world clinical setting. The comparison between salivary test results and clinical findings is used to assess the consistency of wellness indicators with clinical outcomes, rather than to diagnose conditions.

It is important to highlight that while the salivary test results provide valuable insights into health and wellness, the device itself is not intended to diagnose specific diseases. As per FDA guidelines, this device falls under the general wellness category, and its intended use is to support a healthy lifestyle and promote oral and systemic wellness. The clinical diagnosis logs serve to compare health trends and wellness indicators, rather than confirm or establish medical and/or dental diagnoses.

The clinical diagnosis logs document detailed observations and diagnoses made by dental professionals during patient visits. These records will include assessments of oral health conditions such as caries, periodontal disease, and signs of systemic conditions like diabetes. By systematically logging these clinical evaluations, the pilot sites will establish a comprehensive dataset to determine the alignment of the wellness reports to the clinical finding. Additionally, the validated tools, MAUQ and Physicians Satisfaction Surveys provide information on how well the device and mHealth app supported the dental care encounter and patient examination process.

The primary goal is to assess the concordance between the clinical diagnoses and the salivary test outcomes. High agreement rates would indicate that the salivary testing device provides results that are consistent with professional clinical assessments. While the salivary test results are compared to clinical findings, this process is focused on validating the consistency of wellness insights rather than confirming disease diagnoses. The device is intended to support general wellness, not to serve as a diagnostic tool.

Validation and Continuous Improvement

By leveraging clinical diagnosis logs, the pilot program aimed to achieve several key objectives:

- Validation of Wellness Device Findings & Reporting:** Ensure that the salivary testing device accurately aligns with the clinical conditions diagnosed by dental professionals. This validation is crucial for establishing the test as a reliable point-of-care tool, incorporating real-world clinical data into iterative updates of the test algorithms. The continuous improvement process in this pilot program adheres to the standards for general wellness devices, ensuring that updates to the test algorithm and user experience are focused on enhancing the overall wellness of users. These improvements are designed to provide clearer health indicators that align with general wellness goals, such as encouraging healthier behaviors and early interventions in support of overall well-being, without attempting to diagnose or treat specific conditions.
- Identification of Discrepancies:** Highlight any inconsistencies between the clinical diagnoses and salivary test results. Understanding these discrepancies will provide insights into the test's limitations and areas that may require further refinement.
- Enhancement of Evaluation Processes:** Use the data collected to refine both the salivary test and clinical utilization processes. Continuous feedback from clinical diagnosis logs will facilitate ongoing improvements, ensuring the test remains relevant and accurate in diverse clinical settings.

4. **Building Confidence among Practitioners:** Demonstrating high concordance between clinical findings and wellness results will build confidence among dental practitioners in using the salivary test as part of routine diagnostic and preventive care practices.
5. **Patient Empowerment:** In addition to practitioner confidence, patient empowerment is a core focus of this general wellness device. The salivary test results, when paired with patient-facing mHealth apps, provide accessible wellness insights that patients can use to better understand their health trends, leading to more informed decisions regarding oral hygiene and lifestyle changes. This engagement is critical in promoting long-term wellness without the need for clinical intervention in every case.

Progress and Compliance

The project team has completed the Institutional Review Board (IRB) submission to Sterling IRB, ensuring ethical compliance and oversight. This initiative represents a significant step forward in leveraging technology to bridge gaps in oral health care access and improve health outcomes for rural populations. The collaboration between Harmony Health Foundation, ITHC, and the West Virginia Oral Health Coalition is poised to create a scalable and sustainable model for preventive dental care.

The collection and analysis of wellness data adheres to all applicable patient privacy standards, including HIPAA, ensuring that the handling of personal health information is secure and compliant with federal regulations.

The multiple assays, point-of-care, salivary testing device used in this program strictly adheres to FDA general wellness device guidelines, providing non-diagnostic health insights to encourage preventive actions and support healthier lifestyles. Licensed healthcare providers use the wellness data generated by the device to support their holistic care plans and guide discussions with patients about preventive strategies and lifestyle adjustments. Biomarkers provide non-diagnostic insights into an individual's general oral health. These wellness indicators are used to guide preventive strategies and support healthier lifestyle choices, but they are not intended for diagnosing or confirming specific medical conditions.

The sensitivity and specificity metrics of the salivary test were analyzed to assess the consistency and reliability of the wellness insights provided, ensuring that the device supports preventive health measures rather than serving as a diagnostic tool.

Limitations

Despite promising findings, this study has several limitations. The small sample size of 79 participants may not fully represent the broader population, impacting the statistical power and generalizability of the results. Future studies should include larger sample sizes to enhance the robustness and applicability of the findings.

The focus on underserved rural areas may limit the generalizability to urban or more diverse populations. Healthcare access, socioeconomic status, and health behaviors in rural areas can differ significantly from urban settings. Therefore, the cost savings and health outcomes observed may not directly apply to other populations. Future research should include more diverse samples to better understand the applicability across different demographics and geographic locations.

There is potential for selection bias, as participants and care teams in the pilot may differ systematically from those who did not participate, potentially skewing the results.

Cost savings estimates are based on averages and assumptions from the literature, which may not fully capture the variability of healthcare costs and outcomes. Additionally, the short follow-up period limits the ability to assess long-term outcomes and cost savings. We were not able to assess the completion of preventive or minimally invasive interventions, such as SDF application, fluoride varnish, or scaling and prophylaxis, which may have helped mitigate disease and restore oral health. It would also be valuable to compare the uptake of preventive interventions following saliva testing and mHealth app utilization with those who received traditional oral health screening and in-person counseling. Future research should incorporate longer follow-up periods and consider these comparisons to evaluate the sustained impact of early detection and preventive interventions on long-term health outcomes and cost savings.

The study served as a beta test for refining the test kit and mHealth application, with several updates and ongoing training implemented throughout the study. This introduced variability in the testing environment, potentially

impacting the results. Improvements in test performance over time could be attributed to increased familiarity with the app rather than true enhancements in accuracy.

Lastly, some aspects of the study relied on self-reported data from participants, such as oral hygiene practices and dietary habits, which are subject to recall bias and social desirability bias. Addressing these limitations in future research will help improve the reliability and validity of the point-of-care salivary test kit and its associated mHealth application, ultimately leading to better oral health outcomes for diverse populations.

APPENDIX B: Correlation Matrix of Biomarkers and Wellness Scores

Correlation Matrix of Biomarkers and Risk Scores



*The figure above presents a comprehensive comparison of average biomarker levels and risk scores across the three sites (SITE 1, SITE 2, and SITE 3). Each subplot illustrates a specific biomarker or risk score, offering a detailed view of the health and wellness profiles for each location. This matrix integrates biomarker data, such as salivary pH and glucose levels, with risk assessments from surveys like the American Dental Association (ADA) Risk Assessment and the American Diabetes Association (ADA) Diabetes Risk Assessment. By combining these wellness indicators, the matrix provides insights into the overall health trends at each site, supporting the use of these technologies as tools for promoting general wellness and preventive care.

Comprehensive Overview of Biomarker Levels and Wellness Scores by Site

The biomarker data collected from the salivary tests offer valuable insights into overall health and wellness trends. These biomarkers serve as indicators of oral and systemic health, which can prompt lifestyle adjustments aimed at promoting general well-being. Importantly, these biomarkers are not intended to serve as clinical diagnostic tools but rather as part of a wellness framework that empowers patients and providers to manage health proactively.

Key Insights:

Each biomarker assessed in this pilot, from salivary pH to MMP-8 levels, provides a snapshot of the patient's overall wellness and highlights areas where preventive health measures can be applied. For instance, lower buffering capacity may indicate an increased risk for demineralization, signaling a need for dietary modifications or enhanced oral hygiene practices. These indicators are instrumental in helping patients and providers collaboratively manage wellness but should not be interpreted as standalone diagnostic results for specific conditions. Each biomarker assessed in this pilot, from salivary pH to MMP-8 levels, provides insights into wellness trends that suggest potential areas for lifestyle improvements. These biomarkers are not intended for clinical diagnosis, but rather to inform general wellness and support preventive health behaviors.

1. Glucose Levels:

- **Health Department:** Moderate levels.
- **Rural Community Health Center:** Highest average levels, indicating a higher risk for conditions like diabetes and dental caries.
- **Free Mobile Dental Clinic:** Lower levels compared to the Rural Community Health Center, but still elevated.

2. Buffering Capacity:

- **Health Department:** Highest buffering capacity, indicating better protection against dental caries.
- **Rural Community Health Center:** Significantly lower buffering capacity, suggesting a higher risk for demineralization of teeth.
- **Free Mobile Dental Clinic:** Moderate buffering capacity, better than the Rural Community Health Center but lower than the Health Department.

3. pH Levels:

- **Health Department:** Highest pH levels, indicating a less acidic environment favorable for oral health.
- **Rural Community Health Center:** Lowest pH levels, indicating a more acidic environment that favors cariogenic bacteria growth.
- **Free Mobile Dental Clinic:** Moderate pH levels, better than the Rural Community Health Center but lower than the Health Department.

4. Nitric Oxide Levels:

- **Health Department:** Highest levels, associated with a strong immune response.
- **Rural Community Health Center:** Lowest levels, suggesting a compromised immune response.
- **Free Mobile Dental Clinic:** Moderate levels, better than the Rural Community Health Center but lower than the Health Department.

5. MMP-8 Levels:

- **Health Department:** Lowest levels, indicating lower periodontal disease risk attributes.
- **Rural Community Health Center:** Highest levels, correlating with elevated risk of developing periodontal disease.
- **Free Mobile Dental Clinic:** Moderate levels, better than the Rural Community Health Center but higher than the Health Department.

6. P. gingivalis Levels:

- **Health Department:** Lowest levels, indicating lower periodontal disease risk.
- **Rural Community Health Center:** Highest levels, correlating with elevated risk of periodontal disease.
- **Free Mobile Dental Clinic:** Moderate levels, better than the Rural Community Health Center but higher than the Health Department.

7. Risk Scores:

- **Health Department:** Lowest average risk scores, indicating lower overall health risk.
- **Rural Community Health Center:** Highest average risk scores, indicating the highest overall wellness risk.
- **Free Mobile Dental Clinic:** Moderate risk scores, better than the Rural Community Health Center but higher than the Health Department.

The risk scores derived from biomarker analysis are designed to help identify wellness trends and areas where preventive care might be beneficial. These scores are not a replacement for clinical diagnosis but rather a tool that can enhance patient engagement in wellness practices, guiding healthier lifestyle choices to support oral and systemic health.

Considerations

Based on these insights, specific recommendations for each site include:

- **Health Department:**
 - Maintain current health practices and continue regular monitoring.
 - Focus on preventive care to sustain low risk levels.
 - **Rural Community Health Center:**
 - Implement intensive interventions to reduce glucose levels and improve buffering capacity.
 - Enhance education on oral hygiene and dietary practices.
 - Increase frequency of dental check-ups and professional cleanings.
 - Strengthen immune response through targeted health programs.
 - **Free Mobile Dental Clinic:**
 - Improve buffering capacity and pH levels through dietary adjustments and fluoride treatments.
 - Provide additional support for periodontal health, including antimicrobial treatments.
 - Monitor and manage glucose levels to prevent systemic health issues.
-

APPENDIX C: Cost Savings - Methods and Analysis

Cost Effectiveness and Savings Analysis:

The data analysis focused on evaluating the costs associated with untreated caries, periodontal disease, and diabetes. Economic benefits were calculated based on cost savings from early detection of wellness indicators, prevention, and effective interventions. The economic benefits of the salivary testing and mHealth tools in this pilot program are centered around the promotion of general health and wellness. By providing early wellness insights, these tools encourage preventive actions that help reduce the risk of developing more serious oral and systemic health conditions. As a general wellness device, the salivary test facilitates early intervention based on wellness data, which contributes to lower healthcare utilization and cost savings without functioning as a diagnostic tool.

- **Descriptive Statistics:** Descriptive statistics were used to summarize demographic characteristics and test results. For example, Hirsch et al. (2012) utilized descriptive statistics to model effective interventions in early childhood caries, providing a clear summary of population characteristics and intervention impacts. In our study, descriptive statistics provided a simple summary of the sample and measures, including the mean, median, mode, and standard deviation.
- **T-Tests:** T-tests were utilized to compare the means of cost savings between groups with and without early detection. Edelstein et al. (2012) applied T-tests in their simulation model to compare the costs associated with different preventive interventions for early childhood caries. Similarly, our study used T-tests to determine if there was a significant difference between the means of cost savings in patients who received early intervention based indicators for oral disease.
- **Chi-Square Tests:** Chi-square tests were used to analyze categorical variables such as the presence of diseases. Nasseh et al. (2014) employed chi-square tests to analyze the association between chronic disease screenings and healthcare costs. In our analysis, chi-square tests were used to assess whether the presence of caries, periodontal disease, or diabetes was significantly associated with the outcomes of the salivary tests.
- **Linear Regression:** Linear regression analysis was conducted to assess the alignment of the inclusion of a multiple assay point-of-care salivary testing device and mHealth app during a dental encounter and the possibility of finding undiagnosed diabetes. This method has been previously utilized in studies such as that by Gupta et al. (2017), which used linear regression to evaluate the correlation between salivary glucose levels and blood glucose levels. Our study utilized linear regression to evaluate the strength and direction of the relationship between salivary glucose wellness reports and the identification of undiagnosed diabetes, providing valuable insights into the potential of salivary testing with mHealth applications to engage patients with possible wellness indicators associated with diabetes.

Cost Savings Summary Table:

The cost savings are estimates based on literature (*Cost Savings Summary Table*) and are subject to the limitations of the pilot's sample size and population characteristics. The long-term economic impact of integrating wellness data into healthcare decision-making is significant. While this pilot program demonstrated immediate cost savings through

reduced healthcare utilization, the sustained use of wellness-driven tools like the salivary test has the potential to generate even greater economic benefits over time. By emphasizing health maintenance and wellness behaviors, healthcare systems can reduce the incidence of advanced disease states, leading to lower overall healthcare costs and improved population health.

Author	Year	Description of Cost Savings	Range of Cost Savings
Nasseh & Vujicic	2014	Chairside screenings reduced overall healthcare costs	\$300 - \$1,200 per patient
Edelstein et al.	2012	Simulation model for early childhood caries interventions	\$500 - \$1,000 per incident
Vernazza et al.	2021	Economic perspectives on reorienting oral health services	\$800 - \$2,000 annually
CareQuest Institute	2024	Periodontal treatment decreased diabetes costs	\$8,000 - \$10,000 per patient
Casamassimo et al.	2009	Economic impact of early childhood caries prevention	\$500 - \$1,500 per patient
Karter et al.	2009	Economic impact of out-of-pocket costs for diabetes prevention	\$7,000 - \$15,000 per patient
Nasseh et al.	2014	The effect of chronic disease screenings on healthcare costs	\$500 - \$1,200 per patient
Anopa & Conway	2020	Cost-effectiveness of interventions for early childhood caries	\$500 - \$1,500 per incident
O'Neill et al.	2017	Cost-effectiveness of caries prevention in practice	\$500 - \$1,200 per patient
Hirsch et al.	2012	Simulation model for ECC interventions in Colorado	\$500 - \$1,500 per patient
Casamassimo, Thikkurissy, et al	2009	Economic impact of early childhood caries prevention	\$500 - \$1,500 per patient

Discussion: Cost Savings

The pilot program's results underscore the value of integrating salivary-based wellness devices into routine healthcare. The high sensitivity and specificity of the Novel salivary point-of-care, multiple assay test device ensures accurate and timely identification of oral and systemic diseases, enabling early intervention and significant cost savings. The low incidence of false results further enhances its reliability, making it a viable option for widespread adoption in diverse clinical settings.

Diabetes Cost Savings:

Our findings on cost savings from early diabetic wellness indicators align with other studies that have demonstrated significant healthcare cost reductions through early monitoring and management of diabetes. In the pilot program, cases of diabetes were estimated based on diabetes risk assessments and elevated salivary glucose readings along with the use of the American Diabetes Association Diabetes Risk Survey. It is important to emphasize that the salivary test is not intended to diagnose specific conditions. It is important to note that these estimates are speculative, as the pilot process did not confirm diagnoses with a medical provider. Despite this limitation, the projected cost savings are noteworthy. For instance, a study by the CareQuest Institute (2024) indicated that early detection and treatment of

diabetes can save between \$8,000 and \$10,000 per patient annually by preventing severe complications such as neuropathy, retinopathy, and cardiovascular diseases. Similarly, Karter et al. (2009) highlighted the economic impact of out-of-pocket costs for diabetes preventive services, estimating savings of \$7,000 to \$15,000 per patient annually through early intervention. These savings are primarily attributed to the reduced need for extensive medical treatments and hospitalizations, as well as improved quality of life for patients. Therefore, while the estimates from our pilot program should be interpreted with caution, they suggest a substantial economic benefit from the findings of early diabetic trends and intervention using health and wellness findings and holistic treatment regimes. The cost savings projected from the pilot are grounded in the ability of the device to provide wellness insights that promote early preventive actions, supporting healthier behaviors and reducing the need for more intensive interventions. These savings are derived from the proactive health management encouraged by the device, rather than any diagnostic or treatment function.

Preventive care driven by wellness data plays a crucial role in the economic benefits seen in this pilot program. By empowering patients to make informed health choices, the use of salivary biomarkers as wellness indicators supports early intervention efforts that mitigate the progression of conditions like periodontal disease and caries, which can result in substantial cost savings. This cost reduction is achieved by fostering health-conscious behaviors and promoting preventive measures, rather than by diagnosing or treating disease directly.

Caries Cost Savings:

The economic benefits of early detection and prevention of dental caries are well-documented. Our estimated savings of \$500 per patient annually are consistent with findings from other research. Edelstein et al. (2012) demonstrated that preventive measures for early childhood caries could save \$500 to \$1,000 per incident by reducing the need for fillings, root canals, and extractions. Additionally, O'Neill et al. (2017) reported similar cost-effectiveness in caries prevention, emphasizing the reduced need for restorative dental procedures when early interventions are applied.

Periodontal Disease Cost Savings:

Preventive care and early treatment for periodontal disease can significantly lower healthcare costs by avoiding advanced periodontal therapies. Our estimate of \$1,200 per patient annually is supported by Vernazza et al. (2021), who found that reorienting oral health services towards prevention and effective periodontal diseases maintenance interventions, could save \$800 to \$2,000 annually per patient by reducing the need for intensive treatments such as scaling and root planing, and periodontal surgery. Anopa and Conway (2020) further corroborated these findings, highlighting the cost-effectiveness of early interventions in periodontal disease management.

Role of Salivary Testing in Disease Identification:

Salivary testing has emerged as a non-invasive, cost-effective method for identifying early findings associated with wellness indicators of various diseases. The ability of salivary tests to accurately measure biomarkers such as glucose, proteins, and inflammatory markers like MMP8 and *P. gingivalis* has revolutionized disease identification and management. In our study, the Novel salivary point-of-care, multiple assay test device demonstrated high sensitivity and specificity in detecting oral and systemic diseases, aligning with the findings of Arunkumar et al. (2014), who emphasized the potential of salivary testing in improving patient outcomes through earlier prevention or interventions and impacting general wellness. Furthermore, Dawes and Wong (2019) highlighted the utility of salivary pH measurements in assessing periodontal disease risk, reinforcing the relevance of our findings.

APPENDIX D – Usability and Satisfaction Surveys

The usability and satisfaction survey results reflect the role of the salivary testing device and mHealth app as tools that promote health and wellness. These technologies are designed to provide accessible wellness insights, enhancing the user experience by empowering patients and providers to monitor health trends and engage in preventive care. The

Pilot Site Results

Question	Site 1	Site 2	Site 3	Average Mean Score
1.	4	6	6	5.3
2.	5	7	6	6
3.	3	7	5	5
4.	4	7	6	5.7
5.	3	7	7	5.7
6.	4	7	5	5.3
7.	5	4	5	4.7
8.	4	6	6	5.3
9.	4	7	5	5.3
10.	7	7	7	7
11.	7	7	7	7
12.	5	7	6	6
13.	6	5	6	5.7
14.	6	6	6	6
15.	5	4	6	5
16.	4	5	5	4.7
17.	1	6	5	4
18.	4	6	6	5.3
Total Average Mean Score	4.5	6.2	5.8	5.5 STD DEV 1.31

Modified Physician Satisfaction Survey - Ease of Implementation Subscale

- Overall, how satisfied are you with the salivary testing kit accompanying mHealth application? 1 Very dissatisfied 2 Somewhat dissatisfied 3 Neither satisfied nor dissatisfied 4 Somewhat satisfied 5 Very satisfied
- Overall, how easy was the device and mHealth application to implement into your day-to-day operations? 5 Very easy 4 Somewhat easy 3 Neither easy or difficult 2 Somewhat difficult 1 Very difficult
- Overall, how satisfied are you with the implementation of the salivary testing kit accompanying mHealth application into your day-to-day care of patients? 1 Very dissatisfied 2 Somewhat dissatisfied 3 Neither satisfied nor dissatisfied 4 Somewhat satisfied 5 Very satisfied 6 Not applicable
- Overall, how would you rate the improvement in clinical efficiency once the salivary kit and mHealth application was implemented into practice? 5 Outstanding improvement 4 Some improvement 3 Neutral 2 Some disruption 1 A very high level of disruption

5. Overall, did the process, findings and results of the technologies align with your clinical care and diagnosis process? 5 Very high alignment improvement 4 High alignment 3 Neutral 2 Some disagreement 1 Very high disagreement

Pilot Site Results

Question	Site 1	Site 2	Site 3	Average Mean Score
1.	4	5	4	4.3
2.	4	4	4	4
3.	4	5	5	4.7
4.	3	3	4	3.3
5.	4	4	4	4
Total Average Mean Score	3.8	4.2	4.2	4.1 STD DEV 0.59