Skin Cancer Risk Identification Screening in Primary Care

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Abstract

Problem: Melanoma is a prevalent issue within Baltimore County, and despite recommendations for annual screenings for skin cancer, guidelines are not consistently adhered. Within a primary care practice in Baltimore County, Maryland, risk identification screening is not being performed until the patients present with a suspicious presentation or specific dermatologic complaint. Screening to identify high-risk patients allows for targeted prevention and treatment interventions. **Purpose:** The purpose of this quality improvement project is to implement risk identification screening via the Self-Assessment of Melanoma Risk Score (SAMScore) to identify patients at high risk of developing skin cancer. **Methods:** Medical assistants (MA's) utilized the SAMScore to assess patients' level of risk for developing skin cancer. Results of the SAMScore were recorded in the electronic medical record. The clinician then referred patients identified as high-risk via the SAMScore screening to a dermatologist for a skin examination and annual surveillance. **Results:** A total of 401 patients were screened with the SAMScore. A total of 269 (67.1%) were identified as low risk with 132 (32.9%) identified as high risk. Of the 132 patients identified as high-risk, 104 (78.8%) were referred to dermatology for further evaluation. **Conclusions:** Findings indicate that the use of a skin cancer risk identification tool is a feasible and effective means to identify patients at high risk within primary care settings. Maintaining screening compliance by patients and clinicians proved to be the primary challenge and future quality improvement projects should target this barrier to implementation.

Skin Cancer Risk Identification Screening in Primary Care

Problem Description

Over 100,000 new cases of skin cancer were diagnosed in 2021 in the United States leading to over 7,000 deaths (American Cancer Society, 2021). Affecting one in five Americans by the age of 70, skin cancer is more common than all other cancers combined (Skin Cancer Foundation, 2022). This condition disproportionately affects the older adult population, with most new diagnoses of both cutaneous melanoma and non-melanoma skin cancers being found in patients over the age of 65 (Garcovich et al., 2017). Between 2012 and 2016, Baltimore County comprised 1,463 of the 7,590 melanoma cases seen in the state of Maryland, an astounding 18% of the state's total cases and the largest number seen in any county within the state (Maryland Department of Health, 2019). The Skin Cancer Foundation formally recommends at least annual dermatologic screenings with those who have been identified as being high risk for the development of skin cancer based on a variety of genetic and environmental risk factors (2019). Despite this recommendation, not all primary care practices are utilizing standardized risk identification to determine which patients are at greatest risk.

Primary care practices across the country are not adequately identifying patients at high risk of developing skin cancer, with national statistics indicating that only 8% of patients in primary care receive a skin examination at their annual visit (Johnson et al., 2017). Time constraints, lack of confidence in their abilities, and lack of training are cited by clinicians as contributing factors (Johnson et al., 2017). Improvements in patient care can be seen by screening to identify high risk patients, which can facilitate interventions when and if skin cancer is identified. The cost of failing to act comes at the expense of patient health and well-being as well as the burden it places on the health care system. In the United States, skin cancer treatment

cost is estimated at over eight billion dollars, with approximately five billion being directly tied to non-melanoma skin cancers (Skin Cancer Foundation, 2019). Late detection and delayed treatment of melanoma that has spread to distant organs has a five-year survival rate of just 27% (American Academy of Dermatology Association, 2021).

This problem was identified in a primary care practice in Baltimore County, Maryland which manages approximately 5,000 patients. Patients are not being screened for skin cancer until they present with a suspicious presentation or specific dermatologic complaint. Prior to this project's implementation period, risk identification screening was not being performed for any of the patients at this practice. Primary root causes of suboptimal risk identification include time constraints in a busy primary care office, and the lack of a risk identification screening in the electronic medical record. These factors are discussed in more detail in the fishbone diagram (Figure 1).

Specific Aims & Available Knowledge

The Journal of American Medicine Dermatology recognizes that screening to identify high-risk patients can be used to sort patients into risk categories that allow for targeted prevention and treatment interventions (Vuong et al., 2016). Targeted screening is more time efficient and sensitive when managing patients, as opposed to the limited evidence surrounding full skin exams and surveillance on all patients (Wernli et al., 2020). The Self-Assessment of Melanoma Risk Score (SAMScore) is an evidence-based screening tool used to identify patients at elevated risk for developing skin cancer. A conducted evidence synthesis, found in Table 1, discusses the SAMScore as a valid, effective, and efficient tool that allows the care team to make appropriate interventions for patients who are at a greater risk of developing skin cancer (Rat et al., 2014). Identifying patients at high risk utilizing the SAMScore allows for further surveillance

while proving the efficacy of targeted screening and risk stratification. When the SAMScore is utilized to risk stratify patients, providers can, “screen 11 times fewer patients than with a nontargeted screening”, demonstrating the efficacy and efficiency of the tool (Quéreux et al., 2012). By implementing the SAMScore, the provider can identify patients at risk for the development of skin cancer and make the appropriate referrals to monitor patients and intervene early, thus improving patient prognoses and outcomes. The purpose of this project is to implement risk identification screening via the SAMScore to identify patients at high risk of developing skin cancer. The primary process goals include changing the current practices of the medical assistants and the provider. The medical assistants will screen every patient using the SAMScore and communicate this score to the provider. The provider will review the results of the SAMScore and make dermatology referrals for a skin assessment as needed. Outcome goals include having 100% of patients screened using the SAMScore, and 100% who are deemed high risk being referred to dermatology for further evaluation and surveillance.

Rationale and Framework

The Promoting Action in Research Implementation in Health Services framework (PARiHS) (Figure 2) will be used to guide the planning and implementation of the primary intervention (Kitson, Harvey, & McCormack, 1998). The PARiHS framework hypothesizes that implementing research into practice is complex and inherently non-linear requiring flexibility, multiple elements, and responsiveness (Bergstrom et al., 2020). The first element of this framework involves reviewing the evidence, which was accomplished through a literature review surrounding risk identification screening and compiling data surrounding the efficacy of the SAMScore (refer to Table 1 for comprehensive evidence synthesis). This helps transition the project into focusing on the next element, context. The context in which this intervention is being

approached includes strong leadership and support for change from the primary clinician and practice owner. Further context also includes a culture of wanting to benefit patients through new and different approaches. The context allowed for successful facilitation of the project, the final component of the framework. With integration of the SAMScore into the electronic medical record, as well as clearly defined roles for medical assistants and the provider in relation to engaging with the SAMScore, staff have been able to fully utilize their skills to work towards this quality improvement. A thorough review of the current evidence, changing current practices, and identification of the context in which this project is approached, supported the successful implementation of this project.

Methods

Context

This project was implemented in a primary care office in Baltimore County with a patient panel of over 5,000 adult patients. The practice consists of one physician, an office manager, a team of five medical assistants, and an information technology staff member to aid in customizing and troubleshooting the office's proprietary electronic medical record. The medical assistants perform patient intakes via telephone approximately one hour before the patient is seen by the physician. The patient is then seen by the physician who reviews the updated electronic record and updates the plan of care upon concluding each patient visit. Following this, the office manager follows up and aids in possible referrals. No patients are currently being identified as high risk for the development of skin cancer due to the lack of risk stratification being performed. Greater detail surrounding current site procedures during patient visits can be visualized in Figure 3.

Current site structures include an electronic health record without a template in which to document a skin cancer risk assessment. Staffing is adequate to perform the implementation of the SAMScore as utilization of the score will be performed when medical assistant's complete patient intakes prior to their visit with the physician. The clinical staff also possess knowledge surrounding screening tools, as a depression screening tool is utilized on every patient. Time is a factor that must be considered when implementing this additional screening tool as it can increase time needed to check-in patients.

Intervention

The intervention includes utilizing the SAMScore to identify patients at high risk of developing skin cancer, resulting in referral to dermatology for further evaluation and surveillance. The SAMScore (Figure 1) was integrated into the electronic medical record to offer an ease of use for medical assistants who administered it as part of the patient intake. The medical assistants asked patients every component of the SAMScore, thus generating a score representing their overall skin cancer risk and recorded within the EMR. When the physician saw the patient for their visit, they had the ability to review the calculated SAMScore. Patients can be identified as high risk when they meet at least three risk factors out of the seven listed on the SAMScore; they are younger than 60 years of age with more than 20 melanocytic nevi on the arms; or they are older than 60 years of age with a freckling tendency (Quereux et al., 2020). Based on this criteria, if a patient was identified as high risk, the physician placed a referral to dermatology. The physician documented the referral in the patient's medical record, allowing the number of referrals to be tracked and monitored. When the patient left the clinic, the office manager ensured the referral was added to the check-out and orders section of the chart.

Pre-intervention education was conducted surrounding the benefits and utilization of the SAMScore. All clinical staff were trained regarding calculation of a score based on patient responses and how to utilize the SAMScore properly to determine risk level for each patient. This practice change was completed over a fifteen-week period.

Implementation strategies and tactics focused on accountability, collaboration, communication, and education. Formal written commitments were obtained from the physician and owner of the practice expressing interest in the proposed intervention and project. A site champion, the office manager, was identified to drive the implementation and overcome resistance, and one-to-one discussions were conducted to gain buy in from key stakeholders. All clinical staff were trained surrounding calculation of a SAMScore based on patient responses and how to utilize the SAMScore properly to determine risk level for each patient prior to the implementation period beginning. Staff has demonstrated success in utilizing the SAMScore. The EMR was updated to include the SAMScore during week one of implementation, and ongoing trainings were conducted during week four and week eight to ensure clinical staff were well versed and prepared to utilize the SAMScore effectively. Sustainability plans included discussing physician plans to continue utilizing the SAMScore during week six of the project. Assessing the impact of time and efficiency and adjusting as necessary was a central goal of this project throughout the implementation period to contribute to sustainability. The implementation of the SAMScore screening tool was analyzed by weekly chart audits. These audits included the collection of data pertaining to the number of patients seen within that week, the number of SAMScore screening tools completed, the number of patients who were deemed high risk, and if referrals were placed to a dermatologist. Analysis of daily SAMScores completed proved to be challenging due to high compliance and high patient volume. As a result, analysis of data was

reduced to two days of the week as opposed to five days a week as originally planned. This change occurred following the conclusion of the second week of the implementation period going into the third week of project implementation. By week six of the project, the primary provider and owner of the practice expressed the permanent addition of the SAMScore into the practice's clinical workflow due to the efficiency and sensitivity of the SAMScore as a screening tool as well as the successful integration of the SAMScore into the practice's EMR, deeming the sustainability component of the quality-improvement project a success.

Measures

A conducted evidence synthesis, found in Table 1, discusses the SAMScore as an effective, and efficient tool that allows the care team to make appropriate interventions for patients who are identified as being at greater risk of developing skin cancer (Rat et al., 2014). The measures chosen for studying the outcomes of this project implementation included one process goal and one outcome goal. Process and outcome measures were utilized to measure the efficacy of the project intervention. Process goals include screening 100% of patients with the SAMScore and accurately identifying their risk level for developing skin cancer. This was measured post-implementation by comparing the number of patients who completed medical intakes for their office visits compared to the number of patients who were screened with the SAMScore during medical intakes. The outcome goal for this project was that 100% of patients who were deemed high risk of developing skin cancer would be referred to dermatology for further evaluation and surveillance. The provider reviewed the results of the SAMScore and made appropriate referrals based on the results for high-risk patients. This was measured by reviewing the number of patients identified as high risk and determining if they received referrals to dermatology.

Ongoing assessment strategies included giving staff members the opportunity to voice concerns or issues surrounding the project during periodic training sessions regarding use of the SAMScore during the implementation period.

Study of the Intervention

Completed screening forms were audited with results recorded into REDCap every week on Mondays and Wednesdays by the DNP student. The number of completed SAMScore screenings were compared to the number of total patients seen on both screening days. During the initial project launch week, staff voiced a burden on their clinical workflow by recording the results of individual SAMScore screenings within the EMR and REDCap, a HIPAA compliant, password-secured program. As a result, staff began recording SAMScore screenings exclusively within the EMR, with the DNP student recording results into REDCap weekly during chart audits. All patients with identified risk levels for the development of skin cancer can be attributed to the intervention. All referrals made to a dermatologist secondary to a high risk-level for developing skin cancer can be attributed to the intervention.

Analytics

The implementation of the SAMScore screening tool was analyzed by chart audits every week. These audits included the collection of data pertaining to the number of patients seen, the number of SAMScore screening tools completed, the number of patients who were deemed high risk and if referrals were placed to a dermatologist. Risk stratification screening rates, high-risk patients identified from screening, and dermatology referral rates were then calculated as percentages to quantitively infer the change precipitated by implementing the use of the SAMScore from the total number of patients seen. This quantitative data was displayed using run charts and bar charts. Screening rates with the SAMScore were visually represented via run chart

(Figure 2), and referrals to dermatology placed compared to patients who were identified as high-risk can also be seen via run chart (Figure 3).

Change over time was represented by stable screening rates of patients and referral rates throughout the implementation period compared to 0% risk-identification of patient's pre-implementation period. Variation in data was observed and contributed to by a multitude of factors. Increased acuity and problem-based visits created variation in the utilization of the SAMScore due to the implementation period coinciding with peak flu and COVID-19 season. This increased the work burden on the clinicians due to the complex nature of acute visits, thus leading to the underutilization of the SAMScore because of time. Variability in time includes MA utilization of the SAMScore becoming more efficient as familiarity and use of the screening tool increases.

Ethical Considerations

Patient confidentiality including identifiers such as addresses and date of birth were strictly protected throughout this project and were not collected for any data analysis. The secure EMR was the only means in which private data was accessed. This project did not pose threat or harm to patients and all decisions were made regarding screening and referral with respect for patient autonomy and shared decision making between each patient and their primary care provider. Methods to protect patient privacy and data confidentiality included the recording of data and utilization of REDCap, a HIPAA compliant, password-secured program. Patient identifiers such as name were only present in the secure program and were not exported out of REDCap. All information was de-identified to maintain confidentiality. Analysis occurred within REDCap exclusively. Additionally, a non-human subject research determination was obtained through the Human Research Protections Office (HRPO) of the University of Maryland School of Medicine

(UMSOM) Institutional Review Board (IRB). There were no conflicts of interest throughout the project implementation.

Results

The first eight weeks of project implementation yielded daily screening and risk identification with the SAMScore. Due to the volume of patients seen daily, charts were only audited and data collected on Mondays and Wednesdays beginning week three of the implementation period. Patients were only seen on Wednesday during week six of the intervention due to the sole practice clinician being out of the office for the day. In total, seventeen days of data collection occurred during the implementation period. A total of 359 patients were seen during data collection days with an average of 21 patients seen on those days. In total, 221 patients were screened with the SAMScore resulting in a screening rate of 61.5%. Of the 221 patients screened, 139 (62.9%) were identified as being low risk for the development of skin cancer, with 82 (37.1%) being identified as high-risk for the development of skin cancer. Of the 82 patients identified as being high-risk, 65 patients were referred to dermatology for further evaluation and surveillance (79.2%).

Discussion

The structure goal for this project was that the SAMScore would be integrated into this practice's electronic medical record and workflow, this was achieved, with it now being utilized daily. The process goal for this project was that 100% of patients would be screened using the SAMScore, with a total of 61.5% of patients screened during the implementation period. The contributing barriers reported by the medical staff included time restraints during patient intake, acute visits with more urgent medical concerns, and frequent patient refusal to be screened.

Finally, the outcome goal of this project included referring 100% of patients who were identified as high-risk for the development of skin cancer to a dermatologist for further surveillance and evaluation. Due to more acute visits with urgent illnesses taking priority, medically complex patients, and shortages on time during each visit, 79.2% of high-risk patients were referred to dermatology. While the process and outcome goals were not achieved, the substantial improvement in risk-identification and referrals to dermatology has been considered a success for the quality-improvement project.

A detailed table of all frequencies and percentages can be found in Table 2. A run chart of the primary process goal examining the relationship between the number of patients eligible to be screened versus the number of patients screened with the SAMScore can be found in Figure 2. The primary outcome goal examining the relationship between the number of dermatology referrals placed compared to patients identified as high risk can be seen in Figure 3. This run chart demonstrates that a strong change has been made in outcomes with a strong relationship existing between the number of high-risk patients identified and the number of dermatology referrals placed.

Conclusion

Ultimately, the data collected and analyzed demonstrated a substantial increase in dermatology referrals placed as a direct result of the utilization of the SAMScore for risk identification from pre-intervention clinical practice. This finding coupled with the permanent integration of the SAMScore into the practice's EMR and clinical workflow affirms the efficacy of the screening tool and the success of the quality-improvement project.

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Table 1

Evidence Review and Synthesis

Citation: Rat, C., Quereux, G., Riviere, C., Clouet, S., Senand, R., Volteau, C., Dreno, B., & Nguyen, J.-M. (2014). Targeted melanoma prevention intervention: A cluster randomized controlled trial. *The Annals of Family Medicine*, *12*(1), 21–28. https://doi.org/10.13					**Level and Quality** **I-A**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to implement targeted interventions to increase early detection of melanoma	Research: a pilot clustered randomized control trial.	Sampling Technique: Convenience accepted: 470 patients who were being seen by 20 different general practitioners control:76 patients/229 patients (133 patients were excluded due to being deemed low-risk and 20 could not be contacted) intervention: 97 patients/241 patients (120 patients were excluded due to being deemed low-risk and 24 could not be contacted) Power analysis: Power analysis not conducted Group Homogeneity: Control and intervention groups appear	Intervention: In the intervention group, practitioners were able to enter the results of the Self-Assessment of Melanoma Risk Score (SAMScore), that patients had filled out themselves prior to the visit. The results entered into the calculator notified the practitioner of patients at an elevated risk of melanoma development. All patients at an elevated risk received a total skin examination, information leaflet, and preventative counseling. Intervention Fidelity: The investigators provided clear instructions and training to all providers surrounding how to utilize the SAMScore and	DV: The primary outcome was the increase in patients' knowledge regarding their risk for developing the disease based off their personal risk factors such as family history, sunbathing, and phenotype. Secondary outcomes include patients at elevated risk for melanoma performing self-skin examinations and asking their provider to monitor suspicious moles or lesions. DV measure: A telephone questionnaire based off the theory of planned behavior, recommendations of	Statistical Results: Compared with patients in the control group, those in the intervention group were more likely to correctly know that they had an elevated risk of melanoma (71.1% vs 42.1%, P= .001). Knowledge of risk factors was also significantly higher in the intervention group than in the control group. Intervention patients had higher levels of preventative behaviors such as less sunbathing in the summer (24.7% vs 40.8%, P=.048) and were more likely to perform self-skin examinations (52/6% vs 36.8%, P=.029). A two-tailed analysis was performed, and significance was set at .05. No stratification was planned, and results were analyzed with and without adjustment for other cofactors. Clinical Significance/Conclusions: The use of the SAMScore to identify high risk patients and performing targeted interventions has a larger impact than traditional preventative information campaigns and education. The use of the SAMScore provides practitioners the

		homogenous. Comorbidities, health conditions, age, and gender were comparable. P-values for characteristics were not significant.	appropriately interpret and score patients. Investigators ensured that all providers involved were trained and had a clear understanding regardless of being in the control group or not prior to implementation.	the World Health Organization, and questionnaire components adopted by the US National Cancer Institute and the Emory Prevention Center. Results were measured via a knowledge score. Use of a SAMScore was the primary measurement tool which assigned a risk classification to a patient surrounding their risk of developing skin cancer, which was validated by the team.	ability to perform tailored interventions and discuss specific risk factors individual to each patient while increasing patient knowledge surrounding their risks of developing melanoma.

Citation: Quéreux, G., N'Guyen, J.-M., Cary, M., Jumbou, O., Lequeux, Y., & Dréno, B. (2012). Validation of the self-assessment of melanoma risk score for a melanoma-targeted screening. *European Journal of Cancer Prevention, 21*(6), 588–595. https://doi.org/10.1097/	**Level and Quality III-A**

Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to assess the efficacy of targeted screening on the basis of the SAMScore. The primary objective is to prove that the SAMScore allows the selection of	A prospective cohort study.	Sampling Technique: Convenience eligible: 46 general practitioners in France agreed to participate and had all patients over the age of 18 fill out the SAMScore with a goal of approximately 200 patients per provider. accepted: 7953 patients were included with 24	Control: No control group Intervention: Utilization and completion of the SAMScore in primary care to identify high risk patients and presence of dermatological abnormalities following identification. Intervention fidelity: Patients 18 years and older	DV: The primary outcome was the identification of skin cancer including both melanoma and nonmelanomas. This outcome proves that the SAMScore is effective at selecting high risk patients. State the instrument, reliability, and	Statistical Results: Of the 2404 patients with a positive SAMScore, 0.74 patients with a melanoma were expected. Of those deemed high risk by the SAMScore, 10 melanomas were detected among 2404 patients. A logistic model with a random effect was used to include the clustered structure of data.

patients who are at a higher risk of melanoma development.		being excluded due to being under the age of 18. control: No control group identified intervention: 7953 patients completed the SAMScore and 2404 patients were classified as high risk as a result. Power analysis: Power analysis not conducted Group Homogeneity: The group did not display homogeneity as patients from the general French population filled out the SAMScore. All patients were over the age of 18 but ages, ethnicities, and comorbidities varied.	completed the SAMScore. General practitioners identified those who were deemed high risk according to SAMScore criteria and a skin assessment was conducted on those patients. Patients were then referred to a dermatologist for a dermatological skin assessment regardless of suspicious lesions identified, and those with suspicious lesions identified by dermatology were either biopsied or scheduled for follow-up and surveillance. The results of the intervention pathway was then classified by findings including those with: melanoma, nonmelanoma skin cancer, or benign lesions.	measurement procedure: The instrument used was the SAMScore. The efficiency of the SAMScore was defined as, “the ratio of melanoma prevalence in the population selected using the SAMScore to the melanoma prevalence in patients with a negative SAMScore, estimated as the prevalence in the general population” (Quereux et al., 2012)	The efficiency of the SAMScore as assessed as equal to 11.54 (P=0.0016). Clinical Significance In order to detect a new case of melanoma it would be necessary to screen 11.54 times more patients if the SAMScore was not used compared with a targeted screening on the basis of the SAMScore. This means the SAMScore is a cost-effective, and sensitive tool to utilize by clinicians when screening for skin cancer.

Citation: Wernli, K. J., Henrikson, N. B., Morrison, C. C., Nguyen, M., Pocobelli, G., & Blasi, P. R. (2016). Screening for skin cancer in adults: JAMA Patient Page. JAMA, 315(14), 1502. doi:10.1001/jama.2016.5415					Level and Quality III B
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this systematic review was to provide and analyze evidence for the US Preventive Services Task Force surrounding the benefit of clinical skin cancer screenings among adults.	Systematic Review	Search Strategy: MEDLINE, PubMed, and the Cochrane Central Register of Controlled Trials were searched for studies published from January 1st, 1995-June 1st, 2015 with surveillance through February 16th, 2016. eligible: English language studies with asymptomatic populations ages 15 and older at general risk for skin cancer. RCT's, observational studies, ecologic studies were included. Excluded: Screening studies were excluded if they focused on skin examinations in response to patient concerns about lesions. # accepted: 13 studies Power Analysis: Not applicable to SR	Control: Included studies with a control group consisting of no skin cancer screenings. Intervention: Included studies with various interventions including screening tests, efficacy of visual examinations, and early-detection of skin cancer. Protocol: Not applicable to the SR.	DV: primary outcomes included analyzing the efficacy of skin cancer screening, the harms of skin cancer screening, screening diagnostic accuracy, early detection, and morbidity/mortality. Multiple measurement tools were examined. One study launched a population-based screening intervention in 2003, another looked at excisions performed by dermatologists and the thickness of the detected cancer, while another used the number of total body skin examinations being performed as a primary measurement tool.	Statistical Results: "Between 1998 to 1999 (prescreening) and 2008 to 2009 (postscreening), age- and sex-adjusted melanoma mortality decreased by 48% in the intervention region, from 1.7 deaths (95% CI, 1.4-2.0) to 0.9 deaths (95% CI, 0.7-1.1) per 100 000 persons, representing an overall absolute mortality difference of 0.8 melanoma deaths per 100 000 persons" (Wernli et al., 2016). "Tumor thickness greater than 4.0 mm was associated with increased melanoma mortality compared with thinner lesions in multivariable-adjusted models (hazard ratios [HRs] ranging from 3.17; 95% CI, 2.56-3.92, to 32.62; 95% CI, 18.78-56.63). In the largest study, with 68 495 melanoma cases diagnosed from 1992 to 2006 identified through 13 SEER registries, greater tumor thickness was associated with higher melanoma mortality. Compared with thin lesions

					(<1.0 mm), HRs for melanoma mortality by thickness were 2.89 (95% CI, 2.62-3.18) for tumors 1.01 to 2.00 mm, 4.69 (95% CI, 4.24-5.02) for tumors 2.01 to 4.00 mm, and 5.71 (95% CI, 5.10-6.39) for tumors larger than 4.00 mm" (Wernli et al., 2016). Clinical Significance/Conclusion: The literature demonstrates that detecting melanoma at a later stage and a higher skin lesion thickness are associated with increased mortality risk. However, the link between skin cancer screening and mortality is limited. Ultimately, evidence was limited surrounding skin cancer screening. Future studies should focus on targeted screening in those considered to be at high risk for skin cancer.

Citation: Kaiser, I., Pfahlberg, A. B., Uter, W., Heppt, M. V., Veierød, M. B., & Gefeller, O. (2020). Risk prediction models for melanoma: A systematic review on the heterogeneity in model development and validation. *International Journal of Environmental Research*					**Level and Quality III B**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**

The aim of this systematic review was to highlight the heterogeneity in definition and assessment of predictors incorporated into various skin cancer prediction models as well as evaluate a variety of models' performance as they have been employed.	Systematic Review	Search Strategy: Search for studies that describe prediction models quantifying the risk of melanoma and identifying those who are at high risk for development of the disease. Studies that utilized a multivariable prediction model were considered exclusively. Studies that utilized a well-defined statistical method were used exclusively. Search strategy utilized PubMed with terms such as, "risk/risk assessment/probability", "prediction/model/score" and "melanoma/skin cancer". Eligible Studies: Those with well-defined statistical methods aimed at prevention opposed to treatment. Excluded: Those based on expert opinions or consensus meetings were excluded. Included: 40 studies total, 2 excluded due to use of the Russian language (unable to analyze) and the	Control: Included studies with a control group consisting of no risk identification screening tool being utilized on patients to identify high risk patients. Intervention: Included studies with multiple versions of a screening tool to identify high risk patients as part of the intervention. Protocol: Not applicable to the SR.	DV: The primary outcomes included confirming substantial heterogeneity in important aspects of published risk prediction models. Standardization of predictors is necessary to aid providers in choosing a screening tool. The studies were analyzed regarding five components: "the spatio-temporal information, the heterogeneity of risk factors, the disparities in defining and ascertaining individual risk factors, the validation methods, and the evaluation of model performance". Evaluation techniques involve measures of model performance (discrimination and calibration). Almost 75% of the studies reported measures for the discriminative ability.	Statistical Results "The analysis of the evaluation methods employed in the studies showed that the actual standard of validation and reporting of performance measures is quite poor. Nearly half of the studies (n = 18) validated their models internally using methods like bootstrapping and cross-validation, but only six out of 40 studies externally validated their models" (Kaiser et al., 2020). "More than one-quarter of the publications (n = 11) did not report any performance measures, although a quantification of model performance is essential to evaluate if the model is suitable for application. However, we observed an encouraging temporal effect concerning the evaluation of model performance too" (Kaiser et al., 2020). Clinical Significance/Conclusions: Individual risk factors are still mostly estimated based on single risk factors like count of nevi and

		other focused on the identification of risk factors as opposed to melanoma risk prediction. Power Analysis: Not applicable to SR			Fitzpatrick skin type. External validation is largely missing with direct comparisons of models being very challenging. No consensus exists regarding how to predict individual melanoma appropriately. While the risk screening models perform well, standardization is needed to create uniformity when solving this practice problem.

Citation: Shetty, A., Janda, M., Fry, K., Brown, S., Yau, B., Schuckmann, L. V., Thomas, S., Rayner, J. E., Spelman, L., Wagner, G., Jenkins, H., Lun, K., Parbery, J., Soyer, H. P., Neale, R. E., Green, A. C., Whiteman, D. C., Olsen, C. M., & Khosrotehrani, K. (202					**Level and Quality III-B**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
To assess the clinical utility of risk assessment tools to identify patients with prevalent skin cancers in a clinic.	Cross -sectional study.	Sampling Technique: Convenience eligible: 789 patients accepted: 507 patients control: No control group. included: 507 patients. Power analysis: Power analysis not conducted. Group Homogeneity: Participants were all less likely to be under the age of 45 and were evenly distributed across genders.	Control: No control group identified. Intervention: The study had participants complete questions from two risk identification tools, undergo a total skin exam, biopsy as necessary, and then classified into risk groups (low to high). Intervention fidelity: Participants completed a paper questionnaire including items from the Melanoma Risk Stratification Tool and the	DV: The primary outcome was the identification of skin cancer including both melanoma and KC. This outcome proves that the screening is most effective, efficient, sensitive, and affordable when targeted at high-risk patients. The instrument utilized was a combined algorithm with components from the Melanoma Risk	Statistical Results 22 BCC's, five invasive SCC's, one keratoacanthoma and 13 IEC's were identified in 36 patients. Eight participants had a melanoma, with three of these patients also having KC's. Both BCC's and KC's steadily increased as risk identification group increased. BCC's were found in less than 1% of the "very much below average" group and in 12% of the "above average" group.

		The majority were of European descent with fair skin.	Keratinocyte Cancer (KC) Risk Stratification Tool. Participants then underwent a skin examination by a dermatologist with suspicious lesions being biopsied. Management was then communicated to the patients' primary care providers. Participants were provided with education and sunscreen afterwards. A probability score was then calculated for melanoma and KC with a score corresponding to a risk ranging from "very much below average" to "very much above average". The number of melanoma's and KC's were then calculated in each risk group.	Stratification Tool and Keratinocyte Cancer Risk Stratification Tool that assigned patients to 1 out of 5 categories ranging from: very much below average to very much above average. The categories were derived from the quintiles of the risk distribution observed in the QSkin Study sample (n=40,000). The Fisher's exact test was used to evaluate whether prevalence of KCs and melanomas differed significantly by risk category.	Clinical Significance/ Conclusions: Risk stratification tools are efficacious with reliable rates of sensitivity. Findings conclude that risk scores can be used to identify patients most likely to have prevalent skin cancers. A larger study is required if wanting to focus on melanoma alone.

Evidence Synthesis

Category (Level Type)	Total Number of Sources/Level	Overall Quality Rating	Synthesis of Findings
Level 1 - Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis	1 Source: (1) RCTs	A	Rat et al. (2014) effectively noted the efficacy of the SAMScore as well as an increase in patient initiated preventative interventions when patients became aware of their elevated skin cancer risk factors as opposed to when the SAMScore was not used for risk stratification. Rat et al. (2014) also appreciated a significantly higher knowledge of risk factors demonstrated by the patients in the intervention group versus when no risk identification tool was used. It was concluded that performing targeted interventions based off risk identification has been validated and is beneficial.
Level III · Non-experimental study · Systematic review of a combination of RCTs, quasi-experimental, and non-experimental studies, or non-experimental studies only, with or without meta-analysis · Qualitative study or systematic review of qualitative studies with or without meta-synthesis	4 Sources: (2) Systematic Reviews (1) Prospective cohort study (1) Cross-sectional study	B	All studies took place outside of the acute care setting in either outpatient, ambulatory, or primary care settings. All studies set out to test the concept of risk identification for patients at high risk of developing skin cancer. Quereux et al. (2020) tested the performance of the SAMScore seeking to evaluate the efficacy of use for risk stratification. The study showed that it would be necessary to screen 11.54 times more patients if the SAMScore was not used, proving the efficiency and efficacy of targeted screening and risk stratification when using the externally validated SAMScore. Rat et al. (2014) supports the work of Quereux et al. as both studies found the SAMScore to be efficacious. Rat et al. proved that targeted interventions performed on high-risk patients identified with the SAMScore has a larger impact when compared to traditional preventative education (2014). Shetty et al. (2020) was similar to both Quereux et al. and Rat et al. in the sense that the objective of their study involved testing the efficacy of targeted screening in general. By developing their own hybrid tool they risk classified and then performed biopsies when indicated. The vast majority of SCC's, BCC's, and melanoma cases belonged to patients classified amongst the "above average" and "exceedingly above average" risk category, supporting the notion that

			risk identification is an effective screening method. Quereux et al. (2020) and Wernli et al. (2016) both saw benefits in using screening tools, with Wernli et al. (2020) appreciating a decrease in overall morbidity of melanoma deaths and tumor thickness sizes when diagnosed early, creating a strong association between early identification and a better prognosis. However, where Wernli et al. (2020) differs from Quereux et al. (2020) is that their study concluded that the direct evidence to screening all patients and a decrease in mortality is limited, ultimately unable to create a feasible justification for generalized screening. Wernli et al. (2020) however, did conclude that the focus of skin cancer prevention should therefore be on targeted screening as opposed to general screening. This reinforces the importance of both Quereux et al. (2020) and Shetty et al.'s (2020) findings of the efficacy of risk identification. Kaiser et al.'s (2020) systematic review sought to identify the level of heterogeneity of predictors incorporated into various skin cancer prediction models as well as their performance. From a performance perspective, Rat et al., Kaiser et al., Quereux et al., and Shetty et al. all found that risk identification tools perform well with positive performances in sensitivity, identification, and efficiency. However, Kaiser et al.'s systematic review finds that many screening models are missing external validation which is essential in demonstrating efficacy in the clinical setting, a factor that Rat et al. and Quereux et al.'s use of the SAMScore contains. Kaiser et al. found that the models perform well, but some form of standardization is needed. If a screening tool is to be used, it should be proven to have high sensitivity, validity, and reliability, making Rat et al.'s randomized control trial utilizing the SAMScore that much more clinically important. Finally, Rat et al (2020) found that when patients undergo risk identification and are educated on the potential consequences, interventions, and preventative measures surrounding being high risk, they maintain a higher knowledge score about lifestyle changes and modifiable risk factors compared to patients who did not undergo risk identification.

Recommendations Based on Evidence Synthesis: There is good and consistent evidence to support the practice change of implementing the utilization of the SAMScore for risk identification of patients at high risk of developing skin cancer in order to decrease harm and intervene early.

Note. Level and quality ratings based on the Johns Hopkins Nursing Evidence Based Practice (JHNEBP) model criteria .

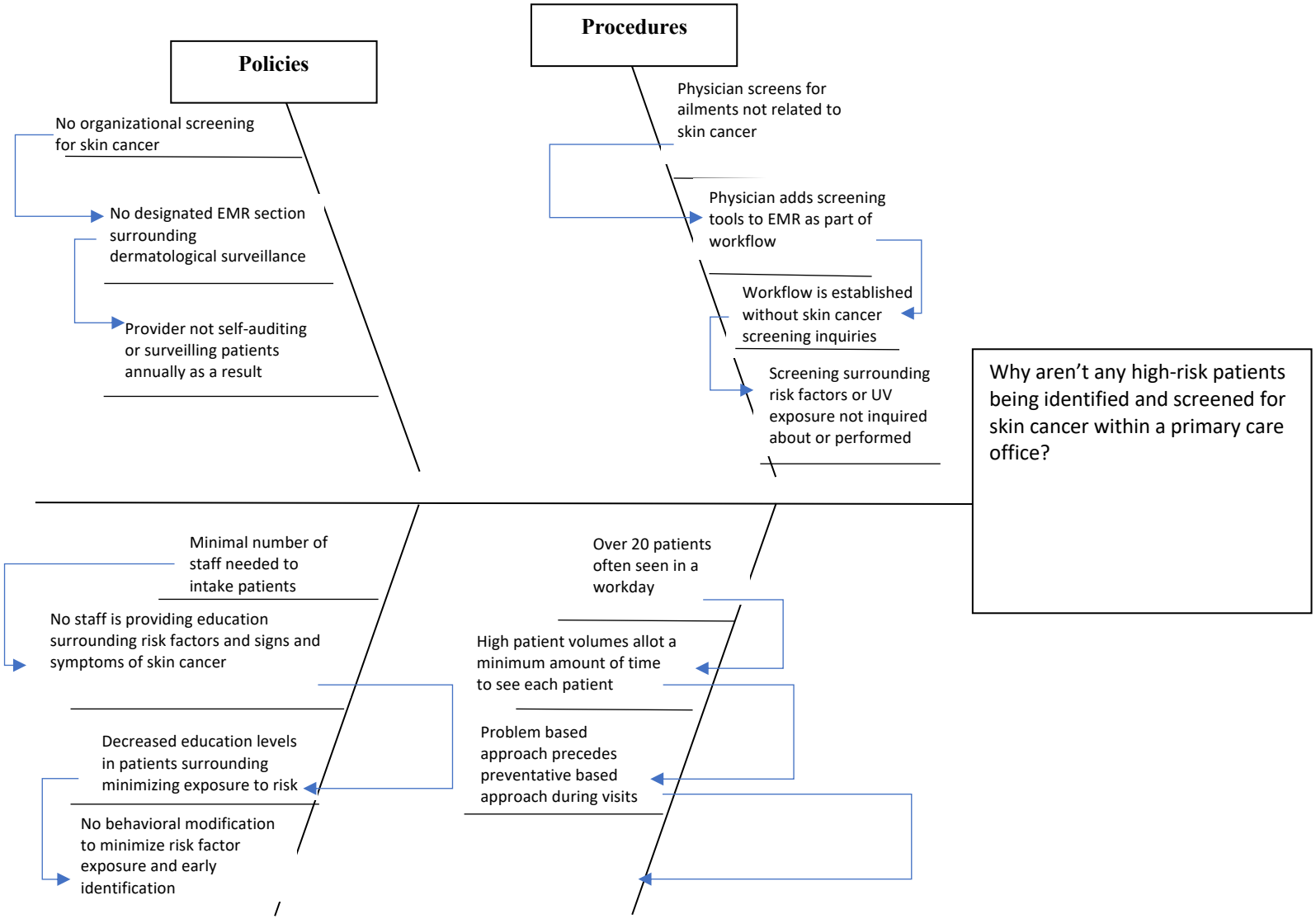
Table 2

Table of Frequencies/Percentages for Screening and Referral

Date	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	Week 14	Week 15
Seen	84	75	48	43	47	22	41	42	26	33	46	35	41	34	33
Screening Completed	50	41	20	22	25	13	22	24	23	29	20	28	33	27	24
Low Risk	31	26	13	15	16	7	11	16	16	24	9	21	26	21	17
High-Risk	19	15	7	7	9	6	11	8	7	5	11	7	7	6	7
Referred to Dermatology	11	15	7	5	8	5	7	7	4	5	10	5	5	4	6
Refused	17	28	25	23	21	9	19	13	3	4	10	15	11	10	11
Percent Screened	59.5%	54.7%	41.7%	51.2%	53.2%	59.1%	53.7%	57.1%	88.5%	87.9%	43.5%	80%	80.5%	79.4%	72.7%
High-Risk Patients Percent Referred	57.9%	100%	100%	71.4%	88.9%	83.3%	63.6%	87.5%	57.1%	100%	90.9%	71.4%	71.4%	66.7%	85.7%

Appendix A

Fishbone Root Cause Problem Analysis of Pre-Screening Challenges for Skin Cancer Risk Identification Implementation.



Skin exams or risk identification not being performed due to time

Appendix B

Framework: Promoting Action on Research Implementation in Health S

Environment

Successful Implementation
= f(EFC)
E= Evidence
F=Facilitation
C=Context

Evidence

- **Research**: multiple randomized control trials and systematic reviews
- **Patient experience**: support direct personal contact, deliberation, and discussion with patients about their vaccination needs

Facilitation

- **Characteristics**: respect for the autonomy of navigator's role and flexible approach by the navigator to adapt to each patient's needs
- **Role**: ambulatory medical director provides authority
- **Style**: Patient outreach will be consistently performed

Context

- **Culture**: patient-centered outreach
- **Leadership**: Effective teamwork and collaboration between physician and navigator
- **Measurement**: internal measures routinely weekly

.

Appendix C

Current and Desired Process Maps

Current Process Map for Skin Cancer Risk Classification

1. Patient chart is updated via phone intake conducted by medical assistants approximately one hour before patient's scheduled visit. Patients are either seen for annual physicals or acute/sick visits
    a. HPI, PMH, PSH, allergies, Medications, and depression screening are all included in the intake conducted by the medical assistants
2. One medical assistant works in the office on-site and screens patients upon arrival for fever or any COVID-19 symptoms such as loss of taste/smell, cough, rhinorrhea
    a. Vital signs are then taken and recorded in the EMR by the medical assistant
3. The patient is taken in to see primary physician
4. Primary physician reads the electronic chart, reviews the HPI, medications, vitals, depression screening, and new onset complaints (if any).
5. Physical exam is conducted based off complaint
    a. If problem-based visit, focused assessment is conducted
    b. If annual physical, patient taken to separate room to change into gown for full physical assessment.

6. Changes are made to the diagnosis' list, medications are either refilled, added, or removed, HPI is modified to include any new details revealed in the visit, plan is discussed with the patient, orders are written, and follow-up timeframe is discussed with the patient.
7. Visit with physician is concluded.
8. Office manager calls to schedule next appointment, lab visits, follow-up paperwork and e-mails patient specific education.

Desired Process Map for Skin Cancer Risk Classification

1. Patient chart is updated via phone intake conducted by medical assistants approximately one hour before patient's scheduled visit. Patients are either seen for annual physicals or acute/sick visits
    a. HPI, PMH, PSH, allergies, Medications, and depression screening, and skin cancer risk identification screening are all included in the intake conducted by the medical assistants
        i. SAMScore, a validated screening tool to assess the risk of skin cancer development, is added into the EMR that medical assistants utilize to conduct patient intakes
2. One medical assistant works in the office on-site and screens patients upon arrival for fever or any COVID-19 symptoms such as loss of taste/smell, cough, rhinorrhea
    a. Vital signs are then taken and recorded in the EMR by the medical assistant
3. The patient is taken in to see physician
4. Primary physician reads the electronic chart, reviews the HPI, medications, vitals, depression screening, skin cancer screening and new onset complaints (if any).

   a. If SAMScore detects high risk patient, physician will refer to dermatology for yearly surveillance/inquire about any suspicious lesions or skin changes
   b. Physician will counsel patients regarding their risk factors for the development of skin cancer
   c. In free text “orders” box completed at the end of the visit, dermatology referral will be documented
5. Physical exam is conducted based off complaint
   a. If problem-based visit, focused assessment is conducted
   b. If annual physical, patient taken to separate room to change into gown for full physical assessment.
6. Changes are made to the diagnosis’ list, medications are either refilled, added, or removed, HPI is modified to include any new details revealed in the visit, plan is discussed with the patient, orders are written, and follow-up timeframe is discussed with the patient.
7. Visit with physician is concluded.
8. Office manager calls to schedule next appointment, lab visits, follow-up paperwork and e-mails patient specific education (if SAMScore detects high risk patient, skin cancer preventative education should be provided).

Figure 1

SAMScore

Answer each question by checking the appropriate square

1. What type of skin do you have?
   - ❑ Skin-type I: very fair skin, blond or red hair, light eyes (blue or green), never tan and always sunburn after sun exposure
   - ❑ Skin-type II: fair skin, blond or light brown hair, light eyes (blue or green), usually sunburn
   - ❑ Skin-type III: dark skin, brown hair, light to medium eye color
   - ❑ Skin-type IV: olive skin, dark brown hair, brown eyes
   - ❑ Skin-type V: brown skin, black hair, black eyes
   - ❑ Skin-type VI: black skin, black hair, black eyes
2. Do you have freckles? ❑ Yes / ❑ No
3. How many moles do you approximately have on both arms? ❑ More than 20 / ❑ Fewer than 20
4. Have you had one or more episodes of severe blistering sunburn during childhood or teenage years? ❑ Yes / ❑ No
5. Did you live more than 1 year in a country where sunshine is high (Africa, French West Indies, South of United States, Australia...)? ❑ Yes / ❑ No
6. Have you been diagnosed with melanoma in the past (it is a skin cancer, arising in melanocytes, skin cells that make skin pigment)? ❑ Yes / ❑ No
7. Has any of your first-degree relatives (parents, children, brother or sister) ever had melanoma? ❑ Yes / ❑ No / ❑ Don't know

Figure 2

Process Goal Run Chart of Patients Screened Vs. Patients Eligible

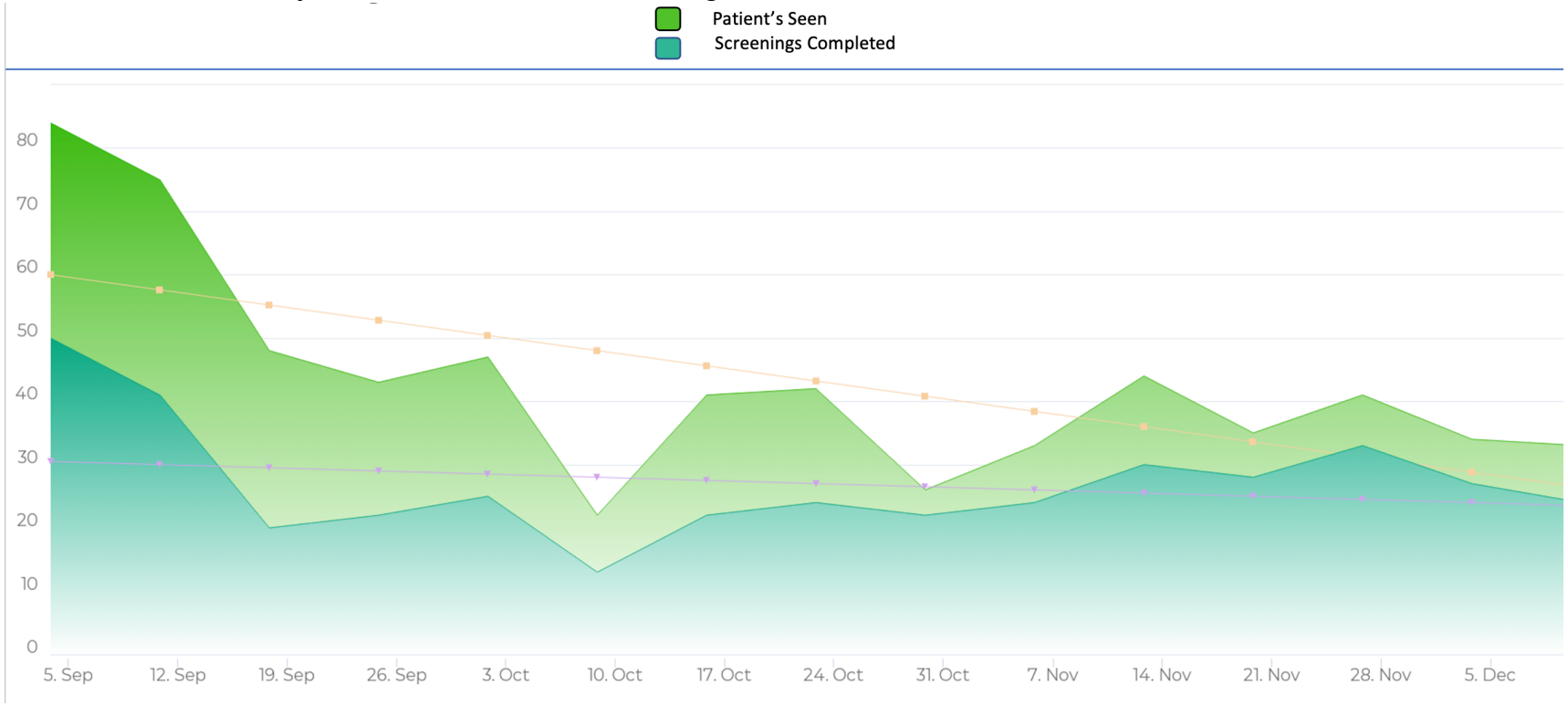


Figure 3

Outcome Goal Run Chart of Referrals Placed Vs. High-Risk Patients