Implementing a Melanoma Risk Screening Tool in Primary Care

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A DNP Project Manuscript
Submitted in Partial Fulfillment of the Requirements for the
Doctor of Nursing Practice Degree

School of Nursing, University of Maryland Baltimore
May 2023

Manuscript: Implementing a Melanoma Risk Screening Tool in Primary Care

Abstract

Problem & Purpose: Full body skin cancer examinations (FBSE) are not being performed at a Baltimore City primary care practice. High-risk melanoma populations (i.e., 33.3% Caucasian, 62.5% Male, 25% Young Adult (20-39), 66.7% Adult (40-64), 8.3% Older Adult (65-79), 12.5% Caucasian & Young Adult, 8% Caucasian, Young Adult & Male) are present at the practice. The purpose of this quality improvement initiative is to implement the Williams Melanoma Self-Risk Screening Tool (WMT) to improve melanoma screening, identification, and management. **Methods:** To implement WMT the office manager (OM), medical director, and nurse practitioner will be educated by the project lead (PL) on how to utilize WMT. Staff will be checked off individually after completion of in-person training in the REDcap Training Compliance Tool by PL. After all staff are educated, implementation and data collection will start. All medical patients (ages 35-74) will be given WMT by the OM to complete upon arrival. WMT will be kept in the patient's medical record. After form completion, the provider will review the screening tool and deem the patient as high/low risk. If the patient is high risk, the provider will refer the patient for FBSE. OM will enter data (patient name, date of birth (DOB), appointment day, if screening was performed, risk score (high/low), and if referral for FBSE was made) into the Data Summary Excel on the office computer. This data will be deidentified by OM and then sent to PL. PL will then enter the deidentified data into the REDcap Deidentified Data Summary for analysis. **Results:** 52.8% of eligible patients have been screened for melanoma risk using WMT. 5.6% of patients have been identified as high risk for melanoma. 100% of high-risk patients have been referred for FBSE. **Conclusion:** Findings suggest WMT may be a feasible screening tool for primary care. The outcome goal of referring 100% of high-risk patients for FBSE was met. The process goal of screening 100% of patients was not met using WMT. Staff have reported competing factors (i.e.: new staff, changes to billing practices) as barriers to screening. Screening increased overtime as staff become accustomed to the practice change.

Implementing a Melanoma Risk Screening Tool in Primary Care

Melanoma, the malignancy of melanocytes, has the highest mortality rate of all skin cancers (American Cancer Society, 2022). Melanoma is the 5th most common type of cancer, accounting for 7180 deaths annually (National Institute of Health, 2021). The National Institute of Health (NIH) (2021) estimates there will be 106,110 new cases of melanoma in 2021. The Centers for Disease Control and Prevention (2019) report 9,008 Americans died from melanoma in 2012-2016. If diagnosed during the early localized stage, the five-year relative survival rate is 99% compared to 30% in late-stage distant melanoma (American Cancer Society, 2022). American Cancer Society (2021) and NIH (2021) report skin cancer (SC) cases are growing annually. In a private primary care practice (PCP) in Baltimore City, SC risk assessments and full body skin examinations (FBSE) were not being performed. There was no standardized process in place to assess risk for SC. Patients at this PCP commonly have several competing chronic conditions (i.e., hypertension, diabetes, chronic pain, osteoarthritis). Providers reported over time, visits have become more focused on chronic condition management with less time to focus on SC screening. Lack of screening has put patients at risk for undetected metastatic disease. High-risk melanoma populations are present at this PCP. The following demographics describe their high-risk population: 33.3% Caucasian, 62.5% Male, 25% Young Adult (20-39), 66.7% Adult (40-64), 8.3% Older adult (65-79), 12.5% Caucasian & young adult, 8% Caucasian, young adult & male. The demographic served at this PCP combined with increasing SC cases nationally mandated SC risk assessments and FBSE for these patients.

Root causes for this problem were explored. Providers at this PCP reported FBSE and risk assessments were performed years ago but not currently. Lack of time has been cited by providers as a contributing factor. Patient priorities such as pain or chronic disease management guided how providers utilize their time in the office. A provider at the PCP cited the COVID-19 pandemic as another contributing factor to the problem. He cited less patients were coming in for annual wellness exams and patients may be less likely to participate in FBSE due to fear of COVID infections. Other root causes included the lack of policy requiring providers to assess for SC risk or perform FBSE. Another root cause

was conflicting guidelines on skin assessments. The United States Preventative Task Force (USPTF) (2016) recommends against universal FBSE. This contrasts to the American Academy of Dermatology Association (AADA) (2018) who recommend universal screening. Providers may have been unaware of patients' SC risk level meaning SC may not have been a priority in patients' preventative care. A provider at this PCP cited a lack of dermatologists available for referral appointments. Lack of access has deterred him from dermatology referral for any diagnosis. Budget was another root cause for this problem. Majority of patients at the PCP are Medicare/ Medicaid patients. Medicare and Medicaid currently do not reimburse for FBSE (Esch, 2021). With the mortality rates of melanoma, lack of requirement to assess for SC risk, and inability to perform FBSE, melanoma risk screening must be performed. The Williams et al. (2011) melanoma self-risk screening tool (WMT) (Appendix A) has been identified as a valid tool in identifying melanoma risk. The purpose of this project was to implement and evaluate the Williams et al. (2011) melanoma self-risk screening tool.

Available Knowledge

USPTF (2016) does not recommend annual SC screening in the general adult population. The lack of recommendation was due to the lack of randomized control trials (RCTs) available. There are no RCTs available due to ethical concerns if conducted (Johnson et al, 2020). USPSTF (2016) acknowledged SC screening needs in individuals with risk factors (i.e., fair skin, personal or family history of SC, history of sunburn, previous use of tanning beds, increased number of nevi, atypical nevi, immunocompromised). USPTF (2018) recommended counseling for populations with risk factors. AADA disagreed with the USPTF recommendations. AADA (2018) recommended SC screening for all populations. To identify populations in need of screening, risk screening must be performed.

A need for SC risk screening is present in primary care. An evidence review and synthesis (Appendices A & B) were conducted to identify an evidence-based risk screening tool. No standard risk screening tool for all SC was found. There were no RCTs exploring this topic. Many studies were case-control or cohort studies (Johnson et al., 2020). Though risk factors of melanoma had equal or higher level of relative risk level when compared to routinely screened cancers, the lack of quality evidence

prevented USPSTF from recommending SC screening (Johnson et al., 2020). The evidence reviewed overall recommended SC screening for those at risk for SC. To identify those at risk for melanoma a disease specific tool was identified for screening.

The validated Williams et al. (2011) Melanoma Self-Risk Screening Tool (WMT) (Appendix A) was utilized in this project. WMT has been utilized in a RCT to identify persons at risk for melanoma (Walter et al., 2020). This study explored the effect of a smart phone application to increase physician consult with patients high risk for melanoma. WMT identified a study population at risk for melanoma. Isabelle et al. (2020) evaluated WMT in a systematic review to describe the validity and similarities between melanoma risk prediction models. Isabelle et al. (2020) described variability in the available melanoma risk screening tools. Common risk factors listed in prediction models included in WMT include sex, age, sunburns, hair color, freckles, nevi, and history of non-melanoma SC (Isabelle et al., 2020). The evidence supported the use of WMT to screen patients for melanoma risk.

Theoretical Framework

The Knowledge to Action Framework (KTA) represented WMT's expected success in providing melanoma risk assessments to patients at this PCP. Identifying patients at risk enabled providers to refer at risk patients for FBSE. The steps of this implementation followed the stages/concepts of KTA (see Figure 1). Knowledge creation and problem identification were performed in tandem. An evidence review was performed to find the validated WMT as a solution to the PCP problem (SC screenings not being performed). Adaptation of WMT to fit the PCP's culture and workflow was planned and is further described in this paper and can be represented by the adapt, assess, select/tailor/implement concept of KTA. Implementation was planned in conjunction with staff within the PCP. Structure and process goals were created to monitor the use of the evidence/intervention. Assessing the process goal was represented by the monitor concept of KTA. An outcome goal, 100% of identified high risk patients will be referred to dermatology for FBSE, was created to ensure expected results were obtained through the intervention. Measuring the outcome goal was represented by the evaluation stage/concept of KTA. Verbal feedback was collected from staff. Staff feedback included the feasibility of the intervention and needed changes

for better incorporation into the PCP. Identified themes of staff feedback moved the project into the sustain stage/concept of KTA. Identifying needed implementation changes enabled reentering of KTA stages/concepts to improve the intervention for best evidence-based practice and fit to the needs of the staff. The use of KTA ensured success of WMT.

Methods

Context

Contextual elements of this PCP are described. It was important to understand the workflow of the office prior to implementing a new screening tool. This PCP contained a nurse practitioner (NP), a medical doctor, and one receptionist/office manager (OM). The doctor at this PCP was the owner of the PCP and sees medical patients two days per month. The NP functioned as an aesthetic medicine provider and saw medical patients if an appointment was scheduled outside of the two "Medical Days". On "non-medical days" the practice served aesthetic medicine patients. The OM assisted in checking patients in and out of the office, following up on paperwork, answering phones, and appointment scheduling.

The office's current process for a patient visit is described in Figure 2. Implementation of WMT followed the workflow of the PCP. Use of an Excel document allowed the OM to ensure all medical patients were offered WMT. This PCP utilized only paper health records. Paper health records at this PCP limited the need for translation of paper forms into an electronic health record.

Intervention

WMT (Appendix A) was implemented at this PCP. Training material was first created for WMT. Training material included a timeframe of implementation, changes to workflow, and role specific WMT education. All training was in-person performed by the project lead (PL). Front desk staff were educated on WMT to assist patients if questions arose during form completion. Providers were trained on how to interpret risk scores (high-risk vs. low-risk), counsel patients, and refer patients based off risk level. Next, an Excel data collection table (see Appendix D) was created. Prior to implementation the CSR was changed due to change in staff. The OM position served as the project Clinical Site Representative (CSR). Additional education was performed to ensure understanding of the data collection process including use

of the data collection tool. One week prior to implementation, an email reminder was sent to all staff. The day before implementation, the PL ensured adequate screening tools were printed and appointments for medical day one (M1) and two (M2) were entered into the Excel data collection tool (Appendix D). On M1, WMT was implemented as described in Figure 3. Only patients aged 35-74 were screened. Eligible patients were given a paper copy of WMT by the OM to complete. After every visit, the CSR entered data for every patient into the Excel Data Summary (Appendix D). On M2 WMT was implemented as described in Figure 3. On days outside of the initial two "Medical Days" a search for patient names on the Excel Data Summary (Appendix D) was performed. If the patient was screened, screening and data collection was not performed. If the patient was not screened, use of the tool and data collection proceeded as on the initial two "Medical Days". Monthly emails sent by the PL notified staff on compliance of WMT and referral for FBSE. The PL was on site on all medical days to support implementation. The total implementation period was 14 weeks.

Measures

Different measurements were created to assess the structure, process, and outcomes of the intervention. A structure goal was identified. All providers and front desk staff will be trained on WMT and follow up. The goal ensured staff were presented with training materials. This training goal aimed to measure understanding of the implementation including WMT and changes to normal workflow. This numerical measure was reliable, as it could be easily reproduced by counting staff who were/were not trained. The validity of this measure may have been low. Count of trained staff only showed if the training was performed. It did not ensure staff understood the material presented in the training.

A process goal was identified to measure the range of implementation. One hundred percent of medical patients will be screened annually for melanoma risk using WMT. If 100% of patients received the intervention, WMT would be feasible for the PCP. This screening goal, a numeric measure of percentage of patients the intervention was implemented on, was reliable. It was valid as it measured the wanted outcome (range of implementation).

An outcome goal was identified to ensure next steps were taken to screen at risk patients. Patients identified as high risk needed FBSE by a dermatology provider. This goal was as follows: 100% of identified high risk patients will be referred to dermatology for skin exams. This referral goal was reliable as it was a quantitative measure of referral or nonreferral of high-risk patients. The outcome goal measured the success of the intervention in providing referrals for FBSE. This measure was valid in measurement of staff referral but did not measure if the patient received a skin examination. The structure, process, and outcome goals measured ensured successful implementation. All goals rated high on reliability as numeric measures. The structure and outcome goals ranked lower on validity than the process goal.

Study of the Intervention

During the pre-implementation period data collection tools were created to assess the structure, process, and outcome goals. To track training compliance, each staff member was entered into the REDcap Training Compliance Tool (Appendix E) after completion of in-person training. The REDcap Training Compliance Tool (Appendix E) was utilized to assess if the structure goal (All providers and front desk staff will be trained on melanoma risk screening and follow up) was met.

To assess the process and outcome goals, weekly data was collected using the Excel Data Summary (Appendix D). Prior to each medical day, patients' names, DOB, and appointment day were entered into the office Excel Data Summary (Appendix D). The Excel Data Summary (Appendix D) included only patients with appointments the next medical day who also needed screening. After each patient visit, data (if screening was performed, risk score (high/low), and if referral for FBSE was made) was entered into the office Excel Data Summary (Appendix D). If there was a high patient volume, some or all data for the day was entered after all patients were seen. To ensure no data was lost during collection daily schedule print outs were utilized to track which patients were seen, screened, or did not show up for their appointment. Each week data was coded, removing patients' names and DOB, and sent to the PL. The PL then uploaded the data to the REDcap Coded Data Summary (Appendix F). All data

was verified after inputting and at each time of data transfer. The PL was on site on medical days to support data collection and ensure the integrity of the data.

Throughout the implementation period qualitative data was collected via staff verbal feedback. The PL and CSR collected feedback from staff on barriers to implementation. The PL kept a list of feedback from staff. This data helped understand patterns in compliance with WMT and referral for FBSE.

Ethical Considerations

Protections were placed to ensure patient privacy and confidentiality. All patient data was stored in a locked office with their medical record. Electronic data was secured in a password protected computer on a private network. Data collection was performed by office staff and PL only. Initially data included patient names and DOB to ensure patients were not screened twice. All data was coded, removing patient names and DOB. Data analysis was performed with REDCap secure data analysis program accessible only via VPN access. Screening patients for melanoma risk did not produce harm. Identifying melanoma risk eliminated unnecessary testing and procedures for those at low risk. Melanoma risk screening identified patients in need of FBSE. No patients were withheld from WMT if scheduled for an appointment during implementation. If patients were outside of the 35-74 years age range, they were offered WMT. Providers utilized clinical judgement on whether further referral was needed, depending on results of WMT. No patients outside of the 35-74 years age range were included in the data analysis. The project was conducted under a Non-human Subject's Research determination from the Human Research Protections Office (HRPO) of the UMSOM Institutional Review Board (IRB). No conflicts of interest were identified to be disclosed.

Results

Process and structure changes were measured by compliance to training and screening. Table 1 summarizes the training compliance of the intervention. One hundred percent of staff were trained on WMT. This meets the structure goal (All providers and front desk staff will be trained on WMT and follow up). Table 2 and Figure 4 summarize the results of screening compliance. Twenty-eight patients

were eligible for WMT and 19 received WMT during implementation (Table 2). A 52.8% compliance rate was seen. The process goal was to screen 100% of eligible patients for melanoma risk using WMT. Staff expressed several barriers contributing to these results. The OM had several competing responsibilities and changes to workflow. Billing changes increased workload for the OM. The OM was also new to the position, starting three months prior to implementation. The Screening Compliance: Run Charts (Figure 4 & Figure 5) depict trends seen during the 14-week period via counts and percentages. On the first day of implementation screening rates were lower due to staff adjusting to changes in workflow. Two new NP students started on M1. As implementation progressed screening compliance increased due to staff becoming accustomed to the new practice change. Weeks 1-4 displayed a compliance rate of 45%. Weeks 5-8 displayed a compliance rate of 66.7%. A 21.7% increase in compliance was seen between weeks 1-4 and weeks 5-8. Weeks 9-12 displayed a compliance rate of 66.7%, the same rate as the previous four-week interval. Weeks 13-14 displayed a compliance rate of 75%. An 8.3% increase in compliance was seen between weeks 9-12 and weeks 13-14. The majority of patients were screened in the first two "Medical Days". These two medical days occurred during weeks 1 & 2. The compliance of M1 to M2 was analyzed (Table 3). Table 3 depicted 53.8% of eligible patients seen on M1 were screened compared to 75% on M2. M2 had a higher compliance rate than M1. The compliance of M1 and M2 to patients outside of the initial two "Medical Days" was analyzed. The initial two "Medical Days" had a higher compliance rate than the other days during implementation (Table 4). Weeks 1, 2, 5, 6, 9, 10, 13, and 14 included medical days. On weeks 3, 4. 7, 8. 11, and 12 no medical patients were seen. Due to the unique scheduling of the PCP no significant runs, trends, or shifts were seen in screening compliance (Figures 4 & 5). The screening compliance run charts (Figures 4 & 5) displayed a decrease in data points as less patients needed screening as time progressed. Some medical patients seen on "non-medical days" were not screened due to the change in workflow. Medial patients were seen during two non-medical days during weeks 2 and 9. Zero out of the seven eligible patients were screened on the non-medical days. Overall, the data displayed an increase in compliance over time (Figure 5).

One hundred percent of patients identified as high risk were referred for FBSE (Table 5 & Figure 6). Two patients seen in week 2 and week 10 were identified as high risk for melanoma. Both patients were referred for FBSE. Their referrals occurred during week 6 and 14 when they were next seen in the office. This met the outcome goal, 100% of identified high risk patients will be referred for FBSE. Email reminders was a tactic supporting the referral of high-risk patients. Email updates included information on compliance of screening and referral. Implementation of WMT increased melanoma risk screening and referral of high-risk melanoma patients at this PCP. The percentage of patients screened reflected the success of the process goal. The percentage of high-risk patients referred for FBSE reflected the success of the outcome goal. The percentage of patients screened and referred reflected the ability of WMT to screen and identify patients high risk for melanoma at this PCP.

Discussion

The outcome goal is met as 100% of high-risk melanoma patients were referred for FBSE. The process goal is not met as 52.8% of patients were screened. The goal of the implementation is to screen 100% of eligible patients. Limitations preventing all patients to be screened include changes to billing practices in the office as well as changes in staff. These competing office priorities cause differences between the observed and anticipated screening goal. Despite limitations, the percentage of patients screened increased over time as staff became more accustomed to WMT (Figure 5). Use of the self-risk melanoma screening tool was a change to the office workflow. The 52.8% compliance rate must be accounted for the frequency of screening compared to the typical paperwork/workload for the front desk staff and providers. Though patients at times complete paperwork in the waiting room, the frequency of screening during implementation was a practice change, for the office. The findings of this quality improvement project can be understood for the context of the practice. The office solely used paper charting. WMT was given to patients as a paper self-screening tool. The paper screening tool blended seamlessly with the paper medical records. If a mix of paper and electronic or all electronic charting was utilized, it is expected that compliance would differ to the compliance seen in this implementation. Prior to implementing WMT 0% of patients were being screened for melanoma risk and 0% of patients were

being referred for FBSE. No previous literature evaluates the feasibility of WMT in the practice setting. The United States Preventative Services Task Force (2016) recommends FBSE for at risk populations. At risk populations are identified with the use of WMT. All high-risk melanoma patients were referred to dermatology for FBSE.

Possible factors limiting internal validity include changes to the CSR, delayed referrals for FBSE, and competing office priorities. Additional training was conducted with the CSR to ensure proper presentation of WMT to patients. Additional training on data collection with the CSR was conducted to ensure understanding of data collection procedures. Referrals for FBSE are intended to occur at the visit patients were screened. All identified high risk patients were referred for FBSE at their following visit. To motivate staff to screen and refer patients, monthly emails with progress of the implementation were sent to all staff. Competing office priorities are identified as barriers to implementation. To adjust to this, the PL was present during all medical days to support screening.

Conclusion

WMT is a useful tool for primary care. WMT is a tool providers can use to easily identify high risk melanoma patients. The self-risk screening tool allows providers to save time while preventing unnecessary screening. Unnecessary cancer screening can lead to treatment complications, overdiagnosis, stress, wasted health expenses, lost time, and unnecessary procedures (Kramer, 2015). WMT enables for high-risk screening. High risk breast cancer screening saves patients and providers time and resources (Harvey et al., 2016). WMT enables primary care providers to screen, educate, treat, and manage melanoma risk.

Implementation of WMT at this PCP allowed for referral of all identified high-risk melanoma patients. WMT will be sustained in the primary care side of the practice. There is possible spread to the aesthetic side of the practice. To sustain WMT new staff will be continually trained on WMT. A WMT resource folder will be maintained as a resource to staff. WMT will be incorporated into the new patient paperwork to ensure new patients are screened. Currently a new system is being created to keep track of screenings and tests in the patient charts. These changes will help sustain WMT at the PCP.

Future quality improvement projects should be performed with WMT. This PCP had a unique scheduling system. Other PCPs with daily medical patient scheduling could benefit from WMT. A quality improvement project on the aesthetic side of the practice could assess the fit of the screening tool in a different setting. Other screening tools including a larger age range could be assessed to screen for other types of SC. Through the success of this implementation, future quality improvement projects surrounding risk screening may be explored.

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Table 1

Training Compliance

	N	%
Training performed	6	100
Training not performed	0	0
Totals	6	100%

Table 2

Screening Compliance

	N	%
Screening preformed	19	52.8
Screening not performed	17	47.2
Totals	28	100%

Table 3

Screening Compliance M1 vs. M2

	M1	M2	Totals
Screening preformed	7	3	10 (58.8%)
Screening not performed	6	1	7 (41.1%)
Totals	13 (76.5 %)	4 (23.5 %)	N= 17 (100 %)

Note. M1= first medical day of implementation period; M2=second medical day of implementation period

Table 4

Screening Compliance M1 and M2 vs. Other Screening Days

	M1 & M2	Other screening days	Totals
Screening preformed	10	9	19
Screening not performed	7	10	17
Totals	17 (47.2 %)	19 (52.8 %)	N= 36 (100 %)

Note. Values will be written as total counts and percentages

[a]M1= first medical day of implementation period; M2=second medical day of implementation period

[b]Other screening days include all other days outside of initial two medical days when patients eligible for screening are seen

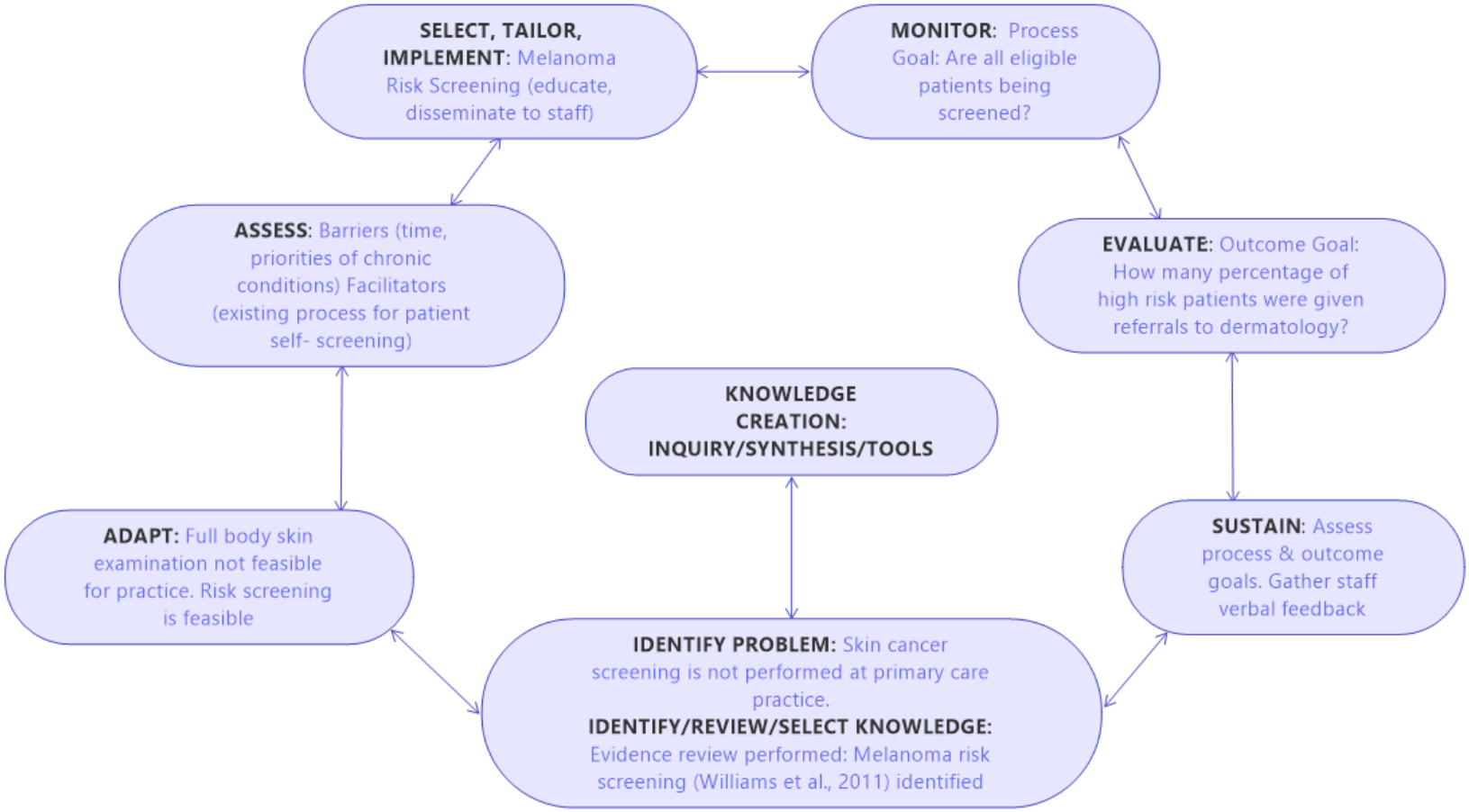
Table 5

Referral Compliance and Risk Category

	High risk	Low risk	Totals
Referral preformed	2	0	2
Referral not performed	0	17	17
Totals	2 (10.5%)	17 (89.5%)	N= 19 (100 %)

Figure 1

Knowledge to Action Framework



Note. Adapted from (Graham et al., 2006)

Figure 2

Current Process Map

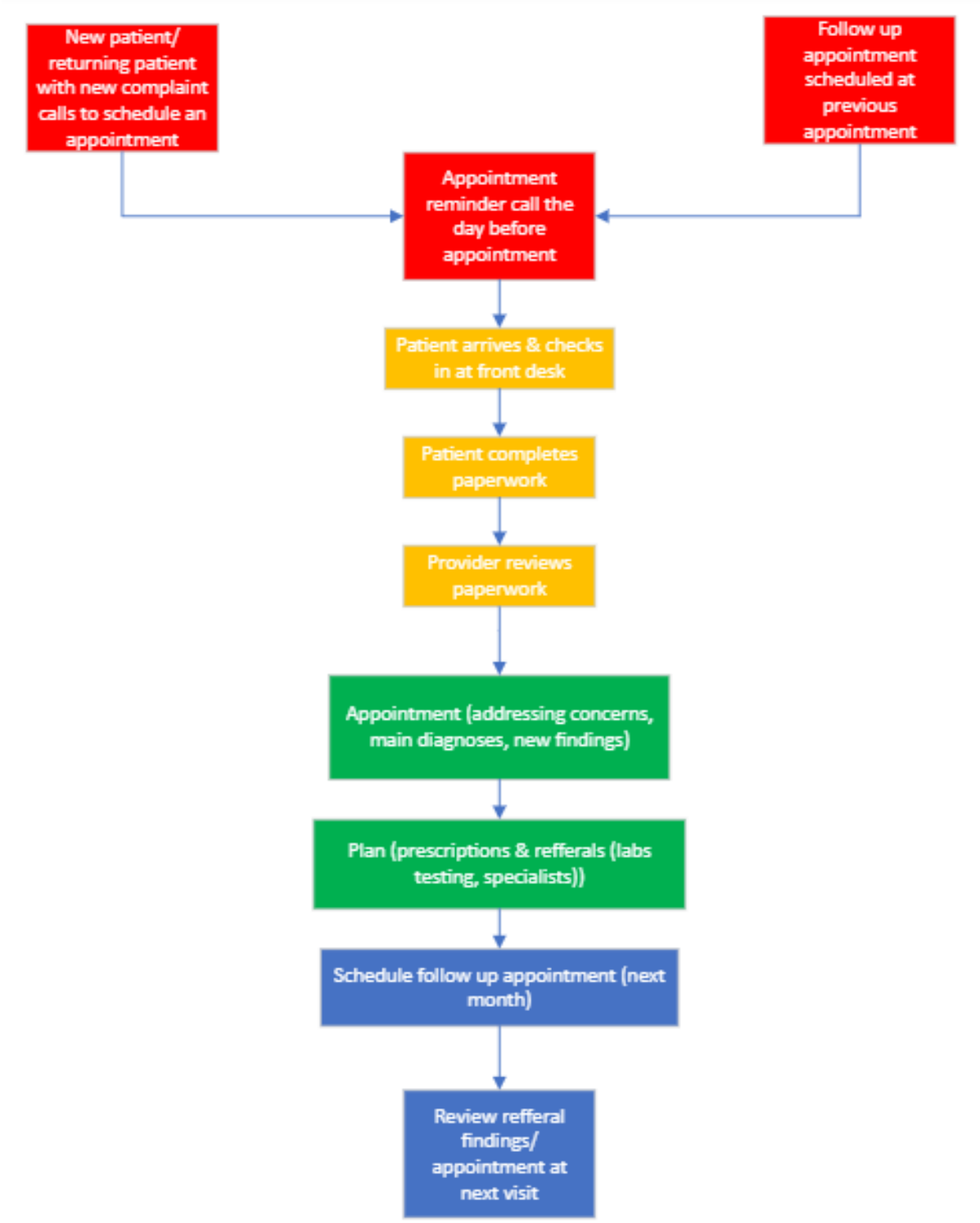
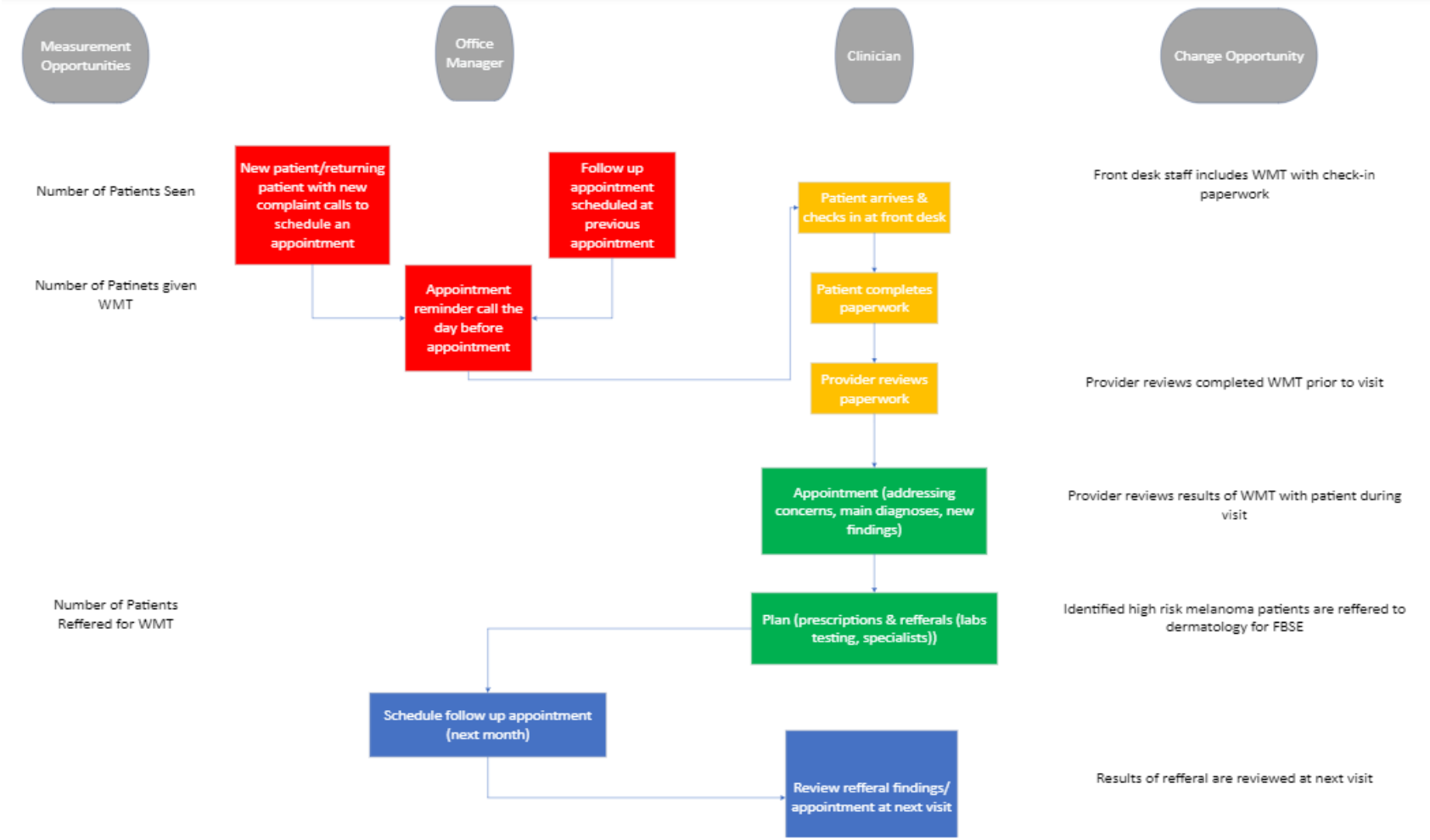


Figure 3

Desired Process Map

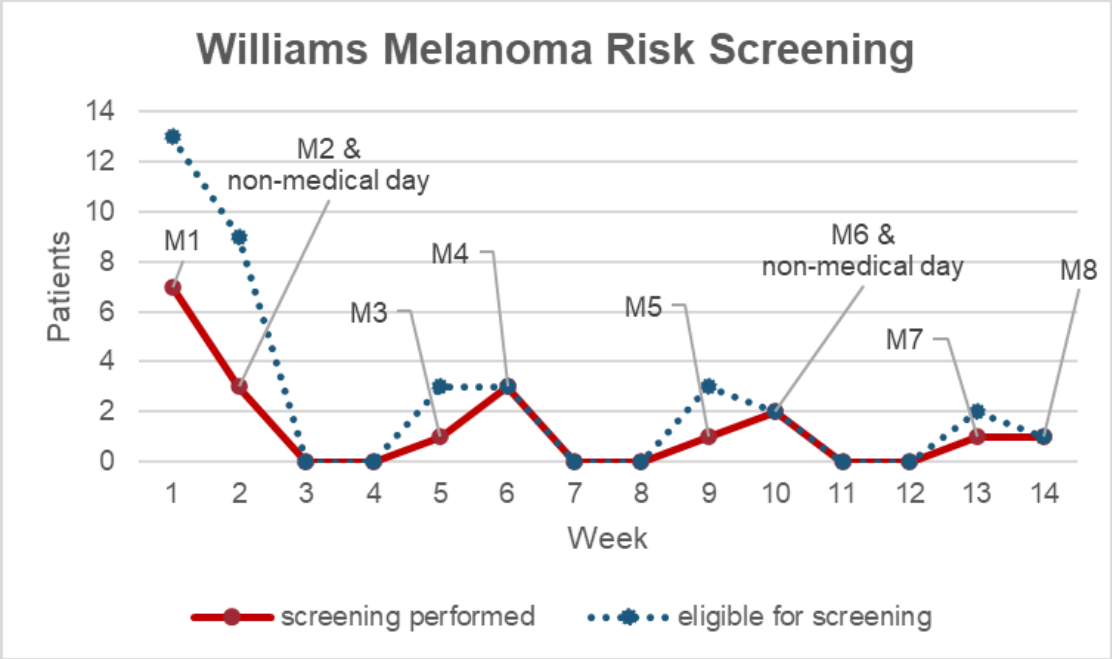


Note. WMT= Williams et al. (2011) Melanoma Self-Risk Screening Tool

[a]FBSE= Full body skin exam

Figure 4

Screening Compliance: Run Chart



Note. M1=medical day 1, M2=medical day 2, M3=medical day 3, M4=medical day 4, M5=medical day 5, M6=medical day 6, M7=medical day 7, M8=medical day 8

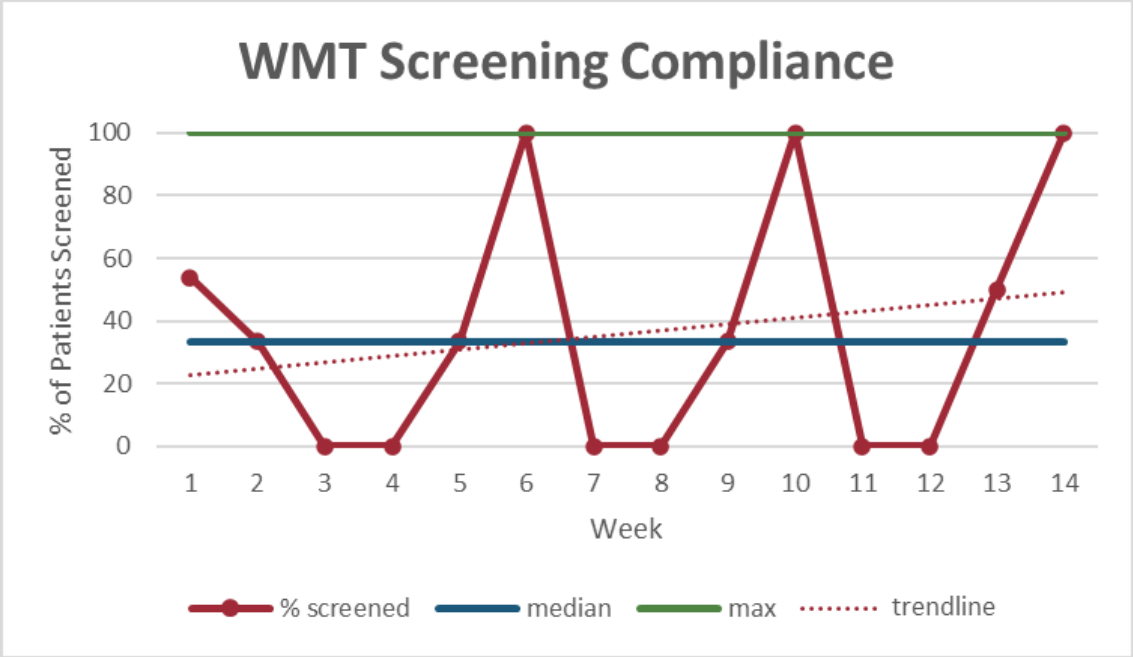
[a]Week 2 included a non-medical day where patients eligible for screening were seen

[b]Week 10 included a non-medical day where patients eligible for screening were seen

[c]Medical patients were not seen in weeks 3, 4, 7, 8, 11, & 12

Figure 5

Percentage of Screening Compliance: Run Chart



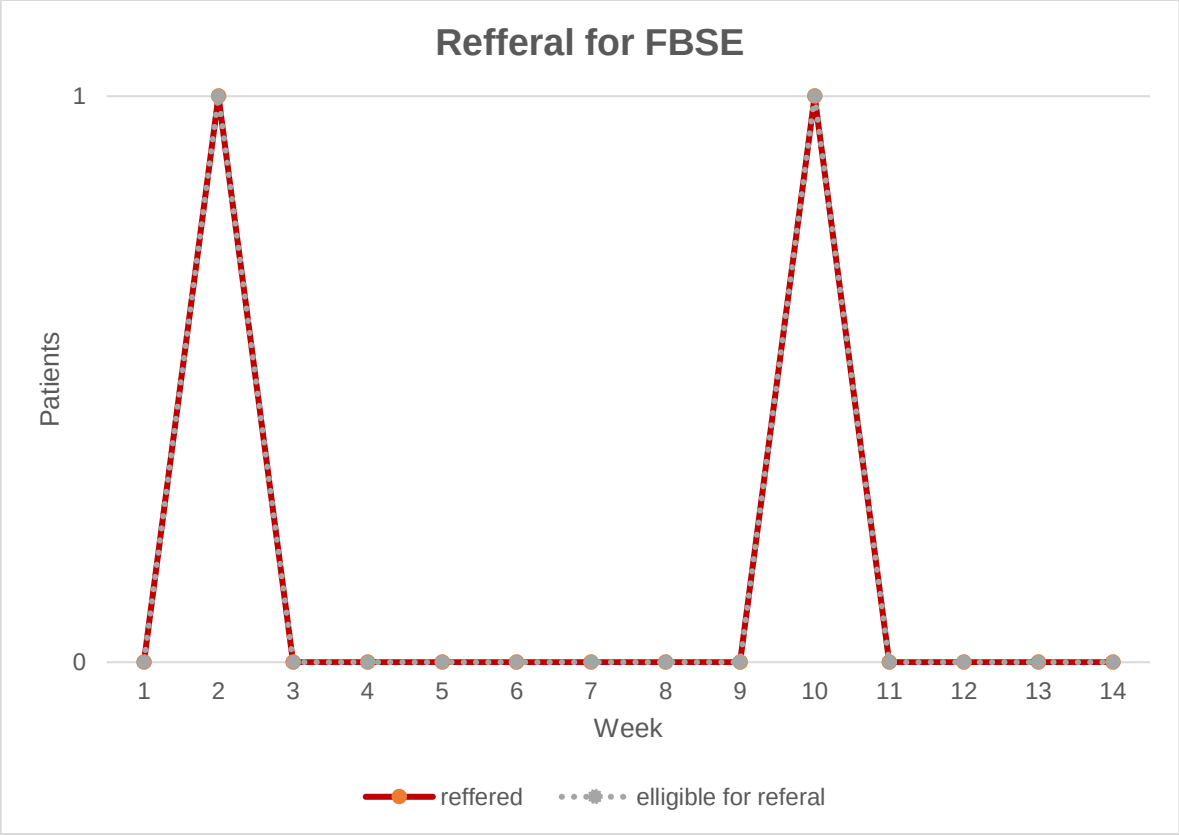
Note. WMT= Williams et al. (2011) melanoma self-risk screening tool

[a]Median= 33.3 %

[b]Trendline shows an increase of screening compliance over time

Figure 6

Screening Compliance: Run Chart



Note. FBSE=full body skin examination

[a]Referral for high-risk melanoma patient seen on week 2 occurred on week 6

[b]Referral for high-risk melanoma patient seen on week 10 occurred on week 14

Appendix A

Melanoma Risk Screening Tool

Melanoma Risk Screening Tool

Please select answer that best describes you.

1. Sex
   Female(0) Male (7)

2. Age in years
   35-44 (0) 45-54 (5) 55-64 (8) 65-74 (11)

3. Number of severe sunburns ages 2-18
   None (0) 1-4 (1) 5-9 (4) 10 or more (7)

4. Natural hair color at age 15
   Dark brown/black (0) Light brown (4) Blond (5) Red (8)

5. Density of freckles on arms before age 20
   None (0) Few (4) Several (6) A lot (10)

6. Number of raised moles on both arms
   None (0) 1 (3) 2 (5) 3 or more (11)

7. Prior non-melanoma skin cancer
   No (0) Yes (13)

----------Do not fill beyond this line----------

Total Points: _____

High Risk (25-67) Low Risk (0-24)

If patient is high risk was referral made? Yes No

Note. Adapted from (Williams et al., 2011)

Appendix B

Evidence Review Table: Skin Cancer Risk Screening

Citation: United States Preventative Services Task Force. (2018). *Skin Cancer Prevention: Behavioral Counseling*. U.S. Preventative Services Task Force. Retrieved from https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/skin-cancer-counseling.					**Level and Quality** II-B
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
To update USPSTF guidelines on behavioral counseling on skin cancer screening with self-skin examinations	Clinical practice guideline based on a systematic evidence review	All asymptomatic persons with no history of skin cancer 16 studies on the adult population 6 studies on children and adolescent population	Counseling patients about sun protection and skin cancer prevention	Behavior change (sunscreen use, sun exposure, sun protection, skin self-examination) Incidence of sunburn, precursor skin lesions, skin cancer	Fair-to-good evidence suggests behavioral change is possible in children and adolescents with skin cancer counseling. Fair-to-good evidence show inconsistent results in increase of sun protective behaviors in adults after skin cancer counseling. Recommendations: -ages 6 months to 24 years with fair skin should be counseled on minimizing exposure to ultraviolet radiation to reduce risk of skin cancer - Adults >24 with fair skin should be offered counseling selectively considering risk factors for skin cancer. -Skin self-examination to prevent skin cancer is not recommended due to inconclusive evidence
Citation: United States Preventive Services Taskforce. (2016, July 26). *Skin cancer: Screening*. United States Preventive Services Taskforce. Retrieved October 12, 2021, from https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/skin-cancer-screening.					**Level and Quality** II-B
Purpose/	**Type of Evidence**	**Sample – Population, Size,**	**Intervention/Procedures**	**Primary**	**Results/Conclusions**

Hypothesis	Research Design	Setting		Outcome/Measures	
To update USPSTF evidence review for guidelines regarding skin cancer screening in adults	Clinical Practice Guideline based on systematic evidence review (No RCTs found)	Asymptomatic adults without history of premalignant/ malignant skin lesions 13 studies on the diagnostic accuracy of screening by primary care clinicians and dermatologists. Population: asymptomatic adults 15years and older	Skin cancer screening by clinicians	Melanoma incidence and mortality Harms of cancer screening Accuracy of diagnosis Stage distribution of melanoma	A study was evaluated on the effectiveness of skin cancer screening. Findings included melanoma mortality decreased 48% from 1.7 to 0.9 melanoma deaths per 100 000 individuals 5 years after the screening program. Absolute reduction was 0.8 melanoma deaths per 100 000 individuals To assess harm, two studies evaluated the number of excisions needed per diagnosis. Data regarded as fair due to high possibility of false positives. Two cohort studies were utilized to assess for accuracy of melanoma diagnosis. By a primary care provider Sensitivity: 40.2% Specificity: 86.1%. By a dermatologist Sensitivity 49% Specificity: 97.6% Eight studies utilized for evaluation of morbidity and mortality. All studies showed increased mortality with increased thickness of the lesion. >4.0mm lesion associated with a 3.1-32.6 increased mortality risk.

					Recommendations: Skin examination by a clinician is not recommended due to inconclusive evidence for asymptomatic adults without risk factors Conclusion: Limited evidence on skin cancer screening.
Citation: Johnson, M. M., Leachman, S. A., Aspinwall, L. G., Cranmer, L. D., Curiel-Lewandrowski, C., Sondak, V. K., Stemwedel, C. E., Swetter, S. M., Vetto, J., Bowles, T., Dellavalle, R. P., Geskin, L. J., Grossman, D., Grossmann, K. F., Hawkes, J. E., Jeter, J. M., Kim, C. C., Kirkwood, J. M., Mangold, A. R., … Wong, M. K. (2017). Skin cancer screening: recommendations for data-driven screening guidelines and a review of the US Preventive Services Task Force controversy. *Melanoma Management*, 4(1), 13–37. https://doi.org/10.2217/mmt-2016-0022					**Level and Quality** Level V
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of these guidelines is to introduce data driven skin cancer screening guidelines equal to those of the United States Preventative Task Force (USPSTF)	Opinion of authorities	Recommendation targeted for: Adults 35-75 years old	Evaluation of guidelines of United States Preventative Services Task Force 2016 Draft Recommendation Statement, American Academy of Dermatology, American Cancer Society, American Acadamy of Family Physicians, Skin Cancer Foundation, Australia, New Zealand, Germany, Netherlands, United Kingdom Include input of melanoma experts in social psychology, epidemiology, clinical research, dermatology, dermatopathology, cutaneous oncology, surgical oncology and medical oncology	Compared relative risks/odds ratios of melanoma risk factors with relative risks/odds ratios associated with risk factors for other common diseases and malignancy - Including age - Target screening age of other cancers by USPSTF Morbidity, mortality of melanoma	Other countries recommend targeted screening for those at risk for melanoma Majority of USPSTF guidline recommendations for other diseases and malignancies are associated rith a relative risk of 1.8-2.0. Melanoma risk factors are equal or greater to these relative risk levels. Due to ethical concerns RCTs are not possible with skin cancer screening, therefore USPSTF has rated their data as “inconclusive” Recommendation: Adults with one or more risk factors (personal history, physical features, ultraviolet radiation exposure) should be screened annually for skin cancer

Citation: Isabelle Kaiser, Annette B. Pfahlberg, Wolfgang Uter, Markus V. Heppt, Marit B. Veierød, & Olaf Gefeller. (2020). Risk Prediction Models for Melanoma: A Systematic Review on the Heterogeneity in Model Development and Validation. *International Journal of Environmental Research and Public Health*, *17*(7919), 7919. https://doi.org/10.3390/ijerph17217919					**Level and Quality** III-C
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this systematic review is to describe similarities and differences of melanoma prediction models and the accuracy of them.	Systematic Review	**Search Strategy**: Forward snowballing with Google Scholar and Web of Science. All studies of 2 systematic reviews were included (26 total) forward snowballing found additional studies (8 additional studies). 8 additional studies found on PubMed. 40 studies in total (46 melanoma prediction models) Study design Case-control (n = 30) Cohort (n = 8) Data from meta-analyses to find risk estimates (n=2) **Inclusion criteria**: include prediction models quantifying the risk of melanoma and identifying people at high risk of developing melanoma, respectively. Multivariable prediction model Absolute risks/risk scores or Mutually adjusted relative risks of individual risk factors and risk factor	46 melanoma prediction models Model Development via Logistic regression (n=29) Gail method (n=5) Cox regression (n=3) Machine learning and decision trees (n=2)	**Studies evaluated by**: 1) Spatio-temporal information 2) Heterogeneity of risk factors in general 3) Disparities in defining and ascertaining individual risk factors 4) Validation methods 5) Model performance Nevi n=35 77.8% Hair color n=26 57.8% Fitzpatrick n=17 37.8% Freckles n=16 35.6% Skin color n=15 33.3% Eye color n=14 31.1% Tanning ability n=10 22.2% Melanocortin 1 receptor genotype n=7 15.6% Polygenic risk score n=5 11.1% Single Nucleotide Polymorphism n=1 2.2% Age n=16 35.6% Sex n=15 33.3% Family history of melanoma n=13 28.9% Residence n=3 6.7% Level of education n=1 2.2% Country of birth n=1 2.2% Health insurance n=1 2.2% Ethnicity n=1 2.2% 1st degree relative with large or unusual moles n=1	Spatio-temporal :studies conducted in Germany, Italy, Greece, Sweden, Austria, France, Scotland, Serbia, United states, Canada, Australia, New Zealand, Brazil, and Multiple countries Studies conducted from 1988-2019 (8 different time intervals). Majority conducted 2012–2015 (n-10) and 2016–2019 (n=10) Heterogeneity 35 different risk factors used -15 risk factors used in only 1 or 2 models -phenotypic factors mot common (nevi, hair color, Fitzpatrick skin type, freckles, skin color, eye color) -nevi most common Disparities in risk factors: Defining and asserting risk factors varied in each study (for nevi: assessment by self/practitioner, location, size, frequency of) **Validation**: Internal validation n=18 45.0% External Validation n=6

		combinations in multifactorial statistical models Developed by well-defined statistical method **Exclusion criteria:** Developed primarily on expert opinions or consensus meetings. Studies unavailable in English Studies evaluating risk factors or identifying people with a high risk of developing melanoma		2.2% Sunburns n=13 28.9% Sunbed sessions n=7 15.6% Sun exposure n=7 15.6% Occupational sun exposure n=2 4.4% Use of sunscreen n=2 4.4% Non-melanoma skin cancer n=10 22.2% Atypical nevi n=10 22.2% Sun damage n=8 17.8% Melanoma history n=5 11.1% Congenital nevi n=2 4.4% Previous skin lesions treated destructively n=2 4.4% Suspicious melanocytic lesions n=1 2.2% Changing moles n=1 2.2% Skin checks n=2 4.4% Hormonal contraceptive therapy n=1 2.2% Age on arrival in Australia n=1 2.2%	15.0% **Model Performance**: Majority of studies measured area under the curve n=26 65.0% No performance measure n=11 27.5% **Conclusions:** Models are substantially heterogeneous including predictive factors and their definitions. Poor validation was found in the studies. There is a need of uniform measures with adequate validation
Citation: Williams, L. H., Shors, A. R., Barlow, W. E., Solomon, C., & White, E. (2011). Identifying Persons at Highest Risk of Melanoma Using Self-Assessed Risk Factors. *Journal of Clinical & Experimental Dermatology Research*, *2*(6). https://doi.org/10.4172/2155-9554.1000129					**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 study is to create a self-risk tool to create a self-assessment tool for melanoma risk	Case Control Study Validating variables for self-assessment tool	**Sampling Technique**: Case-control sampling From a western Washington State study of melanoma	**Control (training set)**: Identified by random-digit dialing **Intervention**: Survey	**Measurement procedure:** Logistic regression used to create a multivariate model predict invasive melanoma Variable selection utilized likelihood ratio test	**Statistical Results:** AUC of model (25% validation set): 0.70 (95% CI: 0.64, 0.77) Indicating moderate predictive ability of melanoma.

		# accepted: 1113 `# in control(training set): 727 (of 2787 eligible) # in validation set: 386 (of 482 eligible) **Group Homogeneity**: All participants white, age 35-74, same geographic region (western Washington state), newly diagnosed primary invasive cutaneous melanoma (excluding lentigo maligna melanoma) Mean participant age: 50.7 (range 35–74, SD 10.5)	**Intervention fidelity**: Subjects were interviewed by phone to capture risk data. Interview conducted by trained interviewers Risk factors in survey included: sex, age, hair color, density of freckles, number of severe sunburns in childhood and adolescence, number of raised moles on the arms, and history of nonmelanoma skin cancer Variables considered for the model: sex, age, education, income, marital status, tendency to sunburn, ability to tan, number of severe sunburns ages 2–18, natural hair color at age 15, density of freckles on arms before age 20, number of raised moles on both arms, prior mole removal, number of moles removed, and prior non-melanoma skin cancer. Tested multiplicative interaction terms: sex*age,	(significance level=0.05) Area under the curve (AUC) calculated for: -75% random sample (i.e., the training set) was used to create the model -25% of the sample (i.e., validation set) was used to test the predictive ability of the model -100% of sample was tested last to generate a risk score Risk scores calculated for each participant and ranked control group participants to create risk strata	AUC of the test set (calculated for comparison to unvalidated models of melanoma risk): 0.77 (95% CI: 0.73, 0.81) Risk score= sum of risk factors x parameter estimates(i.e., betas or log odds ratios). Multivariate models were non-significant (excluded from model) **Conclusions** Male sex, older age, higher number of severe sunburns between ages 2–18, lighter natural hair color at age 15, higher density of freckles on the arms before age 20, higher number of raised moles on both arms, and prior non-melanoma skin cancer are predictive of melanoma in white populations age 35-74. This self-assessment tool can be used to identify high risk melanoma populations in need

			sex*hair color, sex*freckles, hair color*sunburns, freckles*hair color, freckles*sunburns, freckles*moles, and age*moles		of full body skin examinations.

Note. Level and quality ratings by the Johns Hopkins Nursing Evidence-based Practice Model

Appendix C

Evidence Synthesis: Skin Cancer Risk Screening

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			
Level II · Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis	2 Systematic reviews	B	Skin cancer screening is not recommended for the general asymptomatic population. At risk populations should be screened for skin cancer (United States Preventative Task Force, 2016) Behavioral counseling in fair skin patients should be performed in the pediatric population. In the adult fair skin population it should be performed selectively (United States Preventative Task Force, 2016)
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	1 Systematic review 1 Cross-sectional study 1 Case-control study	B	Risk factors for skin cancer vary depending on model (Isabelle et al, 2020). There is overlap in validated predictive factors of predictive models (Isabelle et al, 2020). Risk factors identified show validity in predicting skin keratinocyte carcinoma and presumptive suspicious melanoma lesions (Etzkorn et al., 2013) Use of predictive models can identify those at risk for melanoma carcinoma (Williams et al., 2011)
Level IV · Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence	1 Opinion of respected authorities		Patients with one or more risk factor for skin cancer should be screened for skin cancer (Johnson et al., 2017)
Level V · Evidence obtained from literature reviews, quality improvement, program evaluation, financial evaluation, or case reports · Opinion of nationally recognized expert(s) based on experiential evidence			
Recommendations Based on Evidence Synthesis: Consistent and good quality evidence to support implementation of a validated skin cancer risk model for identifying melanoma.			

Note. Level and quality ratings by the Johns Hopkins Nursing Evidence-based Practice Model

Appendix D

Excel Data Summary

data_set	patient_name	date_of_birth	appointment_day	screening_performed	score	referral_made

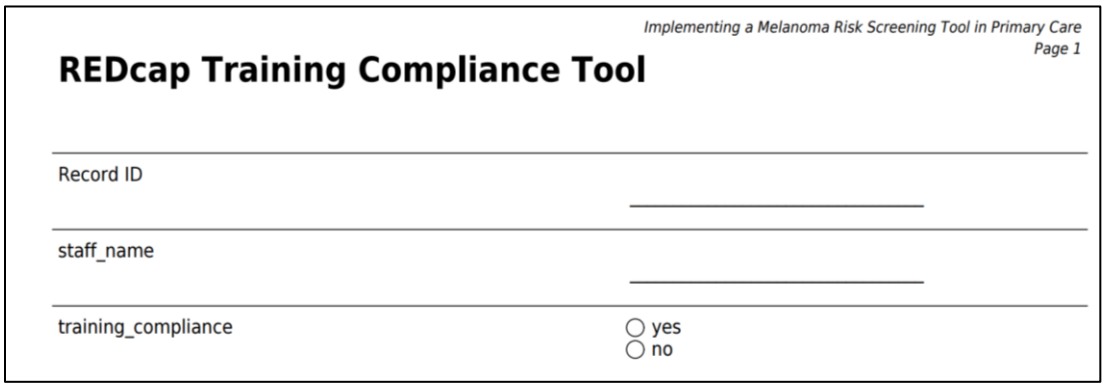
Note. Patient name and date of birth were eliminated for data analysis.

[a]Patient name and date of birth were included for data collection by office staff to ensure all patients are screened.

[b]This collection tool was utilized in office only

Appendix E

REDcap Training Compliance Tool



Implementing a Melanoma Risk Screening Tool in Primary Care
Page 1

REDcap Training Compliance Tool

Record ID	_____
staff_name	_____
training_compliance	◯ yes ◯ no

Appendix F

REDcap Coded Data Summary

Redcap Coded Data Summary

Record ID	_____
appointment_day	_____
screening_performed	◯ yes ◯ no (melanoma risk screening)
score	◯ n/a ◯ low ◯ high
referral_made	◯ yes ◯ no