Project Title: The OneFlorida Cancer Control Alliance: Implementing the 6As in Pediatric Primary Care

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1. Project Title: The OneFlorida Cancer Control Alliance: Implementing the 6As in Pediatric Primary Care

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3. Abstract:

The primary purpose of our study is to conduct a pilot, practice-based intervention focused on increasing adherence to the 6As for youth ages 11 through 17 years. We also will incorporate AAP best practice recommendations to screen and counsel parents. The specific aims of this study are to: (1) Develop and deploy an electronic short screening tool for tobacco and nicotine product use into pediatric primary care workflow in conjunction with clinician and office staff training on the 6As and parent screening through the use of trained Clinical Practice Facilitators, clinician-engaged adaptations of the intervention to fit their practice workflow, and support for Maintenance of Certification (MOC) to engage pediatricians in implementing the best practices; (2) Gather pilot data about the effectiveness of the intervention on clinician adherence to best practices and changes in practice capacity for change, adaptive reserve, and clinician self-efficacy; and (3) Examine the congruence between documentation of the intervention in the EHR and youth report of the intervention.

4. Background:

Cigarette smoking remains the most preventable cause of death in the US and contributes significantly to the occurrence of chronic conditions.[1] *Adolescents are a particularly vulnerable and important group to target for tobacco cessation.* Progression from occasional to daily smoking almost always occurs by age 26, an event that substantially increases the risk for chronic disease in adulthood.[2] Moreover, there has been rapid growth in electronic or e-cigarette use and other non-cigarette tobacco products among youth, which may further increase their risk for transitioning to cigarette use and the development of other addictions.[3] [4]

Primary Care Providers (PCPs) play a critical role in tobacco-related disease screening, counseling, and early intervention among youth.[5] There is an evidence base demonstrating that PCP brief interventions contribute to overall tobacco cessation and reduction.[6] Yet there are significant gaps in screening and management of risk factors, counseling about e-cigarettes, parental counseling, and follow-up interventions to reduce tobacco and e-cigarette use in primary care.[7] [8] [9]

We are proposing a pilot study to increase PCP capacity to follow evidence-based guidelines for tobacco and nicotine product screening and intervention among youth ages 11 through 17. We selected the 6As intervention for two primary reasons. First, the American Academy of Pediatrics (AAP) and the U.S. Preventive Services Task Force recommend their use. Second, the 6As strategy has an evidence base demonstrating that physician screening, advice, and referrals are effective in contributing to tobacco cessation among adolescents.[10] [11] The 6As are: (1) “Anticipate” (future use), (2) “Ask” (about tobacco use), (3) “Advise” (advise the patient to quit using tobacco), (4) “Assess” (the patient’s readiness to quit using tobacco), (5) “Assist” (by setting a quit date, providing materials on quitting tobacco, providing tobacco cessation medications, and referring the patient for additional services and/or counseling)[12], and (6) “Arrange” (by re-contacting the patient after their quit date and arranging a follow-up visit). Consistent with AAP recommendations, we will include screening for e-cigarette, cigars, chewing tobacco, and hookah use.

Despite national recommendations, compliance with the 6As and other PCP office-based best practices are low. The majority of pediatricians advise patients who smoke to quit (81%) but only one-third discuss cessation strategies, and less than 20% make referrals to the quitline or other cessation programs.[13] Facilitators to carrying out the 6As and other best practices in primary care include: incorporation of cues into electronic health records (EHRs); use of short screening tools to identify those at risk for initiating tobacco use as well as current tobacco users; development of patient registries to track outcomes and to facilitate implementation of mHealth applications focused on tobacco cessation; and training of clinicians and office staff on cessation counseling.

The primary purpose of our study is to conduct a pilot, practice-based intervention focused on increasing adherence to the 6As for youth ages 11 through 17 years. We also will incorporate AAP best practice recommendations to screen and counsel parents.[14]

Secondarily, we want to better understand the effects of the practice intervention on enhancing practice capacity to adopt and sustain new interventions in the future. The systematic uptake of evidence-based practices (EBP) into primary care is influenced by multiple organizational characteristics including practice leadership, ability to adopt new interventions (capacity for change) and sustain them (adaptive reserve); HIT availability, and clinician self-efficacy around the particular EBP. [15] [16] Therefore, we will measure practice characteristics including practice capacity for change, adaptive reserve, and HIT capabilities and clinician self-efficacy around the 6As at baseline and at 3 months post intervention.

5. Specific Aims:

Aim 1: Develop and deploy an electronic short screening tool for tobacco and nicotine product use into pediatric primary care workflow in conjunction with 1) clinician and office staff training on the 6As and parent screening through the use of trained Clinical Practice Facilitators (CPFs), 2) clinician-engaged adaptations of the intervention to fit their practice workflow, and 3) support for Maintenance of Certification (MOC) to engage pediatricians in implementing the best practices.

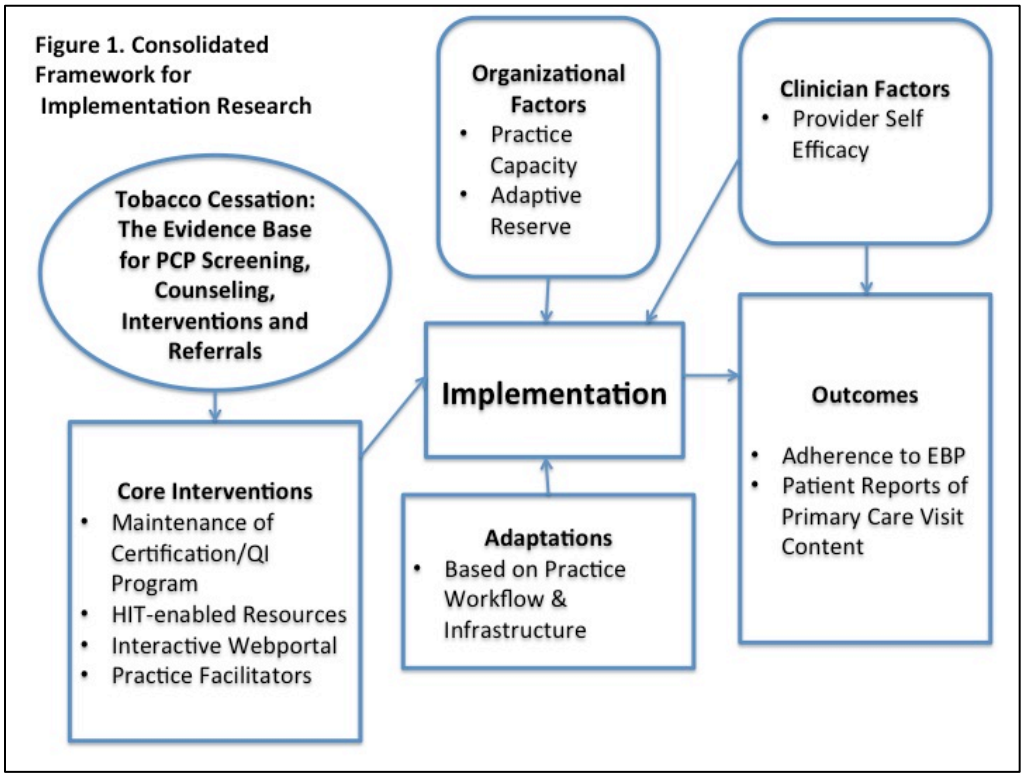
Aim 2: Gather pilot data about the effectiveness of the intervention on clinician adherence to best practices and changes in practice capacity for change, adaptive reserve, and clinician self-efficacy.

Aim 3: Examine the congruence between documentation of the intervention in the EHR and youth report of the intervention.

6. Research Plan

6.1 Conceptual Framework

The Consolidated Framework for Implementation Research (CFIR) is guiding our proposed project (Figure 1).[16] The CFIR emphasizes the influence of internal organizational, clinician, patient, and external factors on the *implementation* of new interventions. We included the CFIR to guide our work because it (1) emphasizes stakeholder engagement to understand local priorities and practice workflow in order to select and adapt patient-centered outcomes research for particular settings; and (2) focuses on understanding and working within the context of internal organizational and individual (clinician) factors when implementing new interventions.[16] This current project is focused on practice and clinician level interventions. Patient factors, such as sociodemographic characteristics, health status, impulsivity, and other factors are integral to tobacco and nicotine product cessation interventions and will be incorporated into future research.[17] [18] Figure 1 reflects our current focus on practice and clinician factors related to implementation of the 6As and recommended best practices related to tobacco and nicotine produce screening and counseling.



6.2 Methods

6.2.1 Study Design

This study will be implemented with a convenience sample of 4 pediatric primary care practices. Two will be randomly assigned to receive the intervention and two will serve as the comparison groups. Two of the practices will be located at UF Health in Gainesville and two will be located at UF Health in Jacksonville. The control group will provide their usual care related to tobacco and nicotine product use screening and cessation recommendations. The control group will be given the opportunity to participate in the intervention following study completion.

6.2.2 Sample

In Florida, only 4.3 percent of children ages 11 to 17 are current cigarette smokers.[19] However, e-cigarette use is increasing from 5 percent of Florida high school students in 2013 to 11 percent in 2014.[20] While the percentage of adolescents at risk to begin smoking is not known, studies have identified maternal smoking, trying tobacco, alcohol or marijuana by 8th grade, and endorsement of sensation seeking behavior as risk factors for tobacco and related product use.[21] Children should be screened for these risks.

We will screen all youth, ages 11 through 17 years, in the practice for current tobacco use and risk behaviors associated with cigarette and nicotine product use with the goal of reaching 20 children per practice who are current tobacco users who could receive at least one or more of Steps 3 through 6 (advise, assess, assist, arrange). To achieve 20 patients per practice who reach the “advise” and “assess” stages, if the practice had the average percentage of children using e-cigarettes, approximately 218 patients would need to be screened. The number screened to reach the “advise” and “assess” stages is based on the e-cigarette use and not the traditional cigarette use.

Intervention practices will be asked to screen patients for tobacco and nicotine product use (using the anticipate and ask components of the 6As) by having youth complete a tobacco and nicotine use screening tool until the practice has identified and completed at least the “advise” and “assess” intervention on 20 tobacco/nicotine users. Parental consent and adolescent assent will be electronically obtained using ResearchActs software. In addition, practices will be asked to implement a short parental screening tool for tobacco use. The parent and child will respond to the surveys separately. After the child completes the survey s/he will be offered a $5 electronic Amazon gift card.

Practices will be asked to identify a location in the waiting room or an exam room where the screening tool can be completed without the parent present. Completing the tool is expected to take 10 minutes of the youth’s time and 10 minutes of the parent’s time, inclusive of the time to complete the informed consent. We estimate practices will need to participate in the project for approximately 6 months. This time period includes baseline and follow-up data collection, study implementation, and participant accrual. The 6-month time period is also necessary for those practices who wish to use the project for participation in their Maintenance of Certification (MOC) requirements.

The total duration of study participation for the practices is estimated to be 10 months. This includes a 3-month start up period, a 6-month intervention (or control) time period and a 1-month follow-up. The 6-month intervention period is necessary for those practices who want to use the study participation to assist them in meeting their MOC requirements. For practices not participating in the MOC Program, the intervention period is finished when 20 patients complete at least the “advise” and “assess” components.

Practices can make some modifications to the intervention to fit with their workflow. For example, some practices have nursing staff screen for tobacco/nicotine use and make recommendations about cessation strategies. Other practices have physicians provide the screening and counseling. Practices can make adaptations regarding who administers the 6As but they must follow the 6A intervention. Any type of primary care visit can be used to conduct the 6As.

The duration of the study participation for patients is variable. For those who do not smoke/use nicotine products or who smoke/use nicotine products but do not want to quit, the duration of the study is the baseline data collection (5 to 10 minutes for the youth and 5 to 10 minutes for the parent, inclusive of the informed consent), clinician screening and advising (2 to 5 minutes for the child and 2 to 5 minutes for the parent), and the follow-up telephone survey administered through the UF Survey Research Center (10 minutes) for a total estimated participation time of approximately 25 to 30 minutes. Adolescent participants will be offered another $5 electronic Amazon gift card after completion of the follow-up telephone survey. For patients who smoke/use nicotine products and want to quit, their participation is an estimated 35 minutes for baseline and follow-up telephone survey data collection and provider discussion during the primary care visit. Practices can customize who conducts the screening and advising. For example, some practices assign that role to the nursing staff. In other practices, the clinician seeing the patient for the visit provides this screening and counseling himself or herself.

6.2.3 Data Collected

A. Clinician Survey (Appendix A): Each clinician in the practice who will be participating in the study will be asked to complete a 10 minute survey about their knowledge of and current practices related to tobacco and nicotine product screening and interventions with their patients. These data will be collected at baseline and at 3 months post the intervention (9 months).

B. Practice Characteristic Data (Appendix B): The Change Process Capability Questionnaire (CPCQ) will be administered to all participating practices at the beginning and end of the study (baseline and 9 months). The CPCQ is designed to assess three domains: (1) the practices' history of change; (2) capacity for internal improvement and refinement; and (3) capacity to initiate and sustain change.[22] Managing change is a key component necessary to adopt evidence-based best practices and the CPCQ provides valuable information about this dimension.[22] Practices also will be asked to complete Adaptive Reserve Questionnaire (short form) at baseline and 9 months. This Survey was used in a National Institutes of Health (NIH)-funded study focused on deploying a health information technology (HIT)-enabled intervention to facilitate medical record reviews in primary care practices. [23] The questions are designed to assess: (1) physician self-efficacy (current practices, comfort with, beliefs about, and barriers toward tobacco screening and counseling); and (2) the organizational structure available to support the implementation of new interventions such as the 6As intervention. This survey also will be administered at baseline and the end of the intervention period. The Medical Director for the practice will be asked to complete both surveys. This individual can ask for assistance from the Office/Practice Manager but most of the questions require a physician who is knowledgeable about the practice to complete the survey. Both surveys will take approximately 20 to 30 minutes to complete..

C. Youth Tobacco and Nicotine Product Questionnaire (Y-TNPQ) (Appendix C): At baseline, approximately 190 patients per practice in the intervention groups will be asked to complete a set of tobacco/nicotine product use questions while waiting for their clinician visit (either in the waiting room or another area designated by the practice without the parent being present). The questions were taken from the National Youth Tobacco Survey, a national survey designed to measure middle and high school youth's attitudes toward and behaviors related to tobacco and nicotine products.[24]

The TNPQ and will be administered using the ResearchACTS software. This software was used in an NIH-funded adolescent health risk assessment pilot project,[24] and also in a Centers for Medicare and Medicaid Services-funded pragmatic clinical trial focused on cardiovascular disease risk reduction among Medicaid enrollees with multiple chronic conditions.[25] ResearchACTS is a powerful, web-based application platform that is optimized for the iPad and collects, summarizes and tracks patient-reported information and can support cross-sectional and longitudinal studies with real-time data access for providers and researchers. Embedded within the application's functionality are regulatory and data quality safeguards to ensure the proper collection of high quality data that can be used by patients, providers, community members, and researchers in real time and support both quality improvement initiatives and pragmatic trials research. A distinctive feature within ResearchACTS is the ability to incorporate summary points of patient-reported data within the workflow

parameters. ResearchACTS software was developed at the University of Florida and all data collected is stored within UF's security environment.

The TNPQ will be programmed into ResearchACTS for the adolescent to answer. The clinician will then log into ResearchACTS and review the child's responses at the point of care. ResearchACTS contains motivational interviewing prompts to guide the clinician through the 6As (as appropriate for the child's responses).

D. Parent Brief Questionnaire (PBQ – Appendix D): The PBQ was developed using questions recommended by the American Academy of Pediatrics.[26] Parents are one of the most important sources of a child's tobacco smoke exposure. [27] Therefore screening parents is a recommended best practice. The PBQ will also be administered using ResearchACTS.

E. 6As and Best Practices Medical Record Review Form (6As MRR - Appendix E): At baseline, we will request the (Medical Record Number) MRN from the Integrated Data Repository (IDR) for 75 randomly selected patients from both control and intervention practices in Gainesville and Jacksonville, which will be reviewed for 1) adherence to the 6As (through whichever number of steps are applicable for that patient) inclusive of tobacco and nicotine product use and 2) parental screening for tobacco use. Specifically, the IDR will be asked to select MRNs from 75 records consecutively from well care visits from participating providers for patients 11 through 17 years of age from the 6 months prior to the start of the study until they reach 75 records. OneFlorida has a medical record review team with certified medical record coders. The medical record review team will measure compliance with the 6As and parental screening using the review tool. At the end of the intervention period, we will request the medical records for those patients participating in the intervention. We will request MRNs from the IDR for control group practices and review 75 consecutive medical records for patients ages 11 through 17 years seen during the 6 month study period.

Dr. Salloum will train the medical record reviewers for the Gainesville and Jacksonville sites. Interrater reliability will be established and training will continue until there is 98% agreement between reviewers. During the record review process, Dr. Salloum will be available to the reviewers to respond to questions. If there is not 98% agreement among the medical record reviewer findings, the medical record reviewers will undergo additional training from Dr. Salloum..

For the medical record review for the UF sites (Gainesville and Jacksonville), certified medical record coders will access Epic, the electronic health record, directly if permission is granted from UF Health to do so. If permission is not granted, the clinic staff will be asked to provide PDFs of the children's records for the selected date ranges for the medical record reviewers to review onsite in the clinics. The 6As and Best Practices Medical Record Review Form (6As MRR - Appendix E) will be stored in UF REDCap.

F. Youth Tobacco and Nicotine Product Primary Care Questionnaire (YTNP-PCQ) (Appendix F): At 30 days post primary care visit, children with parental consent and their assent will be contacted via telephone to complete a 10 minute survey about their recollection of the tobacco and nicotine product discussions held with the clinician during the primary care visit. The YTNP-PCQ is adapted from the questionnaire used in the Adolescent Health Risk Assessment in Primary Care Study.

6.2.4 Intervention

Figure 2 shows a summary of the overall study and intervention. The following steps will be used to implement the intervention:

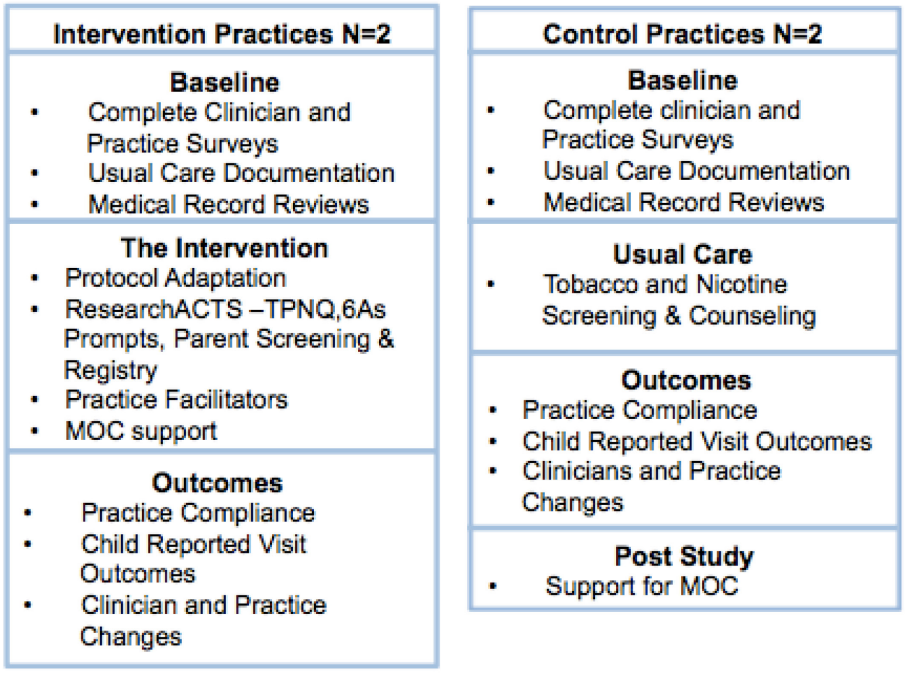
1. Baseline Data: Intervention and control practices will complete the Clinician and Practice Surveys and participate in the medical record review. They also will be asked to provide copies of any youth and parent health risk assessment or screening tools used in their practices related to tobacco and nicotine products.

2. Tobacco and Nicotine Product Screening: The intervention practices will receive the implementation supports listed in Figure 2. Intervention practices can make modifications to the study protocol to fit with their workflow, while maintaining the scientific integrity of the study. The steps for administering the TPNQ and Parent Brief Questionnaire (PBQ) using the ResearchACTS software at the point of care was described in the preceding *Data Collection* Section. As previously noted, the intervention is focused on the practice and not on the youth or the parents per se. Future studies will explore options related to implementing interventions and supports for youth related to tobacco and nicotine product cessation.

3. The control sites will deliver their usual care.

4. Upon study completion, implementation and control sites will complete the Clinician and Practice Surveys, participate in the medical record review, and have child reported outcomes results.

Figure 2. Study Overview and Intervention



6.2.5 Analysis Plan

Intervention effect on clinician adherence to the 6As: The primary outcome is clinician adherence to the 6As inclusive of tobacco and nicotine product use as collected in the medical records. During both the baseline and follow-up periods, we will request and review medical records to identify the following primary outcome measures: discussion of patient's tobacco use, advice to quit, and discussion of parent's tobacco use. Since this is a pre-post design with one intervention group and one control group, we will perform ANCOVA-type analyses assuming that the patients and providers are independent of each other. For each outcome, we will fit a logistic regression model in which the dependent variable is the post-intervention measure of the outcome. The main independent variables will be the pre-intervention measure of the outcome, group (binary: intervention vs. control), and pre-intervention measure by group interaction. In all models, we will also control for age, gender, and race, and clinic (multi-nominal: clinics 1-4). The model building process will follow guidelines provided by Hosmer and Lemeshow.[29]

Intervention effect on practice characteristics: Practice characteristic data will be measured from the Change Process Capability Questionnaire and the Adaptive Reserve Questionnaire (Appendix B). We will collect the practice characteristic data twice, once at baseline and once at 9 months. Therefore, we will fit ANCOVA models for data analysis, assuming the practices are independent of each other. The characteristics include meeting frequency, clinician/staff performance evaluation, and planned communication. The primary predictor of interest is group (intervention vs. control). The model building process will follow guidelines provide by Muller and Fetterman.[30] We will perform residual analysis to check the normality assumption of the models. We will perform box-cox transformation if there is a violation of the normality assumption.

Congruence between documentation of the intervention in the EHR and adolescent report of the intervention: Within 30 days post primary care visit, patients will be contacted via telephone to complete the Tobacco and Nicotine Product Primary Care Questionnaire (TNP-PCQ) (Appendix E), which asks about their recollection of the tobacco and nicotine product discussions with their providers during the primary care visit. For each outcome in the TNP-PCQ survey, we will perform a concordance analysis to evaluate the agreement between the medical record review data and patient-reported data. Concordance will be evaluated using the following statistics: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and the Kappa statistic. Differences in concordance will be tested with the Pearson chi-square test.

7. Possible Discomforts and Risks. There are no known risks associated with this study. The only discomfort that the patient may experience may be associated with discussing something that is personal. Patients will be reminded that they can skip any question on the survey questionnaire that they wish. Patients will be informed that they can choose not to participate in in any portion of the discussion and that answering questions is completely voluntary. There is minimal risk in working with personal health information. However, all data will be in a secure database with access limited to a programmer and the study members conducting data analysis. The medical records will be reviewed onsite and will not leave the practice setting or will be reviewed through a secure computer access if permission is granted for UF Health sites.

8. Possible Benefits. There are no potential benefits to patient participation.

9. Conflict of Interest. None.

10. Data Plan. Precautions will be made to protect participant privacy in the clinic and in the data storage. In the clinic, participants will complete the survey on iPads. The iPad are used to assess the survey website that is stored on a secure server and maintained by UF. No data is stored on the iPads. Identifiable data collected will only be used during the retrospective record review portion of the study. This data will be stored on secure UF servers only accessible to the minimal necessary study staff. Individually identifiable information will not be released to anyone outside the project. After the record review portion of the study is complete any and all identifiable data will be removed from ResearchACTS. Upon closure of the study, data will be de-identified and any study information will be encrypted and labeled with a date for destruction 6 years after the IRB approval date of the study closure.

Appendix A. Clinician Survey

Clinician Survey and Practice Structure Survey

To [Practice Name]:

Your practice has agreed to participate in the study entitled 'The OneFlorida Cancer Control Alliance: Implementing the 6As in Pediatric Primary Care.' We are asking for physicians from your practice site to answer questions about their experiences in screening children and adolescents for tobacco and other nicotine product use. In addition, we are asking each Practice to ask their Medical Director and/or Office Manager to respond to a survey about the overall Practice Structure. The Clinician Survey and the Practice Structure Survey are enclosed with this letter.

Thank you in advance for your help in this work. Please feel free to contact our study coordinator, Kayla Getz, at (352) 273-7345, should you have any questions about this letter or the study.

Sincerely,

Dr. Elizabeth Shenkman

Director, OneFlorida Clinical Research Consortium

Dear Medical Director or Practice Manager:

Your practice has agreed to participate in the research study entitled 'The OneFlorida Cancer Control Alliance: Implementing the 6As in Pediatric Primary Care'. The study is intended to learn about assessing adolescents' tobacco use in the clinic and improving patient-doctor communications about tobacco use. This study is supported by the Florida Department of Health James and Esther King Biomedical Research Program, with Dr. Elizabeth Shenkman serving as the Primary Investigator.

We are asking the Medical Director and/or Office Manager of each participating practice site to complete a survey about the overall practice structure. The brief confidential survey should take approximately 15 minutes to complete. By completing this survey, you are agreeing to participate in this study. Your responses will be analyzed and presented in aggregate. Your participation in this research study is completely voluntary.

You should be able to complete the survey in one sitting. Please fill out the attached paper survey and return it by U.S. mail it using the envelope provided (do not put your name on the survey or your return address on the envelope).

Thank you in advance for your help in this work. Please feel free to contact our study coordinator, Kayla Getz, at 352-273-7345 should you have any questions about this letter or the study.

Sincerely,

Dr. Elizabeth Shenkman,

OneFlorida Clinical Research Consortium

Dear Physician:

Your practice has agreed to participate in the research study entitled 'The OneFlorida Cancer Control Alliance: Implementing the 6As in Pediatric Primary Care'. The study is intended to learn about assessing adolescents' tobacco use in the clinic and improving patient-doctor communications about tobacco use. This study is supported by the Florida Department of Health James and Esther King Biomedical Research Program, with Dr. Elizabeth Shenkman serving as the Primary Investigator.

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Thank you in advance for your help in this work. Please feel free to contact our study coordinator, Kayla Getz, at 352-273-7345 should you have any questions about this letter or the study.

Sincerely,

Dr. Elizabeth Shenkman,

OneFlorida Clinical Research Consortium

Thank you for agreeing to participate in this survey.

We are interested in learning more about your experiences in screening and referring children and adolescents for tobacco and other nicotine product use.

We are also interested in learning more about the barriers you face in screening and referrals.

This questionnaire also includes items about how your practice is organized and the strategies you use when you want to implement a new intervention.

Appendix A is to be completed by each clinician participating in the study. Appendix B is to be completed by the Medical Director and there needs to be only one completed Appendix B per practice.

Section 1: One Florida Clinician Survey (complete for each clinician participating in the study) (Add Code for practice site)

1. What is your terminal degree or primary professional degree?
    a. Medical degree
    b. Nursing degree/diploma
    c. Allied professional diploma in respiratory science/radiation technology, etc.
    d. Other (specify)

2. How would you describe your primary work setting?
    a. University or Academic Center
    b. Hospital based non-academic center
    c. Federally Qualified Health Center
    d. Community Health Center
    e. Stand-alone (non-hospital based) multi-physician practice
    f. Stand-alone (non-hospital based) solo practice
    g. Other (specify)
    h. Not Applicable

3. What percentage of your time do you devote to patient care?
    a. 0%
    b. 1-24%
    c. 25-49%
    d. 50-74%
    e. 75-100%

4. How many years have passed since completion of your most senior degree (i.e. MD, PhD, RN,etc.)?
    a. less than 1 year
    b. 1-5 years
    c. 6-10 years
    d. 11-20 years
    e. 20+ years

5. Please indicate how frequently you do the following in your interactions with patients on during preventive care visits.
    (Response options: Never, Rarely, Some of the time, Most of the time, Always)

    a. Ask your pediatric patients if they smoke cigarettes
    b. Ask your pediatric patients if they use e-cigarettes
    c. Ask your pediatric patients if they use hookah
    d. Ask your pediatric patients about chewing tobacco, snuff or dip

e. Ask your pediatric patients if their parents or other family members living in the home smoke cigarettes or use other tobacco/nicotine products
f. Ask parents/guardians accompanying your pediatric patients if they or other family members living in the home smoke cigarettes or use other tobacco/nicotine products
g. Advise your pediatric patients who smoke or use tobacco/nicotine products to stop
h. Advise parents or guardians of your pediatric patients who smoke or use tobacco/nicotine products to stop for their health and the health of their children
i. Advise parents or guardians of your pediatric patients that any family members residing in the home who use tobacco/nicotine products to stop for their health and the health of their children
j. Refer your pediatric patients to tobacco use cessation intervention programs
k. Refer parents or guardians of your pediatric patients to tobacco use cessation intervention programs
l. Actively treat children for smoking/tobacco use cessation intervention
m. Actively treat parents or guardians of the children for smoking/tobacco use cessation intervention

6. During <u>follow-up</u> appointments for children who have a history of tobacco and nicotine product use, how often do you:
(Response options: Not applicable, Never, Rarely, Some of the time, Most of the time, Always)

a. Ask children about tobacco or nicotine product use
b. Ask parents or guardians about tobacco or nicotine product use
c. Ask children if they have quit smoking or stopped using nicotine products
d. Ask parents/guardians if they have quit smoking or stopped using nicotine products
e. Reinforce the importance of stopping tobacco or nicotine product use to the child
f. Reinforce the importance of stopping tobacco or nicotine product use to the parent/guardian

7. What do you feel are <u>barriers</u> to providing tobacco cessation interventions in pediatric primary care?
(Response options: Strongly agree, Agree, No opinion or neutral, Disagree, Strongly disagree

a. Inability to get children to quit tobacco or nicotine product use
b. Inability to get parents/guardians to quit tobacco or nicotine product use
c. Lack of time for counseling or to set up a referral
d. No or limited provider reimbursement
e. Office layout is not conducive to private conversations with the child about tobacco and nicotine products
f. Child resistance to cessation treatment
g. Parent/guardian resistance to cessation treatment
h. Lack of training or experience in tobacco cessation interventions
i. Lack of available resources or referrals for pediatric cessation interventions
j. Lack of available resources or referrals for parent/guardian cessation interventions

8. Please provide your opinion/judgment for the following statements.
(Response options: Strongly agree, Agree, No opinion or Neutral, Disagree, Strongly disagree)

a. Tobacco and nicotine product cessation should be a standard part of pediatric primary care interventions for the child
b. Tobacco and nicotine product cessation should be a standard part of pediatric primary care interventions for the *parents/guardians*
c. I have had adequate training in tobacco and nicotine product cessation interventions
d. Clinicians need more training in tobacco and nicotine product assessment and cessation interventions

9. Have you smoked at least 100 cigarettes or used other tobacco products in your life?

A. Yes
B. No
C. Don’t know

10. Do you now smoke cigarettes or use other tobacco products every day, some days, or not at all?
    A. Every day
    B. Some days
    C. Not at all
    D. Not willing to answer

Appendix B. Adaptive Reserve and Change Process Capability Questionnaires

B.1 Practice Structure

1. Approximately how often do the clinicians and staff at your practice site **hold meetings** to discuss the practice site's performance on:

   Check (✔) one for each of the following listed meeting topics:
   (Response options: Never, Annually, Quarterly, Monthly, More often than monthly)

   a. Overall pediatric quality of care?
   b. Patient satisfaction ratings?
   c. Productivity?
   d. Utilization or costs of care?
   e. Clinician or staff satisfaction?

2. Does your practice monitor the clinician(s) personal performance on …
   (Response options: No, Yes, Don't know)

   a. Overall pediatric quality of care
   b. Patient satisfaction ratings? (*e.g.,* patient experience surveys)
   c. Productivity? (*e.g.,* patient volume, procedure volume)
   d. Utilization or costs of care?

3. Does your practice monitor staff members' personal performance on…
   (Response options: No, Yes, Don't know)

   a. Overall pediatric quality of care
   b. Patient satisfaction ratings? (*e.g.,* patient experience surveys)
   c. Productivity? (*e.g.,* patient volume, procedure volume)
   d. Utilization or costs of care?

4. Do the clinicians at your practice site use planned communications (*e.g.,* letters, phone calls, text messages) to contact patients who are due for preventive care visits
   (Response options: No, Yes, Don't know)

5. Does your practice site have:
   Check (✔) one for each of the following listed items:
   (Response options: No, Yes, Don't know)

   a. Agreements with community service agencies (e.g., health departments) to enhance services for any of your patients?
   b. A referral system for linking your patients to tobacco cessation programs

6. During a typical day in clinic, how often do providers use a computer or other electronic device (e.g., tablet, smart phone) to look up information about the patients they are seeing?
   Check (✔) one:

   a. Never
   b. Rarely
   c. Sometimes
   d. Usually
   e. Always

7. Does your practice have an electronic medical record?
    a. No
    b. Yes

8. Does your site utilize an electronic medical record (EMR or electronic health record (EHR)?
    a. Yes
    b. No

9. If YES, please select the vendor of your practice's EHR:

    a. Allscripts
    b. CERNER
    c. eClinicalWorks
    d. eMD
    e. EPIC
    f. GE Healthcare Centricity
    g. McKesson
    h. NextGen
    i. Practice Partner
    j. Care360
    k. Practice Fusion
    l. SOAPware
    m. Don't Know
    n. Other, please specify:_____

B.2 Change Process Capability Questionnaire (CPCQ)

1. How would you describe the current status of and attitudes toward quality improvement in your pediatric practice?
(Response options: strongly disagree, somewhat disagree, neither agree or disagree, strongly agree, N/A)

    a. We have greatly improved the quality of care in the past year
    b. We choose new processes of care that are more advantageous than the old to everyone involved (patients, clinicians, and our entire group/clinic)
    c. Our resources (personnel, time, financial) are too tightly limited to improve care quality now
    d. The clinicians and staff in our practice have a shared vision about how we define quality of dental care
    e. The clinicians in our practice adhere to practice policies
    f. Our practice has well-developed administrative structures and processes in place to create change
    g. Our practice is undergoing considerable stress as the result of internal changes
    h. The working environment in our practice is collaborative and cohesive, with a shared purpose, cooperation, and willingness to contribute to the common good
    i. Our practice has a well-defined quality improvement process for designing and introducing changes in the quality of care

2. Our pediatric practice has used the following strategies to implement improved care quality…
(Response options: strongly disagree, somewhat disagree, neither agree or disagree, strongly agree, N/A)

    a. Providing information and skills-training
    b. Use of opinion leaders, role modeling, or other vehicles to encourage support for changes
    c. Changing or creating systems in the practice that make it easier to provide high quality care

d. Removal or reduction of barriers to better quality of care
e. Organizing people into teams focused on accomplishing the change process for improved care
f. Providing to those who are charged with implementing improved care the power and authority to make desired changes
g. Using periodic measurement of health care quality to determine the effects of a new intervention
h. Developing reports documenting the measurements of individual or practice performance
i. Setting goals and benchmarking rates of performance quality at least yearly
j. Customizing the implementation of any care changes to the practice site
k. Deliberately designing care improvements so as to make dentist participation less work than before
l. Deliberately designing care improvements to make the care process more beneficial to the patient

Appendix C. Youth Tobacco and Nicotine Product Questionnaire (Y-TNPQ)

Section 1. Screening Questions:

1. Have you ever used any of the following tobacco products, even one or two times? Check all that apply.
    a. Cigarettes
    b. E-cigarettes, such as Blu or Smoking Everywhere
    c. Cigars, cigarillos, or filtered cigars
    d. Hookah, shisha, or waterpipe
    e. Smokeless tobacco, such as snus, pouches, snuff, dip, or chewing tobacco
    f. I have never used tobacco products

- If Q1=a **[go to Q2]**
- If Q1=b **[go to Q3]**
- If Q1=c [go to Q4]
- If Q1=d [go to Q5]
- If Q1=e [go to Q6]
- If Q1= f *then* **never established tobacco use, [assess susceptibility using the items S1-S3]**

2. Do you currently use any tobacco products such as cigarettes, e-cigarettes, cigars, cigarillos or filtered cigars, hookah, shisha or waterpipe, snus pouches, snuff, dip, or chewing tobacco every day, some days, or not at all?
    a. Everyday
    b. Some days
    c. Not at all

S1. Do you think you might try a cigarette or other tobacco product?
    a. Definitely yes
    b. Probably yes
    c. Probably not
    d. Definitely not

S2. If one of your best friends were to offer you a cigarette or other tobacco product, would you use it?
    a. Definitely yes
    b. Probably yes
    c. Probably not
    d. Definitely not

S3. Do you think you might be smoking cigarettes or using tobacco 1 year from now?
    a. Definitely yes
    b. Probably yes
    c. Probably not
    d. Definitely not

Upon completion of S1-S3 go to Q7.

3. Does anyone who lives with you now…?
   (CHOOSE ALL THAT APPLY)
   a. Smoke cigarettes
   b. Smoke cigars, cigarillos, or little cigars
   c. Use chewing tobacco, snuff, or dip
   d. Use electronic cigarettes or e-cigarettes
   e. Smoke tobacco from a hookah or waterpipe
   f. Smoke pipes filled with tobacco (not waterpipe)
   g. Use snus
   h. Use dissolvable tobacco products
   i. Smoke bidis (small brown cigarettes wrapped in a leaf)
   j. No one who lives with me now uses any form of tobacco

4. How old are you?
   a. 11 years old
   b. 12 years old
   c. 13 years old
   d. 14 years old
   e. 15 years old
   f. 16 years old
   g. 17 years old

5. What is your sex?
   a. Male
   b. Female
   c. Don't know, or something else

6. What grade are you in?
   a. 5^{th}
   b. 6^{th}
   c. 7^{th}
   d. 8^{th}
   e. 9^{th}
   f. 10^{th}
   g. 11^{th}
   h. 12^{th}
   i. Ungraded or other grade
   j. In college/university

7. Are you Hispanic, Latino/a, or Spanish origin (One or more categories may be selected)?
   a. No, not of Hispanic, Latino/a, or Spanish origin
   b. Yes, Mexican, Mexican American, Chicano, or Chicana
   c. Yes, Puerto Rican
   d. Yes, Cuban
   e. Yes, Another Hispanic, Latino/a, or Spanish origin

8. What race or races do you consider yourself to be?
   (You can CHOOSE ONE ANSWER or MORE THAN ONE ANSWER)
   a. American Indian or Alaska Native
   b. Asian
   c. Black or African American
   d. Native Hawaiian or Other Pacific Islander
   e. White

9. Please provide email address if you would like a $5 electronic Amazon gift card.

_____

10. Please provide address if you would like a $5 electronic Amazon gift card.

_____

Appendix D. Parent Brief Questionnaire (PBQ)

1. As far as you know, has your child ever smoked a cigarette or used other tobacco products, such as e-cigarettes, cigars, a pipe, a hookah, smokeless tobacco, dissolvable tobacco, bidis, or kreteks? Please look at this list. Would you say…
    a. You know that s/he has
    b. You strongly suspect that s/he has
    c. You don't think s/he has or
    d. You are confident s/he has not

2. Do you think cigarettes or tobacco might be available to your child at your home?
    1. Yes
    2. No
3. In the past 30 days, have you smoked a cigarette, a cigar, a pipe, even one or two puffs?
    a. Yes
    b. No

4. In the past 30 days, have you used smokeless tobacco, such as chewing tobacco, snuff, snus, or dip, even one or two times?
    [Do not include e-cigarettes or products such as a nicotine patch, gum, inhaler, nasal spray, lozenge, or pill]
    a. Yes
    b. No

5. In the past 30 days, have you used e-cigarettes, a hookah, or dissolvable tobacco, even one or two times?
    a. Yes
    b. No

Appendix E. Pediatric Primary Care Tobacco/Nicotine Best Practices Screening Tool

(Response options: Met? Yes or No)

Best Practice:

1. Documentation that youth was asked about current use of:
   a. Cigarettes
   b. Cigars/Cigarillos
   c. E-cigarettes
   d. Hookah
   e. Smokeless tobacco products

2. If youth smokes or uses nicotine products, was youth asked about amount used (e.g., just a puff, 5 cigarettes a day and so on)?

3. If youth smokes or uses nicotine products, was youth asked about how often used (e.g., daily, monthly and so on)?

4. Was youth asked if he/she anticipated using cigarettes or nicotine products in the future?

5. Was youth advised to not use: Cigarettes, Cigars/cigarillos, E-cigarettes, Hookah, or Smokeless tobacco products

6. For those who smoke or use tobacco products was youth asked if they were ready to quit?

7. For those who were ready to quit, was a referral made?

8. Regardless of readiness to quit, were youth given or told about resources that are available to learn more about the hazards of tobacco and nicotine use?

9. Regardless of readiness to quit, was youth given/told about resources to quit should s/he decide to do so?

10. Was parental tobacco use assessed?

11. Were parent(s) asked about?
    a. Smoke free home
    b. smoke free car
    c. If anyone caring for the child smokes

12. If parent(s) smokes or uses nicotine products in the home or car, was s/he advised to quit smoking?

13. If parent(s) smokes, was s/he referred to smoking cessation programs?

14. If parent(s) smokes was s/he told about educational resources on the influence of parental smoking on the child/youth?

Appendix F. Youth Tobacco and Nicotine Product Primary Care Questionnaire (YTNP-PCQ)

TELEPHONE SURVEY QUESTIONNAIRE

HELLO. Hello, my name is _____ and I'm calling on behalf of the OneFlorida Clinical Research Consortium.

INTRO. May I speak with (insert teen's name here)? You enrolled in a teen health study at your doctor's office, and we are calling to ask you a few follow-up questions.

This survey will take approximately 10-15 minutes. Do you want to start now?

IF NOW IS NOT A GOOD TIME, schedule a time to call back that is convenient for the interviewee.

IF NOW IS A GOOD TIME, go to INTRO2.

INTRO2. Before we begin, I need to tell you a few things.

- You do not have to participate in this survey if you don't want to. Refusal will NOT affect your relationship with your pediatrician/healthcare provider.

- I am going to ask you some specific questions about yourself, including questions about your health and the health care provided by your doctors. You can stop this interview at any time. You can skip any question you don't want to answer.

INTRO3

- All your answers are confidential. We will not report your name or individual responses to your pediatrician/healthcare provider.

- I do not work for your doctor's office. Your doctor's office is part of the OneFlorida Clinical Research Consortium. This is a group of clinics that work together to conduct research in clinical settings**.** I work for a Survey Research Center and I have been asked by the University of Florida to call study participants to ask about their opinions and experiences. If you have any questions about the study, please contact Kayla Getz at (352) 273-7345. If you have any questions about your health care, please contact your provider's office.

1. During this last visit that you had with a doctor or other health provider, did you complete a checklist or survey about your use of cigarettes and/or other nicotine products (for example e-cigarettes, hookah and snuff)?

[1] ☐ Yes
[2] ☐ No
[12] ☐ Don't Know
[13] ☐ Refused

2. During this last visit, did you get a chance to speak with a doctor or other health provider privately? (Meaning one on one - without your parents or other people in the room).

[1] ☐ Yes
[2] ☐ No
[12] ☐ Don't Know
[13] ☐ Refused

3. During this last visit, did a doctor or other health provider tell you that what you talked about with them was confidential? (Meaning it would not be shared with anyone else).

[1] ☐ Yes
[2] ☐ No
[12] ☐ Don't Know
[13] ☐ Refused

4. During this last visit, did a doctor or other health provider talk with you about any of the following?

A. Chewing tobacco or snuff

[1] ☐ Yes
[2] ☐ No
[12] ☐ Don't Know
[13] ☐ Refused

B. Smoking cigarettes?

[1] ☐ Yes →.
[2] ☐ No →
[12] ☐ Don't Know →
[13] ☐ Refused →

C. Using e-cigarettes?

[1] ☐ Yes →.
[2] ☐ No →
[12] ☐ Don't Know →
[13] ☐ Refused →

D. Smoking hookah?

[1] ☐ Yes →.
[2] ☐ No →
[12] ☐ Don't Know →
[13] ☐ Refused →

5. How helpful was this discussion in understanding the risks of cigarettes or using any nicotine products such as e-cigarettes to your health?

[1] ☐ Not at all helpful
[2] ☐ Somewhat helpful
[3] ☐ Helpful
[4] ☐ Very helpful
[5] ☐ Not sure
[13] ☐ Refused

6. During this last visit, did you and a doctor or other health provider talk about how and why to quit smoking or using nicotine products (such as setting a date to quit)?

[1] ☐ No because I do not smoke or use nicotine products
[2] ☐ Yes → **If YES go to 7.**
[2] ☐ No → **If NO go to 8.**
[3] ☐ No, because I did not tell my doctor or other health provider that I smoke cigarettes or use nicotine products → **If NO go to 8.**
[12] ☐ Don't Know → **If DON'T KNOW go to 8.**
[13] ☐ Refused → **If REFUSED go to 8.**

7. How helpful were your discussions in quitting smoking or using nicotine products?

[1] ☐ Not at all helpful
[2] ☐ Somewhat helpful
[3] ☐ Helpful
[4] ☐ Very helpful
[5] ☐ Not sure

8. During this last visit, did a doctor or other health provider ask you if your parents or anyone else living with you smoked cigarettes or used nicotine products?

[1] ☐ Yes. **Go to 9**
[2] ☐ No. **Go to** closing thank you
[12] ☐ Don't Know Go to closing thank you
[13] ☐ Refused Go to closing thank you

9. During this last visit, did a doctor or other health provider talk to you a parent or family member about quitting smoking or using nicotine products?

[1] ☐ No because no one living with me smokes cigarettes or uses tobacco products
[2] ☐ Yes Go to closing thank you
[3] ☐ No Go to closing thank you
[4] ☐ No because my parent/family member did not tell the doctor (or health care provider) they smoke or use nicotine products Go to closing thank you
[12] ☐ Don't Know Go to closing thank you
[13] ☐ Refused Go to closing thank you

Those are all of the questions we have. In order to receive your $5.00 Amazon electronic gift card, we need to verify that we have your correct address and email address.

CONFIRM1

Could you confirm with me that I have the correct address?

1. Yes
2. No (INT: RECORD ADDRESS)

CONFIRM2

Could you confirm with me that I have the correct Email address?

1. Yes
2. No (INT: RECORD CORRECT ADDRESS)

Thank you for participating

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