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Cohort Profile for the Loma Linda University Health BREATHE Program: A Model to Study Continuously Incentivized Employee Smoking Cessation

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ABSTRACT

Purpose: The purpose of the LLUH BREATHE Cohort is to test the efficacy of a novel method of continuously incentivizing participation in workplace smoking cessation on participation, long term abstinence, health outcomes, healthcare costs, and health care utilization.

Participants: In 2014, Loma Linda University Health (LLUH) – a US academic medical center and university – incentivized participation in a workplace smoking cessation program (LLUH BREATHE) by lowering health plan costs. Specifically, LLUH introduced a Wholeness Health Plan (WHP) option that, for the smokers, continuously incentivizes participation in nicotine screening and the LLUH BREATHE smoking cessation program by offering an "opt-in wellness discount" that consisted of 50-53% lower out of pocket health plan costs (i.e. monthly employee premiums, co-payments). This novel "continuously incentivized" model lowers annual health plan costs for smokers who, on an annual basis, attempt or maintain cessation from tobacco use. The annual WHP cost savings for smokers far exceeds the value of short term incentives that have been tested in workplace cessation trials to date. This ongoing health plan option offered to over 16,000 employees has created an open, dynamic LLUH BREATHE cohort of current and former smokers (n=1,092).

Findings to Date: Our profile of the LLUH BREATHE cohort indicates that after five years of follow-up in a prospective cohort study (2014-2019), continuously incentivized smoking cessation produced a 74% participation (95% confidence interval=[71% to 77%]) in employer sponsored smoking cessation attempts that were occurring less than a year after the incentive was offered. The cohort can be purposed to examine the effect of continuously incentivized cessation on cessation outcomes, health plan utilization/costs, use of electronic nicotine delivery systems, and COVID-19 outcomes.

Strengths and Limitations of the Study

Strengths

- **An open employee cohort of over 16,000 that is continuously incentivized through health plan discounts to maintain abstinence or attempt cessation from tobacco.**
- **Linkages to a wide range of employee cohort data on health outcomes, health plan utilization costs, and cessation outcomes.**

Limitations

- **Findings are based on a cohort of university and medical center employees and the effects of incentives needs investigation in other employee groups.**

1.INTRODUCTION

Loma Linda University Health (LLUH) is an academic medical center with over 16,000 employees working in eight health science schools, six hospitals, and a physician practice corporation. In 2014, LLUH introduced an option within the employee health plan – The Wholeness Health Plan (WHP) – that provided employees with an "opt-in wellness discount" that consisted of 50-53% lower out of pocket health plan costs (i.e. monthly employee premiums, co-payments for prescriptions)[1]. To qualify for the WHP wellness discount, employee smokers (identified through organization-wide health risk assessments and biometric screening) were required to participate in LLUH BREATHE – the WHP's smoking cessation program[1]. Our group has reported that the participation rate (73% of employee smokers opted into the WHP and participated in smoking cessation through the LLUH BREATHE program)[1] in the incentivized model of employee smoking cessation in LLUH BREATHE was much higher than the norms (median of 28%) for employee participation in more than 20 studies of employee smoking cessation in affluent nations[2, 3]. Moreover, the cessation rate of LLUH BREATHE participants was also notably high (48% achieved a four month point prevalence abstinence)[1].

A particularly innovative feature of the LLUH BREATHE smoking cessation model was that the "opt in discount" through the WHP was available on an annual basis to all employee smokers as long as they met the requirement of annual participation in smoking cessation for current smokers. Thus, employee smokers were **continuously incentivized** into smoking cessation through two mechanisms: 1) those who did not initially choose the discounted WHP with the smoking cessation requirement could, during an annual buy in period, re-visit that choice and "opt-in" to WHP and the requirement to participate in smoking cessation, 2) WHP members who had participated in LLUH BREATHE smoking cessation program but later relapsed were required to enroll in the next member wide biometric screening campaign in order to maintain their wellness discount through the WHP. This organizational model of **continuously incentivized employee smoking cessation** implemented at LLUH provides a

"natural experiment" to prospectively study the LLUH BREATHE cohort - a dynamic, open employee cohort of current smokers (non-participants in LLUH BREATHE), former smokers (cessation through LLUH BREATHE), and relapsed smokers (relapse after cessation through LLUH BREATHE) who are, on a continuous basis, offered an "opt in" incentive (i.e. discounted WHP coverage) by their employer to attempt, achieve, or maintain abstinence from tobacco smoking. The overall aim of this report is to provide a cohort profile of the first 5 years of follow-up (2014-2019) of the LLUH BREATHE cohort that enables the development of a research framework for longitudinal study of the effects of a continuously incentivized employee smoking cessation model on a wide range of population health outcomes. The specific aims are as follows: 1)To examine the effect of continuously incentivized smoking cessation on participation in an employer sponsored smoking cessation attempt, 2) To examine the effect of continuously incentivized smoking cessation on temporal trends in participation in employer sponsored smoking cessation attempts during the first five years of LLUH BREATHE follow-up, 3) To compare the profiles of participants and non-participants in employer-sponsored smoking cessation attempts during the first five years of LLUH BREATHE follow-up.

The secondary analysis of these health plan data received IRB approval (IRB #5170126) the Institutional Review Board of Loma Linda University .

2.METHODS

2.1 Rationale for the LLLUH Breathe Cohort

Background of the Wholeness Health Plan

Loma Linda University Health (LLUH) is an Innovator in Wellness and Population Health. LLUH is a Seventh-day Adventist institution that as part of its mission to "Keep Man Whole" promotes specific faith-based principles of healthy lifestyle and disease prevention in its healthcare, academic teaching, administration, and campus and hospital environment[4, 5]. These include avoidance of tobacco and alcohol, and adherence to a plant-based diet pattern that encourages consumption of specific plant

foods (i.e., legumes, nuts) in place of animal products[4]. Academic entities of LLUH (Schools of Medicine, Public Health) have completed more than 60 years of landmark, NIH-funded prospective cohort studies [1960 Adventist Mortality Study, 1976 Adventist Health Study-1, 2002 Adventist Health Study-2][6, 7] that have documented how healthy lifestyle behaviors (avoidance of tobacco and alcohol, plant-based diet patterns) practiced by Seventh-day Adventists are associated with lower risk of cancer, coronary heart disease, stroke, diabetes, and a longer life expectancy[4, 8].

Living Whole Employee Wellness Program at LLUH. The Department of Risk Management at LLUH administers a health plan that is offered to all benefit-eligible employees and their families. The health plan is employer-sponsored and designed to provide reimbursement of a broad range of medical expenses for benefit-eligible employees. To align the health plan with LLUH mission-focused principles on wellness, the Department of Risk Management implemented the Living Whole Employee Wellness program to provide a comprehensive range of wellness and disease management services to support employee health. Employees could participate in this program on a voluntary basis. The program included but was not limited to programs on weight management, diabetes management through lifestyle interventions, smoking cessation, and cooking classes.

Evolution of the Wholeness Health Plan (WHP) at LLUH. In 2014, the Department of Risk Management expanded upon the success of the Living Whole Employee Wellness Program by incorporating incentivized wellness options into a new employer-provided health plan option (WHP) that was based on an “opt in wellness discount”. The wellness discount consisted of a 50-53% reduction in out of pocket health plan costs (monthly costs, co-pays for prescriptions) in the existing health plan options from LLUH Risk Management. The rationale for WHP was as follows: 1) Participation in a biometric screening, health risk assessment (HRA), and wellness and prevention information provided at enrollment empowered each health plan member and their families to be actively involved in managing personal health and wellness, 2) The biometric screening and HRA data obtained at enrollment allowed

the health plan to assess member health to enhance the precision of health/wellness resources and population health interventions that are offered. Employees received the wellness discount through WHP enrollment if they completed a biometric screening, a health risk assessment, created an account in the hospital's patient/doctor portal, and agreed to participate in a care management program based on results obtained from the screening and risk assessments. The care management program included 1) biometric result review appointments with a primary care physician, 2) appointments with a nurse care manager for health plan members classified as high risk and/or multiple chronic diseases, and 3) smoking cessation for those identified as tobacco users based on either self-reported health risk assessment or biometric screening.

LLUH Breathe Cohort: A Natural Experiment to Study Employee Smoking Cessation that is Continuously Incentivized by an Employer-Provided Health Plan

The LLUH Breathe Cohort can be used to study the effects of an innovative model to incentivize employees who are current or former smokers to attempt or maintain abstinence from smoking tobacco. There are two innovative features of the LLUH BREATHE model that are noteworthy: 1) Decreasing out of pocket health plan costs by 50-53% provides a financial incentive that far exceeds ($600 to $1200 in lower health plan costs per year) other incentivized employee smoking cessation models that have been reported in the peer reviewed scientific literature[2, 9, 10], 2) Annual "Opt in" periods continuously incentivize smoking cessation attempts and continued abstinence from tobacco among those employees identified as smokers. To provide a context for studying the effects of these innovative features, we describe here the incentive-based smoking cessation models used by other organizations. Incentive-based programs fall into the categories of rewards-based incentives, cash-based incentives, deposit-based incentives, and mixed models using a combination of these approaches[2].

Rewards Based Incentives. Programs at CVS Pharmacy[9, 10] and Blue Cross/Blue Shield[11] have used a rewards-based mechanism ($100 to $800 in value) whereby at key smoking cessation milestones (quit

date set, quit date, 14 day/30-day/6 month point prevalence abstinence) reward points are earned towards 1) subsidized co-payments and costs for prescription and over the counter cessation aids, 2) redemption as cash credits for groceries and personal items in selected stores.

Cash-based Incentives. Direct cash-based incentives include models that provide cash payments for attending a health assessment for smoking cessation (i.e. $50 for a first appointment and setting a quit date) and then provide payments on achieving abstinence goals (amounts summing from $120 to in excess of $800 for long term abstinence)[2].

Deposit-based Incentives. Under deposit based incentives, subjects deposit money into a health savings account and are refunded the money upon achieving abstinence goals[9].

Mixed Models. Under the mixed models[9], combinations of reward, cash, and/or deposit-based incentives are used. For example, reward points for cessation behaviors can be redeemed as cash. Also, deposits are often combined with cash incentives in excess of the amount deposited by a smoker who quits.

Summary Points. Studies that have compared participation and efficacy rates for incentivized models tend to show that deposit-based incentive models have a lower participation rate than cash/reward-based incentives but may have increased point prevalence abstinence rates[10]. We note that incentives can be a component of smoking cessation but are not a "stand alone" cessation method for employees or in other contexts.

Relative to previous incentivized models, LLUH BREATHE provides a novel approach to incentivized intervention that consists of: 1) a mixed model of cash-based (a lower paycheck deduction for health plan coverage equates to more cash per pay period) and reward based incentives (lower co-pays for prescriptions), 2) a socio-ecologic framework whereby participants are choosing smoking cessation as part of a personal and familial choice to "opt in" to the WHP directed choices of health and

wellness programs, and 3) a continuous incentive as an WHP member to attempt and maintain abstinence from tobacco use.

2.2 How did we enroll the LLLUH BREATHE Cohort?

Organization-wide Biometric Screening for WHP enrolls the LLU BREATHE Cohort.

Overview. At the inception of the WHP as a health plan option in 2014, WHP enrollees underwent a series of biometric screenings and health risk assessments to provide employee health profile data. The biometric screening and health risk assessments were done as an organization-wide enrollment campaign during a specific open-enrollment periods in November of 2014 and 2017. New hires were enrolled into the WHP on a rolling enrollment basis. Benefit-eligible employees have the opportunity to enroll in the WHP and qualify for the wellness discount every year. The biometric screenings and health risk assessments during 2014-2019 identified a cohort of employee smokers who were offered participation in employer-sponsored smoking cessation as part of the WHP wellness activities. This cohort became the LLUH BREATHE cohort (n=1,092) described in this report and is depicted in Figure 1 and Table 1.

WHP Screening and Risk Assessment. During organization-wide health plan enrollment campaigns in 2014 and 2017, advertising for the Wholeness Health Plan's wellness discount activities began with a formal letter sent by mail to each benefit-eligible employee's home. Subsequent communications were via postcard, email, mass telephone communications, fliers sent to each department, announcements posted in the organization's internal home webpage and articles in the employee newsletter. All communications invited employees to biometric screening and health risk assessment appointments

Biometric screenings were made available at the workplace to all employees, through a third party vendor and included anthropometric assessment, a metabolic panel, and screening for nicotine exposure (by self report and health plan claims data during 2014-2017; by salivary cotinine test from 2017-2019). Rolling admissions into the health plan outside these periods in 2014 and 2017 used a

similar methodology. A health risk assessment questionnaire included sections on health behaviors, psychological stress and personal safety.

Nicotine Screening during Health Plan Enrollment. Nicotine screening results from self-report, health plan claims data, or salivary cotinine testing were used to offer all employee smokers smoking cessation through their "opt in" for the WHP. Health Plan members were given a chance to appeal "nicotine positive" results and, if approved, allowed to enroll in the WHP without the requirement for smoking cessation as habitual tobacco user.

Smoking Cessation Interventions for WHP Members. The intervention has been described elsewhere[1]. Briefly, Cohort members who participated in the intervention were asked to complete two electronic survey forms (Intake/Pre- and Post-intervention), two physician visits, and either an online or in-person group version of the American Lung Association (ALA) 'Freedom from Smoking' course. This was an 8-week course that educated participants on the benefits of smoking cessation and assisted individuals in setting a 'quit date'. This program consisted of 8 weekly sessions that took approximately 1 hour to complete.

2.3 Statistical Analysis

Participation rates and 95% confidence intervals were computed with a continuity correction. Participants and non-participants were compared in chi-squared and t-tests. A non-parametric kernel smoother[12] was used to examine the trends in smoking cessation attempts, invites, and screens for tobacco use.

3. RESULTS

3.1 LLUH BREATHE Cohort Profile at Five Years of Follow-up (2014-2019)

During the first five years of follow-up, 415 current employee smokers were identified at the baseline enrollment campaign, and during subsequent follow-up and screening the cohort grew to 1,092 current and former (quit through screening and incentivized cessation sponsored by health plan) employee smokers (Figure 1). The continuously incentivized model produced a 74% (95% confidence interval=[71%

to 77%]) participation in an at least one employer sponsored, annual smoking cessation attempt during the follow-up. In table 1 we compare the biometric profiles of participants and non-participants in smoking cessation among LLUH BREATHE cohort members and found no significant differences. Total cholesterol was however higher in non-participants. We note that the unique design of LLUH BREATHE is such that non-participants can become participants during annual "opt in" periods to whether they can join the health plan with continuously incentivized smoking cessation.

In figure 2 (panel 1) we show that the enrollment campaigns produced two peaks (1/2014, 8/2017) of screen positive for tobacco use during the five years of follow-up (panel 1). Less than a year after an incentives were offered to those screening positive for tobacco use, we observed two peaks of smoking cessation attempts (figure 2, panels 2-3).

3.2 Plan of Analysis for the Cohort Profile

Participation, Point Prevalence Abstinence, and Time to Cessation.

Further analyses are needed to quantify the effect of successive enrollment campaigns on enhancing 1) participation rate, 2) point prevalence abstinence, 3) cessation attempts, and 4) time to cessation in a survival analysis. These outcomes can be related to demographic, behavioral, and health plan services used and costs incurred.

Modeling Dynamic Relapse in LLUH BREATHE

Traditional statistical models often cannot fully capture the dynamic relapse process in a nicotine cessation process where smokers often transition from one stage (current nicotine users) to another (early abstinence) and experience multiple quit attempts prior to quitting. Some smokers who are able to quit may even move onto a stage of long term cessation (long term abstinence) while many smokers often relapse back into their initial stage (current nicotine users). Dynamic modeling of nicotine cessation require novel methods such as Markov models to capture the transient nature of the relapse stages[13]. Figure 3 and Equation 1 shows a potential 3-stage Markov model where cessation moves the participants through stages left to right with probabilities, λ or θ, and relapsing moves the participants

from right to left with probabilities, γ or δ. In Markov models, transition probabilities (i.e. λ, θ, δ,γ; probability matrix of transitioning to next or previous stage; Figure 4) are usually pre-specified based on a-priori data, but can also be estimated. The Markov model can be expanded to include more stages to depict the natural behavioral process in nicotine cessation.

4. DISCUSSION

Our profile of the LLUH BREATHE Cohort reveals that our model of continuously incentivizing employee smokers to maintain or attempt employer sponsored smoking cessation was successful in promoting 74% of smokers to attempt smoking cessation less than a year after being offered the incentive. We note than even among the LLUH BREATHE employee smokers who did not participate, the incentive remains continuous since each year they are offered an annual "opt in" period to join the incentivized health plan model of cessation. Among the 415 current smokers identified at baseline in the LLUH BREATHE Cohort we have previously reported a 48% four month point prevalence abstinence among the 73% who participated[1].

4.1 What Questions are we going to ask (Moving Forward)?

LLUH BREATHE is a dynamic cohort that derives from a parent cohort of over 16,000 benefit-eligible employees. A number of recent developments in tobacco use and cessation in the US impact outcomes in this ongoing follow-up study and need measurement. First, the rapid proliferation of electronic nicotine delivery systems (i.e. e-cigarettes, e-pipes, and vaping pens) and heated tobacco devices needs more complete measurement in the employee smoking cessation program. Sensitivity analysis that considers electronic nicotine delivery systems, heated tobacco use, and poly-tobacco use in the cohort outcome variables is needed. The emergence of COVID 19 pandemic conditions among employees impacts smoking behaviors[14]. The relationship between smoking cessation and pertinent outcomes such as SARS-Cov-2 antibodies, infection and progression needs examination as population health measures become available.

4.2 Conclusions

The LLUH BREATHE cohort profiled in this report is an open, dynamic cohort of current and former smokers who are continuously incentivized to maintain or attempt tobacco cessation through an annual offer of a substantial "opt in wellness discount" on the out of pocket cost of their health plan. The initial findings from LLUH BREATHE indicated high rates of participation and four month abstinence rates [1]. Our profile of the cohort after more than 5 years of follow-up identifies a rich dataset for inquiry into workplace and health-plan based incentives for achieving long term abstinence from tobacco among employed adults.

Table 1. Demographics and health among LLUH employees who tested positive for nicotine and were offered participation in an incentivized health plan model for smoking cessation

Variable	Did Not Participate (n=282)	Participated (n=810)
Age	42.74 (11.09)	45.56 (11.49)
Gender: n (%)		
Male	180 (63.83%)	494 (60.99%)
Female	102 (36.17%)	316 (39.01%)
Enrollment Type: n (%)		
Subscriber	153 (54.26%)	453 (55.93%)
Spouse	129 (45.74%)	357 (44.07%)
Biometrics		
Weight (lbs)	191.24 (51.86)	192.83 (48.06)
Body Fat (%)	26.61 (8.9)	28.05 (9.19)
Waist Circumference	38.46 (6.7)	39.38 (12.72)
BMI (kg/m^2)	29.62 (6.51)	29.96 (6.41)
Systolic Blood Pressure (mmHg)	128.57 (17.02)	128.3 (17.62)
Diastolic Blood Pressure (mmHg)	79.7 (11.76)	78.62 (11.34)
Total Cholesterol (mg/dL)	185.49 (37.95)	179.77 (35.37)
HDL (mg/dL)	46.75 (16.45)	44.35 (15.18)
HDL Ratio	4.51 (2.1)	4.5 (1.82)
Fasting Glucose (mg/dL)	94.78 (25.97)	95.39 (29.1)
Non Fasting Glucose (mg/dL)	102.08 (21.47)	103.95 (35.31)
LDL (mg/dL)	115.11 (35.72)	109.19 (33.39)
Triglycerides (mg/dL)	146.41 (115.38)	157.81 (117.73)

Figure Legends

Figure 1. Enrollment of LLUH BREATHE Employee Smoker Cohort (2014-2019). ENDS denotes electronic nicotine delivery systems.

Figure 2. Rate of tobacco screening, incentivized health plan invites, and smoking cessation attempts among LLUH employees (2014-2019).

Figure 3. A 3-stage Markov model of the smoking cessation relapse process with Latin symbols indicating the transition probabilities. Cessation moves the participants through stages left to right with lapses from long term abstinence to early abstinence with probability, γ, and lapses from early abstinence to current nicotine users with probability, δ.

Figure 4. Transition probability matrix of current stages of nicotine cessation. Current nicotine users who continue to use and remain in "Current Nicotine Users" stage with probability (1-λ) or go into next stage, "Early Abstinence," with probability λ. Participants in "Early Abstinence" stage may relapse with probability, δ, stay in current "Early Abstinence" with probability $(1 - \delta - \theta)$, or move to the next phase.

Contributor-ship statement

PS wrote the final version of the paper, analyzed the data, obtained the funding; OM conceived the study, edited the paper; WS analyzed the data and wrote sections of the paper; MH edited the paper.

Competing Interest

The authors declare no competing interest.

Data Sharing Statement

The authors will honor all reasonable requests for de-identified data.

Patient and Public Involvement Statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

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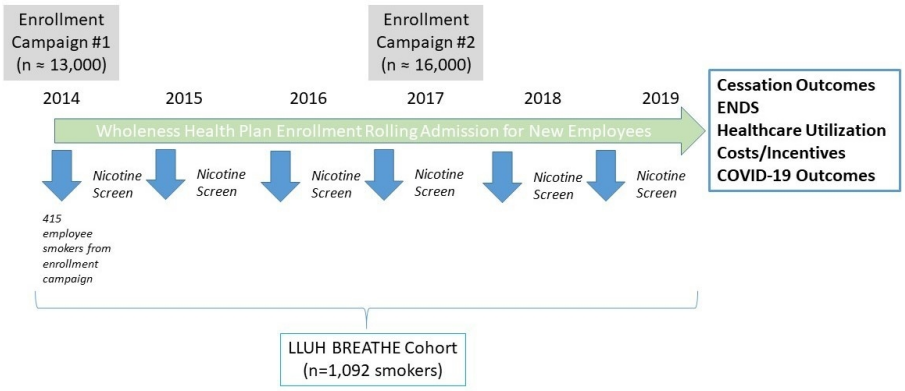

Figure 1. Enrollment of LLUH BREATHE Employee Smoker Cohort (2014-2019). ENDS denotes electronic nicotine delivery systems.

338x138mm (96 x 96 DPI)

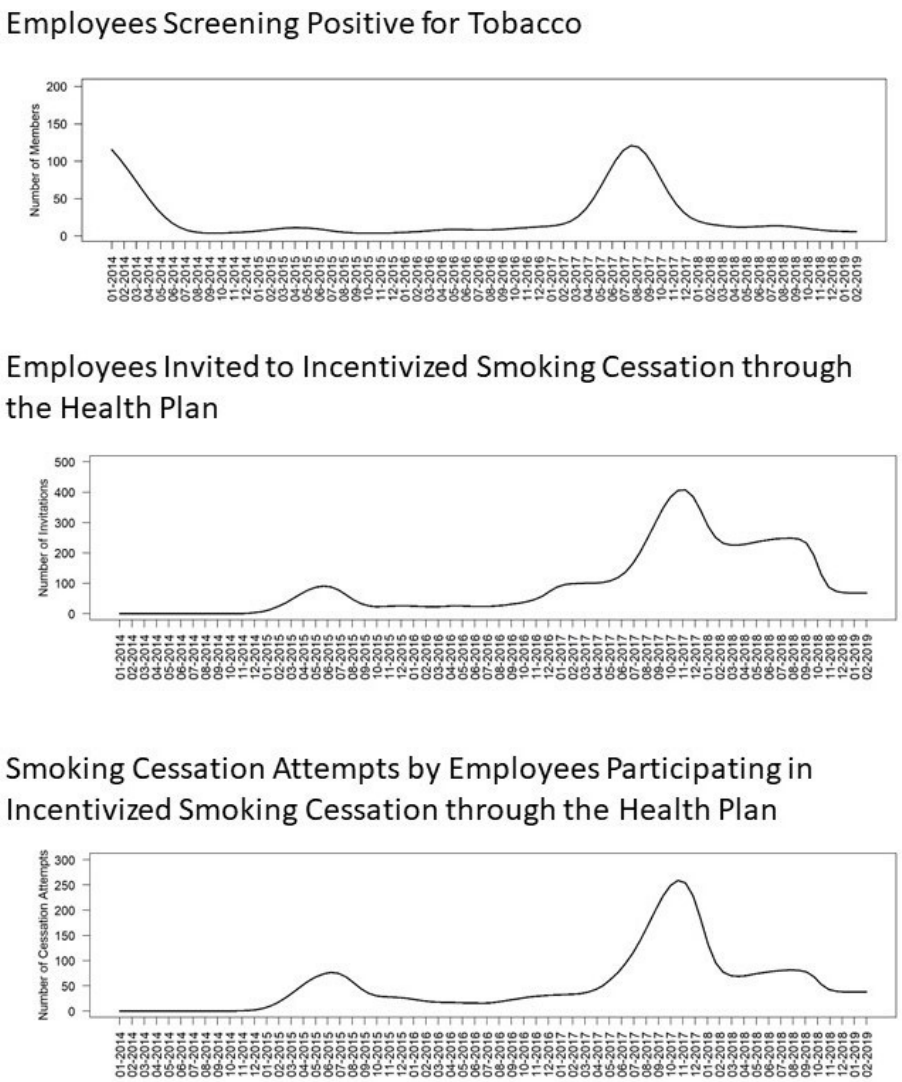

Figure 2. Rate of tobacco screening, incentivized health plan invites, and smoking cessation attempts among LLUH employees (2014-2019).

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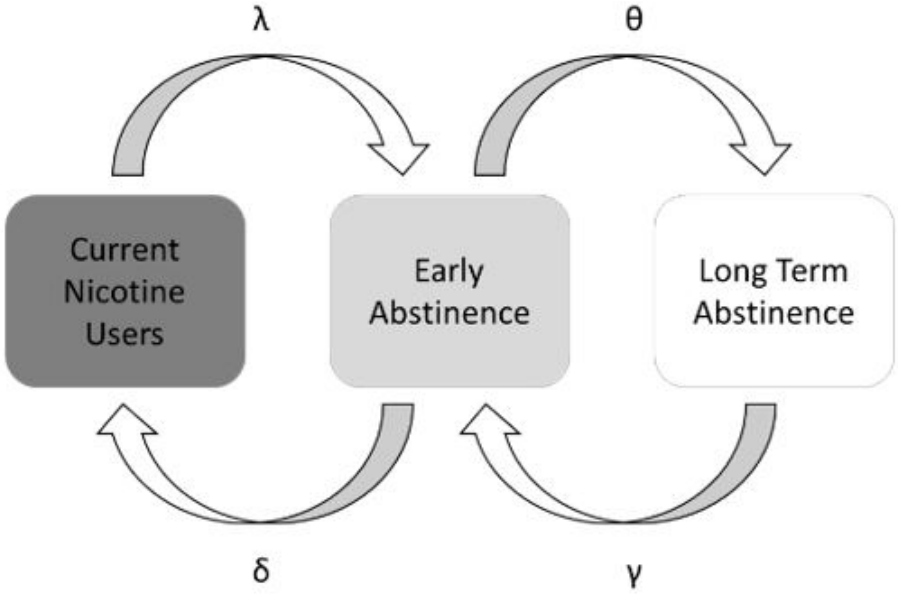

Figure 3. A 3-stage Markov model of the smoking cessation relapse process with Latin symbols indicating the transition probabilities. Cessation moves the participants through stages left to right with lapses from long term abstinence to early abstinence with probability, γ, and lapses from early abstinence to current nicotine users with probability, δ.

117x74mm (120 x 120 DPI)

$$P = \begin{bmatrix} 1-\lambda & \lambda & 0 \\ \delta & 1-\delta-\theta & \theta \\ 0 & \gamma & 1-\gamma \end{bmatrix}$$

Figure 4. Transition probability matrix of current stages of nicotine cessation. Current nicotine users who continue to use and remain in "Current Nicotine Users" stage with probability (1-λ) or go into next stage, "Early Abstinence," with probability λ. Participants in "Early Abstinence" stage may relapse with probability, δ, stay in current "Early Abstinence" with probability (1-δ-θ), or move to the next phase.

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Cohort Profile for the Loma Linda University Health BREATHE Program: A Model to Study Continuously Incentivized Employee Smoking Cessation

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ABSTRACT

Purpose: The purpose of the LLUH BREATHE Cohort is to test the efficacy of a novel method of continuously incentivizing participation in workplace smoking cessation on participation, long-term abstinence, health outcomes, healthcare costs, and health care utilization.

Participants: In 2014, Loma Linda University Health (LLUH) – a US academic medical center and university – incentivized participation in a workplace smoking cessation program (LLUH BREATHE) by lowering health plan costs. Specifically, LLUH introduced a Wholeness Health Plan (WHP) option that, for the smokers, continuously incentivizes participation in nicotine screening and the LLUH BREATHE smoking cessation program by offering an "opt-in wellness discount" that consisted of 50-53% lower out of pocket health plan costs (i.e. monthly employee premiums, co-payments). This novel "continuously incentivized" model lowers annual health plan costs for smokers who, on an annual basis, attempt or maintain cessation from tobacco use. The annual WHP cost savings for smokers far exceeds the value of short-term incentives that have been tested in workplace cessation trials to date. This ongoing health plan option offered to over 16,000 employees has created an open, dynamic LLUH BREATHE cohort of current and former smokers (n=1,092).

Findings to Date: Our profile of the LLUH BREATHE cohort indicates that after five years of follow-up in a prospective cohort study (2014-2019), continuously incentivized smoking cessation produced a 74% participation (95% confidence interval=[71% to 77%]) in employer-sponsored smoking cessation attempts that were occurring less than a year after the incentive was offered. The cohort can be purposed to examine the effect of continuously incentivized cessation on cessation outcomes, health plan utilization/costs, use of electronic nicotine delivery systems, and COVID-19 outcomes.

Strengths and Limitations of the Study

Strengths

- **An open employee cohort of over 16,000 that is continuously incentivized through health plan discounts to maintain abstinence or attempt cessation from tobacco.**
- **Linkages to a wide range of employee cohort data on health outcomes, health plan utilization costs, and cessation outcomes.**

Limitations

- **Findings are based on a cohort of university and medical center employees and the effects of incentives need investigation in other employee groups.**

1. INTRODUCTION

Loma Linda University Health (LLUH) is an academic medical center with over 16,000 employees working in eight health science schools, six hospitals, and a physician practice corporation. In 2014, LLUH introduced an option within the employee health plan – The Wholeness Health Plan (WHP) – that provided employees with an "opt-in wellness discount" that consisted of 50-53% lower out of pocket health plan costs (i.e. monthly employee premiums, co-payments for prescriptions)[1]. The rationale for the WHP "opt-in wellness discount" was to address the burdens caused by social determinants of employee health by investing health plan resources in an incentivized prevention model.

To qualify for the WHP "opt-in wellness discount", employee smokers (identified through self-report, health claims data, organization-wide health risk assessments and biometric screening) were required to participate in LLUH BREATHE – the WHP's smoking cessation program[1].

A particularly innovative feature of the LLUH BREATHE smoking cessation model was that the "opt-in wellness discount" through the WHP was available to all employee smokers as long as they met the requirement of annual participation in smoking cessation for current employee smokers. Thus, **employee smokers on the WHP were continuously incentivized into smoking cessation through two mechanisms**: 1) WHP members who had participated in LLUH BREATHE smoking cessation program and did not relapse, maintained their "opt-in wellness discount" through the WHP, and 2) WHP members who had participated in LLUH BREATHE smoking cessation program but later relapsed were required to enroll in the annual LLUH BREATHE smoking cessation program in order to maintain their "opt-in wellness discount" through the WHP. **Additional features of the "continuous incentive" model include**: 1) WHP members who were non- or never-smokers since hiring needed to maintain abstinence to retain their "opt-in wellness discount", and 2) Employee smokers who did not enroll in the WHP could, during an annual buy-in period, re-visit that choice and "opt-in" to WHP and the requirement to participate in smoking cessation.

This organizational model of **continuously incentivized employee smoking cessation** implemented at LLUH provides a "natural experiment" to prospectively study the LLUH BREATHE cohort - a dynamic, open employee cohort of current smokers (non-participants in LLUH BREATHE), former smokers (cessation through LLUH BREATHE), and relapsed smokers (relapse after cessation through LLUH BREATHE) who are, on a continuous basis, offered an "opt in" incentive (i.e. discounted WHP coverage) by their employer to attempt, achieve, or maintain abstinence from tobacco smoking.

The overall aim of this report is to provide a cohort profile of the first 5 years of follow-up (2014-2019) of the LLUH BREATHE cohort that enables the development of a research framework for a longitudinal study of the effects of a continuously incentivized employee smoking cessation model on a wide range of population health outcomes. The cohort profile will include the most current 5-year estimate of participation rate, temporal trends during 5-years of enrollment, and future plans of analysis of high impact outcomes of incentivized smoking cessation model (i.e. early and long term abstinence, relapse patterns, health care utilization, health economics, COVID-19 outcomes).

The secondary analysis of these health plan data received IRB approval (IRB #5170126) from the Institutional Review Board of Loma Linda University .

2.Cohort Description

2.1 How did we develop the Wholeness Health Plan that produced the LLUH BREATHE Cohort?

Background of the Wholeness Health Plan

Loma Linda University Health (LLUH) is an Innovator in Wellness and Population Health. LLUH is a Seventh-day Adventist institution that as part of its mission to "Keep Man Whole" promotes specific faith-based principles of healthy lifestyle and disease prevention in its healthcare, academic teaching, administration, and campus and hospital environment[2, 3]. These include avoidance of tobacco and alcohol, and adherence to a plant-based diet pattern that encourages consumption of specific plant foods (i.e., legumes, nuts) in place of animal products[2]. Academic entities of LLUH (Schools of

Medicine, Public Health) have completed more than 60 years of landmark, NIH-funded prospective cohort studies [1960 Adventist Mortality Study, 1976 Adventist Health Study-1, 2002 Adventist Health Study-2][4, 5] that have documented how healthy lifestyle behaviors (avoidance of tobacco and alcohol, plant-based diet patterns) practiced by Seventh-day Adventists are associated with lower risk of cancer, coronary heart disease, stroke, diabetes, and a longer life expectancy[2, 6].

Living Whole Employee Wellness Program at LLUH. The Department of Risk Management at LLUH administers a health plan that is offered to all benefit-eligible employees and their families. The health plan is employer-sponsored and designed to reimburse a broad range of medical expenses for benefit-eligible employees. To align the health plan with LLUH mission-focused principles on wellness, the Department of Risk Management implemented the Living Whole Employee Wellness program to provide a comprehensive range of wellness and disease management services to support employee health. Employees could participate in this program voluntarily. The program included but was not limited to programs on weight management, diabetes management through lifestyle interventions, smoking cessation, and cooking classes.

Development of the Wholeness Health Plan (WHP) at LLUH. In 2014, the Department of Risk Management expanded upon the success of the Living Whole Employee Wellness Program by incorporating incentivized wellness options into a new employer-provided health plan option (WHP) that was based on an "opt-in wellness discount". The wellness discount consisted of a 50-53% reduction in out of pocket health plan costs (monthly costs, co-pays for prescriptions) in the existing health plan options from LLUH Risk Management. The rationale for WHP was as follows: 1) Participation in a biometric screening, health risk assessment (HRA), and wellness and prevention information provided at enrollment empowered each health plan member and their families to be actively involved in managing personal health and wellness, 2) The biometric screening and HRA data obtained at enrollment allowed the health plan to assess member health to enhance the precision of

health/wellness resources and population health interventions that are offered. Employees received the wellness discount through WHP enrollment if they completed a biometric screening, a health risk assessment, created an account in the hospital's patient/doctor portal, and agreed to participate in a care management program based on results obtained from the screening and risk assessments. The care management program included 1) biometric result review appointments with a primary care physician, 2) appointments with a nurse care manager for health plan members classified as high risk and/or multiple chronic diseases, and 3) smoking cessation for those identified as tobacco users based on either self-reported health risk assessment or biometric screening.

LLUH Breathe Cohort: A Natural Experiment to Study Employee Smoking Cessation that is Continuously Incentivized by the employer-provided Wholeness Health Plan (WHP)

The LLUH Breathe Cohort can be used to study the effects of an innovative model to continuously incentivize employees who are current or former smokers to continue quit attempts or maintain abstinence from smoking tobacco. To provide a context for our methods of studying the effects of LLUH BREATHE, we describe and compare the efficacy of incentive-based smoking cessation models used by other organizations. Incentive-based programs fall into the categories of rewards-based incentives, cash-based incentives, deposit-based incentives, lottery- or completion-based incentives, and mixed models using a combination of these approaches[7].

Rewards Based Incentives. Programs at CVS Pharmacy[8, 9] and Blue Cross/Blue Shield[10] have used a rewards-based mechanism ($100 to $800 in value) whereby at key smoking cessation milestones (quit date set, quit date, 14 day/30-day/6 month point prevalence abstinence) reward points are earned towards 1) subsidized co-payments and costs for prescription and over the counter cessation aids, 2) redemption as cash credits for groceries and personal items in selected stores.

Cash-based Incentives. Direct cash-based incentives include models that provide cash payments for attending a health assessment for smoking cessation (i.e. $50 for a first appointment and setting a quit

date) and then provide payments on achieving abstinence goals (amounts summing from $120 to in excess of $800 for long term abstinence)[7].

Deposit-based Incentives. Under deposit-based incentives, subjects deposit money into a health savings account and are refunded upon achieving abstinence goals[8].

Competition and Lottery-based Incentives. This incentive model included designs where groups of employees compete against each other for cash prizes given to the highest cessation rate[11]. Also, in lottery based incentive programs ("Quit and Win") an individual employee in the cessation group is eligible to win a cash prize[11].

Mixed Models. Under the mixed models[8], combinations of reward, cash, deposit-based, and/or competition/lottery-based incentives are used. For example, reward points for cessation behaviors can be redeemed as cash. Also, deposits are often combined with cash incentives in excess of the amount deposited by a smoker who quits.

Comparison of Incentive Models with LLUH BREATHE. Several large-scale meta-analyses of the incentive models have consistently shown that cash/reward-based incentives have higher participation and efficacy than deposit or competition/lottery-based incentives[7, 11]. Moreover in direct comparison of these models in CVS/Caremark employees, Halpern et al. specifically demonstrated the efficacy of cash/reward programs that used higher value (up to $800) incentives[8, 9].

Relative to previous incentivized models, LLUH BREATHE provides a novel approach to incentivized intervention that consists of: 1) a mixed model of cash-based (a lower paycheck deduction for health plan coverage equates to more cash per pay period) and reward-based incentives (lower co-pays for prescriptions), 2) a socio-ecologic framework whereby participants are choosing smoking cessation as part of a personal and familial/spousal choice to "opt-in" to the WHP directed choices of health and wellness programs, and 3) a continuous incentive as a WHP member to continue quit attempts or maintain abstinence from tobacco use.

2.2 How did we enroll the LLUH BREATHE Cohort (Figure 1)?

Organization-wide Biometric Screening for WHP enrolls the LLU BREATHE Cohort.

Overview. At the inception of the WHP as a health plan option in 2014, WHP enrollees underwent a series of biometric screenings and health risk assessments to provide employee health profile data. The biometric screening and health risk assessments were done as an organization-wide enrollment campaign during specific open-enrollment periods in November of 2014 and 2017. New hires were enrolled into the WHP on a rolling enrollment basis. Benefit-eligible employees have the opportunity to enroll in the WHP and qualify for the wellness discount every year. The biometric screenings and health risk assessments during 2014-2019 identified a cohort of employee smokers who were offered participation in employer-sponsored smoking cessation as part of the WHP wellness activities. This cohort became the LLUH BREATHE cohort (n=1,092) described in this report and is depicted in Figure 1 and Table 1.

WHP Screening and Risk Assessment. During organization-wide health plan enrollment campaigns in 2014 and 2017, advertising for the Wholeness Health Plan's wellness discount activities began with a formal letter sent by mail to each benefit-eligible employee's home. Subsequent communications were via postcard, email, mass telephone communications, fliers sent to each department, announcements posted in the organization's internal home webpage and articles in the employee newsletter. All communications invited employees to biometric screening and health risk assessment appointments

Biometric screenings were made available at the workplace to all employees through a third party vendor and included anthropometric assessment, a metabolic panel, and screening for nicotine exposure (by self-report and health plan claims data during 2014-2017; by salivary cotinine test from 2017-2019). Rolling admissions into the health plan outside these periods in 2014 and 2017 used a similar methodology. A health risk assessment questionnaire included sections on health behaviors, psychological stress and personal safety.

Nicotine Screening during Health Plan Enrollment. Nicotine screening results from self-report, health plan claims data, or salivary cotinine testing were used to offer all employee smokers smoking cessation through their "opt in" for the WHP. Health Plan members were given a chance to appeal "nicotine positive" results and, if approved, allowed to enroll in the WHP without the requirement for smoking cessation as habitual tobacco user.

Smoking Cessation Interventions for WHP Members. The intervention has been described elsewhere[1]. Briefly, Cohort members who participated in the intervention were asked to complete two electronic survey forms (Intake/Pre- and Post-intervention), two physician visits, and either an online or in-person group version of the American Lung Association (ALA) 'Freedom from Smoking' course. This was an 8-week course that educated participants on the benefits of smoking cessation and assisted individuals in setting a 'quit date'. This program consisted of 8 weekly sessions that took approximately 1 hour to complete.

Relapse in WHP Members. Relapses were detected through voluntary self-report to provider, health plan claims data, or salivary cotinine testing during opt-in enrollment periods. It is noteworthy, however, that a relapsed WHP smoker who continues annual quit attempts on the LLUH BREATHE program remains a WHP member.

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2.3 Statistical Analysis

To achieve our overall aim of providing a cohort profile, we conducted analyses to give the latest participation rate in the cohort and to provide temporal trends in screening, enrollment, and completion of smoking cessation of the employee smokers. Participation rates and 95% confidence intervals were computed with a continuity correction[12]. Participants and non-participants were compared in chi-squared and t-tests[12]. A non-parametric kernel smoother[13] was used to examine the trends in count-based data on smoking cessation attempts, invites, and screens for tobacco use.

2.4 Patient and Public Involvement

The data for this cohort study is from the employee health plan of a private non profit organization. It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

3. Findings to Date

3.1 LLUH BREATHE Cohort Profile at Five Years of Follow-up (2014-2019)

Our group has reported that, during the first year of follow-up, there was a 73% participation rate among in the continuously incentivized model of employee smoking cessation in LLUH BREATHE. The first year cessation rate of LLUH BREATHE participants was also notably high (48% achieved a four month point prevalence abstinence)[1]. Pilot qualitative data provide preliminary clues that the WHP cohort members and their providers are receptive to the incentivized intervention model[14]

During the first five years of follow-up, the cohort grew to 1,092 current and former (quit through screening and incentivized cessation sponsored by health plan) employee smokers identified among more than 16,000 employees(Figure 1). The continuously incentivized model produced a 74% (95% confidence interval=[71% to 77%]) participation in an at least one employer sponsored, annual smoking cessation attempt during the follow-up. In table 1 we compare the biometric profiles of participants and non-participants in smoking cessation among LLUH BREATHE cohort members and found no significant differences. Total cholesterol was however higher in non-participants. We note that the unique design of LLUH BREATHE is such that non-participants can become participants during annual “opt in” periods.

In figure 2 (panel 1) we show that the enrollment campaigns produced two peaks (1/2014, 8/2017) of screen positive for tobacco use during the five years of follow-up (panel 1). Less than a year after incentives were offered to those screening positive, we observed two peaks of smoking cessation attempts (figure 2, panels 2-3).

3.2 Plan of Analysis for the Cohort Profile

Participation, Point Prevalence Abstinence, and Time to Cessation.

We will conduct further quantitative and qualitative analyses to measure the effect of successive enrollment campaigns on enhancing 1) participation rate, 2) point prevalence abstinence, 3) cessation attempts, and 4) time to cessation in a survival analysis. These outcomes can be related to demographic, behavioral, health plan services used, nicotine screening methods (self-report, bio-specimen testing, re-testing appeals), and costs incurred. We are beginning to publish exploratory qualitative analyses of WHP and LLUH BREATHE cohort member program experiences to identify programmatic areas for improvement[14].

Modeling Dynamic Relapse in LLUH BREATHE

Traditional statistical models often cannot fully capture the dynamic relapse process in a nicotine cessation process where smokers often transition from one stage (current nicotine users) to another (early abstinence) and experience multiple quit attempts prior to quitting. Some smokers who are able to quit may even move onto a stage of long term cessation (long term abstinence) while many smokers often relapse back into their initial stage (current nicotine users). Dynamic modeling of nicotine cessation require novel methods such as Markov models to capture the transient nature of the relapse stages[15]. Figure 3 and Equation 1 shows a potential 3-stage Markov model where cessation moves the participants through stages left to right with probabilities, λ or θ, and relapsing moves the participants from right to left with probabilities, γ or δ. In Markov models, transition probabilities (i.e. λ, θ, δ,γ; probability matrix of transitioning to next or previous stage; Figure 4) are usually pre-specified based on a-priori data, but can also be estimated. The Markov model can be expanded to include more stages to depict the natural behavioral process in nicotine cessation.

4. DISCUSSION

Our profile of the LLUH BREATHE Cohort reveals that our model of continuously incentivizing employee smoking cessation produced a 74% participation rate in an employer-sponsored quit attempt less than a

year after being offered the incentive. This participation rate among employee smokers is much higher than the norms (median of 28%) for employee participation in more than 20 studies of employee smoking cessation in affluent nations[7, 16].

One potential reason why the overall participation rate of employee smokers in LLUH BREATHE is higher than national norms is that the cash/reward model is of particularly high cash value[1]. Specifically, the LLUH BREATHE model[1] of decreasing out of pocket health plan costs by 50-53% provides a financial incentive ($600 to $1200 in lower health plan costs per year) that far exceeds other incentivized cash/reward employee smoking cessation models (up to $800 is annual cash/rewards) that have been reported in the peer-reviewed scientific literature[7-9]. For the LLUH BREATHE cohort, further study is needed to measure the relationship between the cash value of the incentive on long-term abstinence. We note that incentives can be a component of long term smoking cessation but are not a "stand-alone" cessation method for employees or in other contexts.

4.1 What Questions are we going to ask (Moving Forward)?

LLUH BREATHE is a dynamic cohort that derives from a parent cohort of over 16,000 benefit-eligible employees. A number of recent developments in tobacco use and cessation in the US impact outcomes in this ongoing follow-up study and need measurement. First, the rapid proliferation of electronic nicotine delivery systems (i.e. e-cigarettes, e-pipes, and vaping pens) and heated tobacco devices needs more complete measurement in the employee smoking cessation program. Sensitivity analysis that considers electronic nicotine delivery systems, heated tobacco use, and poly-tobacco use in the cohort outcome variables is needed. The emergence of COVID 19 pandemic conditions among employees impacts smoking behaviors[17]. The relationship between smoking cessation and pertinent outcomes such as SARS-Cov-2 antibodies, infection and progression needs examination as population health measures become available.

4.2 Conclusions

The LLUH BREATHE cohort profiled in this report is an open, dynamic cohort of current and former smokers who are continuously incentivized to maintain or attempt tobacco cessation through an "opt-in wellness discount" on the out of pocket cost of their health plan. The initial findings from LLUH BREATHE indicated 1) high rates of participation and four month abstinence rates [1], and 2) preliminary findings of acceptability of the incentivized health plan model to members and providers[14]. Our profile of the cohort after more than 5 years of follow-up identifies a rich dataset for inquiry into workplace and health-plan based incentives for achieving long term abstinence from tobacco among employed adults.

5. Collaboration Statement

The authors encourage collaborative work with other investigators and will make the de-identified data on the abstinence, relapse, and basic demographics available in response to all reasonable requests. These collaborations can include pooling projects, meta-analyses, and re-analysis of the cohort data.

Table 1. Demographics and health among LLUH employees who tested positive for nicotine and were offered participation in an incentivized health plan model for smoking cessation

Variable	Did Not Participate (n=282)	Participated (n=810)
Age	42.74 (11.09)	45.56 (11.49)
Gender: n (%)		
Male	180 (63.83%)	494 (60.99%)
Female	102 (36.17%)	316 (39.01%)
Enrollment Type: n (%)		
Subscriber	153 (54.26%)	453 (55.93%)
Spouse	129 (45.74%)	357 (44.07%)
Biometrics		
Weight (lbs)	191.24 (51.86)	192.83 (48.06)
Body Fat (%)	26.61 (8.9)	28.05 (9.19)
Waist Circumference	38.46 (6.7)	39.38 (12.72)
BMI (kg/m^2)	29.62 (6.51)	29.96 (6.41)
Systolic Blood Pressure (mmHg)	128.57 (17.02)	128.3 (17.62)
Diastolic Blood Pressure (mmHg)	79.7 (11.76)	78.62 (11.34)
Total Cholesterol (mg/dL)	185.49 (37.95)	179.77 (35.37)
HDL (mg/dL)	46.75 (16.45)	44.35 (15.18)
HDL Ratio	4.51 (2.1)	4.5 (1.82)
Fasting Glucose (mg/dL)	94.78 (25.97)	95.39 (29.1)
Non Fasting Glucose (mg/dL)	102.08 (21.47)	103.95 (35.31)
LDL (mg/dL)	115.11 (35.72)	109.19 (33.39)
Triglycerides (mg/dL)	146.41 (115.38)	157.81 (117.73)

Figure Legends

Figure 1. Enrollment of LLUH BREATHE Employee Smoker Cohort (2014-2019). ENDS denotes electronic nicotine delivery systems.

Figure 2. Rate of tobacco screening, incentivized health plan invites, and smoking cessation attempts among LLUH employees (2014-2019).

Figure 3. A 3-stage Markov model of the smoking cessation relapse process with Latin symbols indicating the transition probabilities. Cessation moves the participants through stages left to right with lapses from long term abstinence to early abstinence with probability, γ, and lapses from early abstinence to current nicotine users with probability, δ.

Figure 4. Transition probability matrix of current stages of nicotine cessation. Current nicotine users who continue to use and remain in "Current Nicotine Users" stage with probability (1-λ) or go into next stage, "Early Abstinence," with probability λ. Participants in "Early Abstinence" stage may relapse with probability, δ, stay in current "Early Abstinence" with probability $(1 - \delta - \theta)$, or move to the next phase.

Contributor-ship statement
PS wrote the final version of the paper, analyzed the data, obtained the funding; OM conceived the study, edited the paper; WS analyzed the data and wrote sections of the paper; MH edited the paper.

Competing Interest
The authors declare no competing interest.

Data Sharing Statement
The authors will honor all reasonable requests for de-identified data.

Patient and Public Involvement Statement
Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

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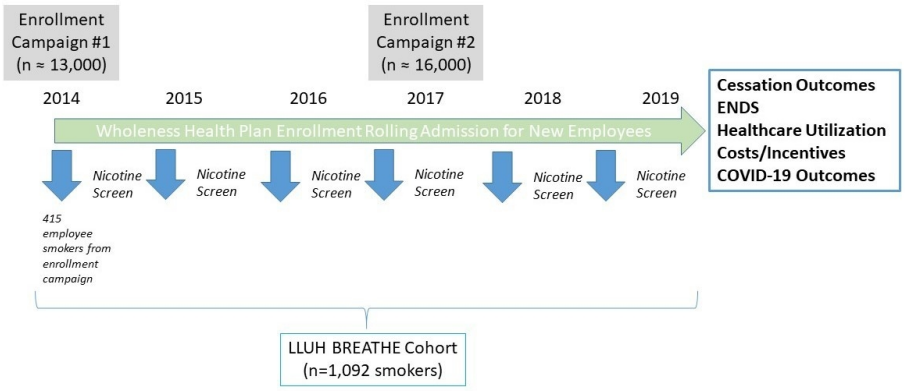

Figure 1. Enrollment of LLUH BREATHE Employee Smoker Cohort (2014-2019). ENDS denotes electronic nicotine delivery systems.

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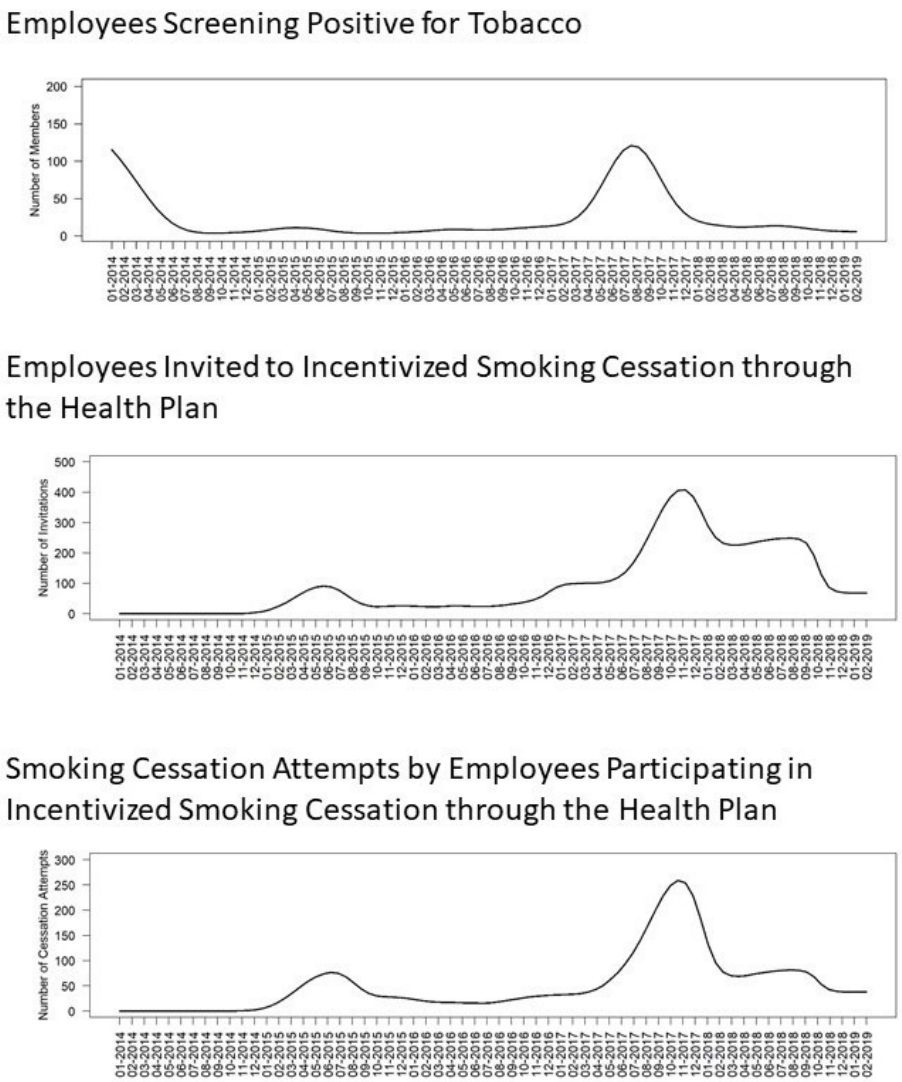

Figure 2. Rate of tobacco screening, incentivized health plan invites, and smoking cessation attempts among LLUH employees (2014-2019).

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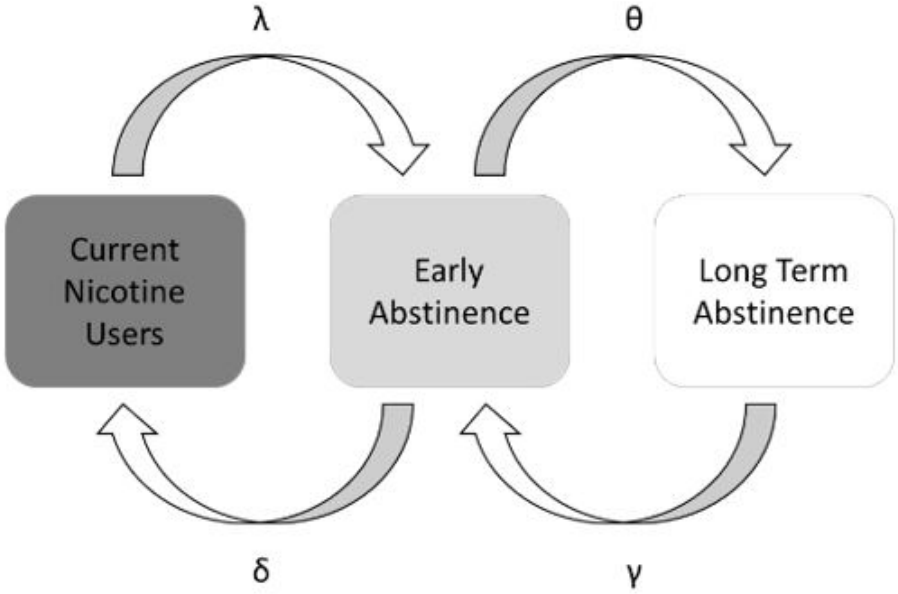

Figure 3. A 3-stage Markov model of the smoking cessation relapse process with Latin symbols indicating the transition probabilities. Cessation moves the participants through stages left to right with lapses from long term abstinence to early abstinence with probability, γ, and lapses from early abstinence to current nicotine users with probability, δ.

117x74mm (120 x 120 DPI)

$$P = \begin{bmatrix} 1-\lambda & \lambda & 0 \\ \delta & 1-\delta-\theta & \theta \\ 0 & \gamma & 1-\gamma \end{bmatrix}$$

Figure 4. Transition probability matrix of current stages of nicotine cessation. Current nicotine users who continue to use and remain in "Current Nicotine Users" stage with probability (1-λ) or go into next stage, "Early Abstinence," with probability λ. Participants in "Early Abstinence" stage may relapse with probability, δ, stay in current "Early Abstinence" with probability (1-δ-θ), or move to the next phase.

111x35mm (120 x 120 DPI)

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Cohort Profile for the Loma Linda University Health BREATHE Program: A Model to Study Continuously Incentivized Employee Smoking Cessation

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Cohort Profile for the Loma Linda University Health BREATHE Program: A Model to Study Continuously Incentivized Employee Smoking Cessation

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ABSTRACT

Purpose: The purpose of the LLUH BREATHE Cohort is to test the efficacy of a novel method of continuously incentivizing participation in workplace smoking cessation on participation, long-term abstinence, health outcomes, healthcare costs, and health care utilization.

Participants: In 2014, Loma Linda University Health (LLUH) – a US academic medical center and university – incentivized participation in a workplace smoking cessation program (LLUH BREATHE) by lowering health plan costs. Specifically, LLUH introduced a Wholeness Health Plan (WHP) option that, for the smokers, continuously incentivizes participation in nicotine screening and the LLUH BREATHE smoking cessation program by offering an "opt-in wellness discount" that consisted of 50-53% lower out of pocket health plan costs (i.e. monthly employee premiums, co-payments). This novel "continuously incentivized" model lowers annual health plan costs for smokers who, on an annual basis, attempt or maintain cessation from tobacco use. The annual WHP cost savings for smokers far exceeds the value of short-term incentives that have been tested in workplace cessation trials to date. This ongoing health plan option offered to over 16,000 employees has created an open, dynamic LLUH BREATHE cohort of current and former smokers (n=1,092).

Findings to Date: Our profile of the LLUH BREATHE cohort indicates that after five years of follow-up in a prospective cohort study (2014-2019), continuously incentivized smoking cessation produced a 74% participation (95% confidence interval=[71% to 77%]) in employer-sponsored smoking cessation attempts that were occurring less than a year after the incentive was offered. The cohort can be purposed to examine the effect of continuously incentivized cessation on cessation outcomes, health plan utilization/costs, use of electronic nicotine delivery systems, and COVID-19 outcomes.

Strengths and Limitations of the Study

Strengths

- **An open employee cohort of over 16,000 that is continuously incentivized through health plan discounts to maintain abstinence or attempt cessation from tobacco.**
- **Linkages to a wide range of employee cohort data on health outcomes, health plan utilization costs, and cessation outcomes.**

Limitations

- **Findings are based on a cohort of university and medical center employees and the effects of incentives need investigation in other employee groups.**

1. INTRODUCTION

Loma Linda University Health (LLUH) is an academic medical center with over 16,000 employees working in eight health science schools, six hospitals, and a physician practice corporation. In 2014, LLUH introduced an option within the employee health plan – The Wholeness Health Plan (WHP) – that provided employees with an "opt-in wellness discount" that consisted of 50-53% lower out of pocket health plan costs (i.e. monthly employee premiums, co-payments for prescriptions)[1]. The rationale for the WHP "opt-in wellness discount" was to address the burdens caused by social determinants of employee health by investing health plan resources in an incentivized prevention model.

To qualify for the WHP "opt-in wellness discount", employee smokers (identified through self-report, health claims data, organization-wide health risk assessments and biometric screening) were required to participate in LLUH BREATHE – the WHP's smoking cessation program[1].

A particularly innovative feature of the LLUH BREATHE smoking cessation model was that the "opt-in wellness discount" through the WHP was available to all employee smokers as long as they met the requirement of annual participation in smoking cessation for current employee smokers. Thus, **employee smokers on the WHP were continuously incentivized into smoking cessation through two mechanisms**: 1) WHP members who had participated in LLUH BREATHE smoking cessation program and did not relapse, maintained their "opt-in wellness discount" through the WHP, and 2) WHP members who had participated in LLUH BREATHE smoking cessation program but later relapsed were required to enroll in the annual LLUH BREATHE smoking cessation program in order to maintain their "opt-in wellness discount" through the WHP. **Additional features of the "continuous incentive" model include**: 1) WHP members who were non- or never-smokers since hiring needed to maintain abstinence to retain their "opt-in wellness discount", and 2) Employee smokers who did not enroll in the WHP could, during an annual buy-in period, re-visit that choice and "opt-in" to WHP and the requirement to participate in smoking cessation.

This organizational model of **continuously incentivized employee smoking cessation** implemented at LLUH provides a "natural experiment" to prospectively study the LLUH BREATHE cohort - a dynamic, open employee cohort of current smokers (non-participants in LLUH BREATHE), former smokers (cessation through LLUH BREATHE), and relapsed smokers (relapse after cessation through LLUH BREATHE) who are, on a continuous basis, offered an "opt in" incentive (i.e. discounted WHP coverage) by their employer to attempt, achieve, or maintain abstinence from tobacco smoking.

The overall aim of this report is to provide a cohort profile of the first 5 years of follow-up (2014-2019) of the LLUH BREATHE cohort that enables the development of a research framework for a longitudinal study of the effects of a continuously incentivized employee smoking cessation model on a wide range of population health outcomes. The cohort profile will include the most current 5-year estimate of participation rate, temporal trends during 5-years of enrollment, and future plans of analysis of high impact outcomes of incentivized smoking cessation model (i.e. early and long term abstinence, relapse patterns, health care utilization, health economics, COVID-19 outcomes).

The secondary analysis of these health plan data received IRB approval (IRB #5170126) from the Institutional Review Board of Loma Linda University .

2.Cohort Description

2.1 How did we develop the Wholeness Health Plan that produced the LLUH BREATHE Cohort?

Background of the Wholeness Health Plan

Loma Linda University Health (LLUH) is an Innovator in Wellness and Population Health. LLUH is a Seventh-day Adventist institution that as part of its mission to "Keep Man Whole" promotes specific faith-based principles of healthy lifestyle and disease prevention in its healthcare, academic teaching, administration, and campus and hospital environment[2, 3]. These include avoidance of tobacco and alcohol, and adherence to a plant-based diet pattern that encourages consumption of specific plant foods (i.e., legumes, nuts) in place of animal products[2]. Academic entities of LLUH (Schools of

Medicine, Public Health) have completed more than 60 years of landmark, NIH-funded prospective cohort studies [1960 Adventist Mortality Study, 1976 Adventist Health Study-1, 2002 Adventist Health Study-2][4, 5] that have documented how healthy lifestyle behaviors (avoidance of tobacco and alcohol, plant-based diet patterns) practiced by Seventh-day Adventists are associated with lower risk of cancer, coronary heart disease, stroke, diabetes, and a longer life expectancy[2, 6].

Living Whole Employee Wellness Program at LLUH. The Department of Risk Management at LLUH administers a health plan that is offered to all benefit-eligible employees and their families. The health plan is employer-sponsored and designed to reimburse a broad range of medical expenses for benefit-eligible employees. To align the health plan with LLUH mission-focused principles on wellness, the Department of Risk Management implemented the Living Whole Employee Wellness program to provide a comprehensive range of wellness and disease management services to support employee health. Employees could participate in this program voluntarily. The program included but was not limited to programs on weight management, diabetes management through lifestyle interventions, smoking cessation, and cooking classes.

Development of the Wholeness Health Plan (WHP) at LLUH. In 2014, the Department of Risk Management expanded upon the success of the Living Whole Employee Wellness Program by incorporating incentivized wellness options into a new employer-provided health plan option (WHP) that was based on an "opt-in wellness discount". The wellness discount consisted of a 50-53% reduction in out of pocket health plan costs (monthly costs, co-pays for prescriptions) in the existing health plan options from LLUH Risk Management. The rationale for WHP was as follows: 1) Participation in a biometric screening, health risk assessment (HRA), and wellness and prevention information provided at enrollment empowered each health plan member and their families to be actively involved in managing personal health and wellness, 2) The biometric screening and HRA data obtained at enrollment allowed the health plan to assess member health to enhance the precision of

health/wellness resources and population health interventions that are offered. Employees received the wellness discount through WHP enrollment if they completed a biometric screening, a health risk assessment, created an account in the hospital's patient/doctor portal, and agreed to participate in a care management program based on results obtained from the screening and risk assessments. The care management program included 1) biometric result review appointments with a primary care physician, 2) appointments with a nurse care manager for health plan members classified as high risk and/or multiple chronic diseases, and 3) smoking cessation for those identified as tobacco users based on either self-reported health risk assessment or biometric screening.

LLUH Breathe Cohort: A Natural Experiment to Study Employee Smoking Cessation that is Continuously Incentivized by the employer-provided Wholeness Health Plan (WHP)

The LLUH Breathe Cohort can be used to study the effects of an innovative model to continuously incentivize employees who are current or former smokers to continue quit attempts or maintain abstinence from smoking tobacco. To provide a context for our methods of studying the effects of LLUH BREATHE, we describe and compare the efficacy of incentive-based smoking cessation models used by other organizations. Incentive-based programs fall into the categories of rewards-based incentives, cash-based incentives, deposit-based incentives, lottery- or completion-based incentives, and mixed models using a combination of these approaches[7].

Rewards Based Incentives. Programs at CVS Pharmacy[8, 9] and Blue Cross/Blue Shield[10] have used a rewards-based mechanism ($100 to $800 in value) whereby at key smoking cessation milestones (quit date set, quit date, 14 day/30-day/6 month point prevalence abstinence) reward points are earned towards 1) subsidized co-payments and costs for prescription and over the counter cessation aids, 2) redemption as cash credits for groceries and personal items in selected stores.

Cash-based Incentives. Direct cash-based incentives include models that provide cash payments for attending a health assessment for smoking cessation (i.e. $50 for a first appointment and setting a quit

date) and then provide payments on achieving abstinence goals (amounts summing from $120 to in excess of $800 for long term abstinence)[7].

Deposit-based Incentives. Under deposit-based incentives, subjects deposit money into a health savings account and are refunded upon achieving abstinence goals[8].

Competition and Lottery-based Incentives. This incentive model included designs where groups of employees compete against each other for cash prizes given to the highest cessation rate[11]. Also, in lottery based incentive programs ("Quit and Win") an individual employee in the cessation group is eligible to win a cash prize[11].

Mixed Models. Under the mixed models[8], combinations of reward, cash, deposit-based, and/or competition/lottery-based incentives are used. For example, reward points for cessation behaviors can be redeemed as cash. Also, deposits are often combined with cash incentives in excess of the amount deposited by a smoker who quits.

Comparison of Incentive Models with LLUH BREATHE. Several large-scale meta-analyses of the incentive models have consistently shown that cash/reward-based incentives have higher participation and efficacy than deposit or competition/lottery-based incentives[7, 11]. Moreover in direct comparison of these models in CVS/Caremark employees, Halpern et al. specifically demonstrated the efficacy of cash/reward programs that used higher value (up to $800) incentives[8, 9].

Relative to previous incentivized models, LLUH BREATHE provides a novel approach to incentivized intervention that consists of: 1) a mixed model of cash-based (a lower paycheck deduction for health plan coverage equates to more cash per pay period; paycheck indicates a higher amount due to a discounted health coverage deduction printed on the paycheck) and reward-based incentives (lower co-pays for prescriptions), 2) a socio-ecologic framework whereby participants are choosing smoking cessation as part of a personal and familial/spousal choice to "opt-in" to the WHP directed

choices of health and wellness programs, and 3) a continuous incentive as a WHP member to continue quit attempts or maintain abstinence from tobacco use.

2.2 How did we enroll the LLUH BREATHE Cohort (Figure 1)?

Organization-wide Biometric Screening for WHP enrolls the LLU BREATHE Cohort.

Overview. At the inception of the WHP as a health plan option in 2014, WHP enrollees underwent a series of biometric screenings and health risk assessments to provide employee health profile data. The biometric screening and health risk assessments were done as an organization-wide enrollment campaign during specific open-enrollment periods in November of 2014 and 2017. New hires were enrolled into the WHP on a rolling enrollment basis. Benefit-eligible employees have the opportunity to enroll in the WHP and qualify for the wellness discount every year. The biometric screenings and health risk assessments during 2014-2019 identified a cohort of employee smokers who were offered participation in employer-sponsored smoking cessation as part of the WHP wellness activities. This cohort became the LLUH BREATHE cohort (n=1,092) described in this report and is depicted in Figure 1 and Table 1.

WHP Screening and Risk Assessment. During organization-wide health plan enrollment campaigns in 2014 and 2017, advertising for the Wholeness Health Plan's wellness discount activities began with a formal letter sent by mail to each benefit-eligible employee's home. Subsequent communications were via postcard, email, mass telephone communications, fliers sent to each department, announcements posted in the organization's internal home webpage and articles in the employee newsletter. All communications invited employees to biometric screening and health risk assessment appointments

Biometric screenings were made available at the workplace to all employees through a third party vendor and included anthropometric assessment, a metabolic panel, and screening for nicotine exposure (by self-report and health plan claims data during 2014-2017; by salivary cotinine test from 2017-2019). Rolling admissions into the health plan outside these periods in 2014 and 2017 used a

similar methodology. A health risk assessment questionnaire included sections on health behaviors, psychological stress and personal safety.

Nicotine Screening during Health Plan Enrollment. Nicotine screening results from self-report, health plan claims data, or salivary cotinine testing were used to offer all employee smokers smoking cessation through their "opt in" for the WHP. Health Plan members were given a chance to appeal "nicotine positive" results and, if approved, allowed to enroll in the WHP without the requirement for smoking cessation as habitual tobacco user.

Smoking Cessation Interventions for WHP Members. The intervention has been described elsewhere[1]. Briefly, Cohort members who participated in the intervention were asked to complete two electronic survey forms (Intake/Pre- and Post-intervention), two physician visits, and either an online or in-person group version of the American Lung Association (ALA) 'Freedom from Smoking' course. This was an 8-week course that educated participants on the benefits of smoking cessation and assisted individuals in setting a 'quit date'. This program consisted of 8 weekly sessions that took approximately 1 hour to complete.

Relapse in WHP Members. Relapses were detected through voluntary self-report to provider, health plan claims data, or salivary cotinine testing during opt-in enrollment periods. It is noteworthy, however, that a relapsed WHP smoker who continues annual quit attempts on the LLUH BREATHE program remains a WHP member.

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2.3 Statistical Analysis

To achieve our overall aim of providing a cohort profile, we conducted analyses to give the latest participation rate in the cohort and to provide temporal trends in screening, enrollment, and completion of smoking cessation of the employee smokers. Participation rates and 95% confidence intervals were computed with a continuity correction[12]. Participants and non-participants were compared in chi-

squared and t-tests[12]. A non-parametric kernel smoother[13] was used to examine the trends in count-based data on smoking cessation attempts, invites, and screens for tobacco use.

2.4 Patient and Public Involvement

The data for this cohort study is from the employee health plan of a private non profit organization. It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

3. Findings to Date

3.1 LLUH BREATHE Cohort Profile at Five Years of Follow-up (2014-2019)

Our group has reported that, during the first year of follow-up, there was a 73% participation rate among in the continuously incentivized model of employee smoking cessation in LLUH BREATHE. The first year cessation rate of LLUH BREATHE participants was also notably high (48% achieved a four month point prevalence abstinence)[1]. Pilot qualitative data provide preliminary clues that the WHP cohort members and their providers are receptive to the incentivized intervention model[14]

During the first five years of follow-up, the cohort grew to 1,092 current and former (quit through screening and incentivized cessation sponsored by health plan) employee smokers identified among more than 16,000 employees(Figure 1). The continuously incentivized model produced a 74% (95% confidence interval=[71% to 77%]) participation in an at least one employer sponsored, annual smoking cessation attempt during the follow-up. In table 1 we compare the biometric profiles of participants and non-participants in smoking cessation among LLUH BREATHE cohort members and found no significant differences. Total cholesterol was however higher in non-participants. We note that the unique design of LLUH BREATHE is such that non-participants can become participants during annual “opt in” periods.

In figure 2 (panel 1) we show that the enrollment campaigns produced two peaks (1/2014, 8/2017) of screen positive for tobacco use during the five years of follow-up (panel 1). Less than a year

after incentives were offered to those screening positive, we observed two peaks of smoking cessation attempts (figure 2, panels 2-3).

3.2 Plan of Analysis for the Cohort Profile

Participation, Point Prevalence Abstinence, and Time to Cessation.

We will conduct further quantitative and qualitative analyses to measure the effect of successive enrollment campaigns on enhancing 1) participation rate, 2) point prevalence abstinence, 3) cessation attempts, and 4) time to cessation in a survival analysis. These outcomes can be related to demographic, behavioral, health plan services used, nicotine screening methods (self-report, bio-specimen testing, re-testing appeals), and costs incurred. We are beginning to publish exploratory qualitative analyses of WHP and LLUH BREATHE cohort member program experiences to identify programmatic areas for improvement[14].

Modeling Dynamic Relapse in LLUH BREATHE

Traditional statistical models often cannot fully capture the dynamic relapse process in a nicotine cessation process where smokers often transition from one stage (current nicotine users) to another (early abstinence) and experience multiple quit attempts prior to quitting. Some smokers who are able to quit may even move onto a stage of long term cessation (long term abstinence) while many smokers often relapse back into their initial stage (current nicotine users). Dynamic modeling of nicotine cessation require novel methods such as Markov models to capture the transient nature of the relapse stages[15]. Figure 3 and Equation 1 shows a potential 3-stage Markov model where cessation moves the participants through stages left to right with probabilities, λ or θ, and relapsing moves the participants from right to left with probabilities, γ or δ. In Markov models, transition probabilities (i.e. λ, θ, δ,γ; probability matrix of transitioning to next or previous stage; Figure 4) are usually pre-specified based on a-priori data, but can also be estimated. The Markov model can be expanded to include more stages to depict the natural behavioral process in nicotine cessation.

4. DISCUSSION

Our profile of the LLUH BREATHE Cohort reveals that our model of continuously incentivizing employee smoking cessation produced a 74% participation rate in an employer-sponsored quit attempt less than a year after being offered the incentive. This participation rate among employee smokers is much higher than the norms (median of 28%) for employee participation in more than 20 studies of employee smoking cessation in affluent nations[7, 16].

One potential reason why the overall participation rate of employee smokers in LLUH BREATHE is higher than national norms is that the cash/reward model is of particularly high cash value[1]. Specifically, the LLUH BREATHE model[1] of decreasing out of pocket health plan costs by 50-53% provides a financial incentive ($600 to $1200 in lower health plan costs per year) that far exceeds other incentivized cash/reward employee smoking cessation models (up to $800 is annual cash/rewards) that have been reported in the peer-reviewed scientific literature[7-9]. For the LLUH BREATHE cohort, further study is needed to measure the relationship between the cash value of the incentive on long-term abstinence. We note that incentives can be a component of long term smoking cessation but are not a "stand-alone" cessation method for employees or in other contexts.

Another potential reason for the higher participation rate is that the incentivized model under LLUH BREATHE is not a surcharge model that is punitive to smokers. This because, under the LLUH BREATHE Plan, the "opt-in" discount on premiums and co-pays is maintained even in the case of relapse and only stipulates that the relapsed smoker participates in an annual smoking cessation attempt through LLUH BREATHE. Analyses of the Affordable Care Act model of adding a surcharge to the premiums of all smokers do not indicate efficacy in promoting smoking cessation[17].

4.1 What Questions are we going to ask (Moving Forward)?

LLUH BREATHE is a dynamic cohort that derives from a parent cohort of over 16,000 benefit-eligible employees. A number of recent developments in tobacco use and cessation in the US impact outcomes in this ongoing follow-up study and need measurement. First, the rapid proliferation of electronic

nicotine delivery systems (i.e. e-cigarettes, e-pipes, and vaping pens) and heated tobacco devices needs more complete measurement in the employee smoking cessation program. Sensitivity analysis that considers electronic nicotine delivery systems, heated tobacco use, and poly-tobacco use in the cohort outcome variables is needed. The emergence of COVID 19 pandemic conditions among employees impacts smoking behaviors[18]. The relationship between smoking cessation and pertinent outcomes such as SARS-Cov-2 antibodies, infection and progression needs examination as population health measures become available.

4.2 Conclusions

The LLUH BREATHE cohort profiled in this report is an open, dynamic cohort of current and former smokers who are continuously incentivized to maintain or attempt tobacco cessation through an "opt-in wellness discount" on the out of pocket cost of their health plan. The initial findings from LLUH BREATHE indicated 1) high rates of participation and four month abstinence rates [1], and 2) preliminary findings of acceptability of the incentivized health plan model to members and providers[14]. Our profile of the cohort after more than 5 years of follow-up identifies a rich dataset for inquiry into workplace and health-plan based incentives for achieving long term abstinence from tobacco among employed adults.

5. Collaboration Statement

The authors encourage collaborative work with other investigators and will make the de-identified data on the abstinence, relapse, and basic demographics available in response to all reasonable requests. These collaborations can include pooling projects, meta-analyses, and re-analysis of the cohort data.

Table 1. Demographics and health among LLUH employees who tested positive for nicotine and were offered participation in an incentivized health plan model for smoking cessation

Variable	Did Not Participate (n=282)	Participated (n=810)
Age	42.74 (11.09)	45.56 (11.49)
Gender: n (%)		
Male	180 (63.83%)	494 (60.99%)
Female	102 (36.17%)	316 (39.01%)
Enrollment Type: n (%)		
Subscriber	153 (54.26%)	453 (55.93%)
Spouse	129 (45.74%)	357 (44.07%)
Biometrics		
Weight (lbs)	191.24 (51.86)	192.83 (48.06)
Body Fat (%)	26.61 (8.9)	28.05 (9.19)
Waist Circumference	38.46 (6.7)	39.38 (12.72)
BMI (kg/m^2)	29.62 (6.51)	29.96 (6.41)
Systolic Blood Pressure (mmHg)	128.57 (17.02)	128.3 (17.62)
Diastolic Blood Pressure (mmHg)	79.7 (11.76)	78.62 (11.34)
Total Cholesterol (mg/dL)	185.49 (37.95)	179.77 (35.37)
HDL (mg/dL)	46.75 (16.45)	44.35 (15.18)
HDL Ratio	4.51 (2.1)	4.5 (1.82)
Fasting Glucose (mg/dL)	94.78 (25.97)	95.39 (29.1)
Non Fasting Glucose (mg/dL)	102.08 (21.47)	103.95 (35.31)
LDL (mg/dL)	115.11 (35.72)	109.19 (33.39)
Triglycerides (mg/dL)	146.41 (115.38)	157.81 (117.73)

Figure Legends

Figure 1. Enrollment of LLUH BREATHE Employee Smoker Cohort (2014-2019). ENDS denotes electronic nicotine delivery systems.

Figure 2. Rate of tobacco screening, incentivized health plan invites, and smoking cessation attempts among LLUH employees (2014-2019).

Figure 3. A 3-stage Markov model of the smoking cessation relapse process with Latin symbols indicating the transition probabilities. Cessation moves the participants through stages left to right with lapses from long term abstinence to early abstinence with probability, γ, and lapses from early abstinence to current nicotine users with probability, δ.

Figure 4. Transition probability matrix of current stages of nicotine cessation. Current nicotine users who continue to use and remain in "Current Nicotine Users" stage with probability (1-λ) or go into next stage, "Early Abstinence," with probability λ. Participants in "Early Abstinence" stage may relapse with probability, δ, stay in current "Early Abstinence" with probability $(1 - \delta - \theta)$, or move to the next phase.

Contributor-ship statement

PS wrote the final version of the paper, analyzed the data, obtained the funding; OM conceived the study, edited the paper; WS analyzed the data and wrote sections of the paper; MH edited the paper.

Competing Interest

The authors declare no competing interest.

Data Sharing Statement

The authors will honor all reasonable requests for de-identified data.

Patient and Public Involvement Statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

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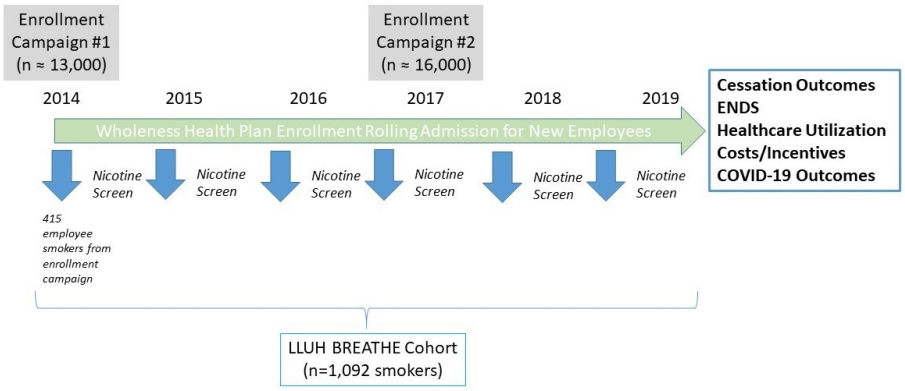

Figure 1. Enrollment of LLUH BREATHE Employee Smoker Cohort (2014-2019). ENDS denotes electronic nicotine delivery systems.

338x138mm (96 x 96 DPI)

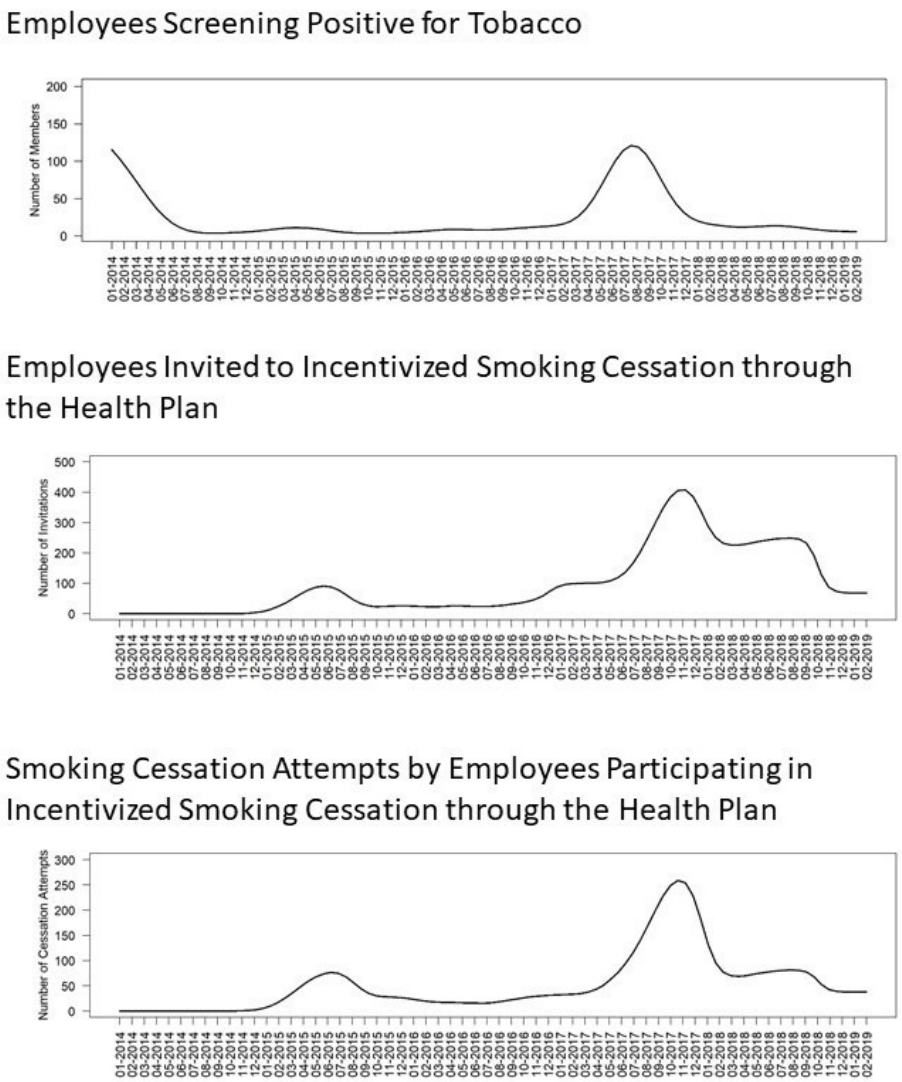

Figure 2. Rate of tobacco screening, incentivized health plan invites, and smoking cessation attempts among LLUH employees (2014-2019).

186x211mm (96 x 96 DPI)

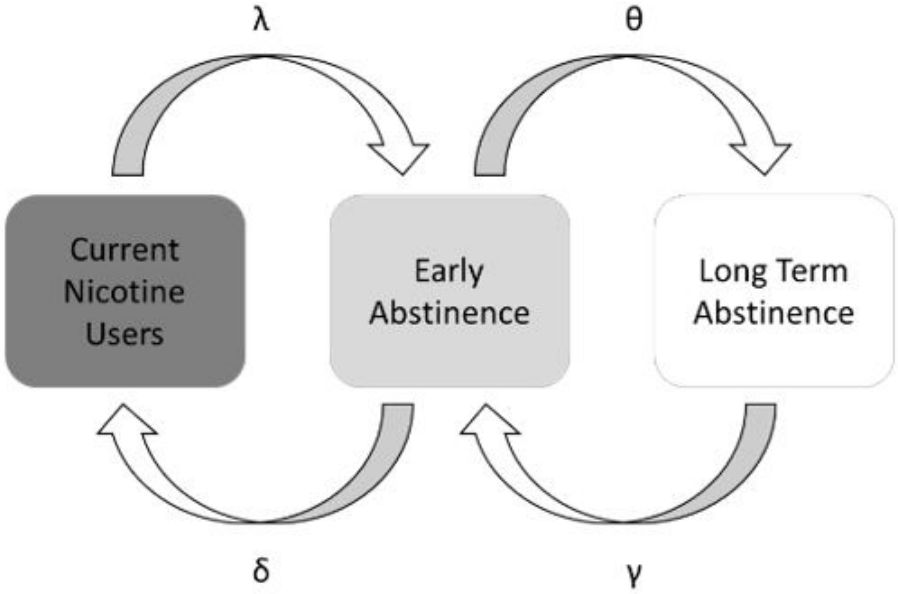

Figure 3. A 3-stage Markov model of the smoking cessation relapse process with Latin symbols indicating the transition probabilities. Cessation moves the participants through stages left to right with lapses from long term abstinence to early abstinence with probability, γ, and lapses from early abstinence to current nicotine users with probability, δ.

117x74mm (120 x 120 DPI)

$$P = \begin{bmatrix} 1-\lambda & \lambda & 0 \\ \delta & 1-\delta-\theta & \theta \\ 0 & \gamma & 1-\gamma \end{bmatrix}$$

Figure 4. Transition probability matrix of current stages of nicotine cessation. Current nicotine users who continue to use and remain in "Current Nicotine Users" stage with probability (1-λ) or go into next stage, "Early Abstinence," with probability λ. Participants in "Early Abstinence" stage may relapse with probability, δ, stay in current "Early Abstinence" with probability (1-δ-θ), or move to the next phase.

111x35mm (120 x 120 DPI)