Assessing the Evidence on the Differential Impact of Menthol versus Non-menthol Cigarette Use on Initiation and Progression to Regular Smoking: A Systematic Review and Meta-analysis

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Background: Despite numerous assessments of the public health impact of menthol cigarettes, a rigorous synthesis related to menthol cigarettes and behavioral outcomes is lacking. This systematic review and meta-analysis examined the question: Does menthol cigarette use have a differential impact on initiation and progression to regular smoking compared to non-menthol cigarette use? **Methods:** We consulted 6 databases from their inception to October 15, 2021. We included articles comparing menthol versus non-menthol smokers among 4 predefined smoking initiation and progression outcomes. We assessed risk of bias was using the Agency for Healthcare Research and Quality Evidence-Based Practice Center approach. We applied a random-effects model to pool adjusted odds ratios. **Results:** We qualitatively synthesized 16 adjusted studies across the outcomes. Results from one meta-analysis suggested no difference between menthol and non-menthol smokers in likelihood to report daily versus non-daily smoking. **Conclusion:** This systematic review and meta-analysis did not identify a consistent, statistically significant, or differential association between menthol use and progression to regular smoking. Varying definitions of outcome measures and lack of longitudinal evidence limited the confident conclusions that could be drawn from this evidence base.

Key words: smoking; menthol cigarettes; systematic reviews; meta-analysis; initiation; progression to regular smoking

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Despite a steady decline in rates of adult cigarette smoking in recent years, the current proportion of menthol smokers is higher among youth than among adults, with about 3 of 10 adult smokers choosing to smoke menthol brands.[1,2] According to the Substance Abuse and Mental Health Services Administration (SAMHSA), menthol cigarette use seems characterized by a contradictory upward trend among younger adults, females, males, Hispanics, and Asians.[1] Overall, the trends of mentholated and non-mentholated cigarette use for both adults and young adults are discrepant and are limited in generalizability.

The issue of menthol has been brought to the forefront of tobacco policy, as evidenced by the Food and Drug Administration's (FDA) declared intent to explore a ban on mentholated tobacco products. Given the FDA's own commitment to evidenced-based actions,[3] there is a need for the potential associations between menthol and smoking behaviors to be explored scientifically.

Existing Evidence

Despite numerous assessments of the public health impact of menthol in cigarettes,[4-8] a rigorous systematic review of the evidence related to menthol cigarettes and behavioral outcomes

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is lacking. In March 2011, the TPSAC issued a report and recommendation on menthol cigarettes from a public health perspective.[5] The Committee concluded that "removal of menthol cigarettes from the marketplace would benefit public health in the United States." Also, in March 2011, tobacco industry stakeholders published "The Industry Menthol Report. Menthol Cigarettes: No Disproportionate Impact on Public Health," that detailed the possible associations between menthol cigarettes and smoking initiation, cessation, and dependence.[4] The authors concluded that the "evidence [was] inadequate to infer the presence or absence of a causal relationship" between menthol status and initiation behaviors, and that the "evidence [was] suggestive of no causal relationship" between menthol status and smoking cessation or smoking dependence.

Two years later, the FDA published a preliminary report titled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Non-menthol Cigarettes," that found the evidence was sufficient to conclude that menthol in cigarettes is likely associated with increased initiation and progression to regular smoking, increased dependence, and reduced success in smoking cessation.[6] In August of 2015, the FDA published an addendum to its preliminary report, titled "Reference Addendum: Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Non-menthol Cigarettes," that included articles published between July 2011 and the end of March 2013.[7] The inclusion of newer data did not impact the initial conclusions from the Preliminary Report, and the FDA maintained that menthol in cigarettes was likely associated with increased initiation and progression to regular smoking, increased dependence, and reduced success in cessation.

Few systematic reviews, which would provide a higher level of evidence, have been conducted on the association between menthol cigarettes and cigarette smoking behaviors. A systematic review of the literature to identify articles reporting on menthol versus non-menthol cigarette initiation, dependence, and cessation was performed by Villanti et al.[8] The authors reported an association between menthol cigarette smoking and increased initiation among youth, increased dependence especially among youth, and reduced cessation among non-Hispanic Whites and racial and ethnic subgroups. According to the AMSTAR 2 appraisal tool for systematic review quality,[9] there were significant methodological insufficiencies in this review, including no PICO (population, intervention/exposure, control group, outcomes) framework for inclusion/exclusion criteria, a limited literature search strategy with only 2 key words, only searching through PubMed, and no reported quality or risk of bias assessment. Instead, a subjective methodology was used to evaluate the evidence and determine associations. Thus, the systematic review did not provide a comprehensive synthesis of the best available evidence.

A second systematic review by Smith et al[10] examined gender differences in menthol cigarette use and their association with smoking prevalence, initiation, cessation, correlates of menthol use, and health outcomes. In terms of initiation, the authors found that both men and women exhibit minimal switching between menthol and non-menthol cigarettes, suggesting that preference is established early in individual smoking trajectories. However, these findings were based on a single included study in the review of smoking initiation, and therefore conclusions cannot be reliably drawn.

Objective

Given the methodological deficiencies in the current evidence base, in this systematic review, we sought to apply an increased level of scientific rigor to the assessment of potential associations between menthol cigarette use and smoking initiation and progression to regular smoking, with a strict methodological focus to the measures and methods used by the included studies, and a quantitative analysis of findings via meta-analyses.

METHODS

Overview

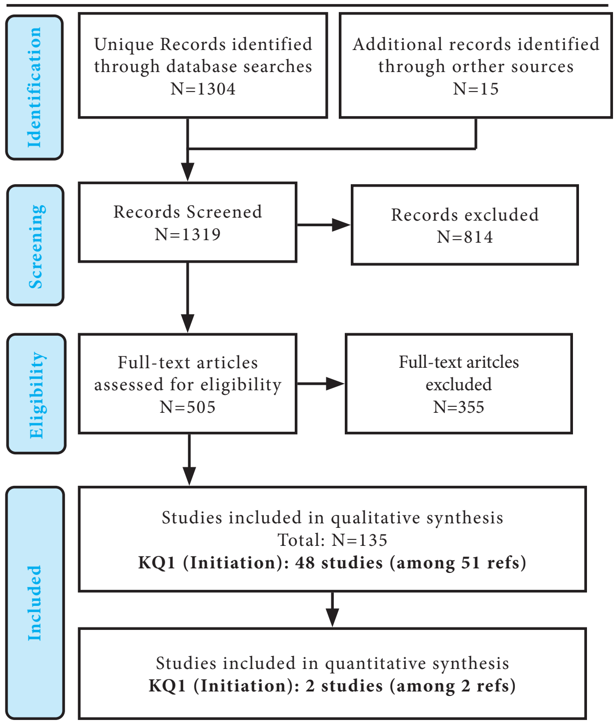
The methods used for this review were applied to a larger systematic review of the association between menthol cigarette use and 3 smoking behaviors (Figure 1), an arm of which has been published elsewhere.[11] Current results assess the Key Question (KQ): "Does menthol cigarette use have a differential impact on initiation and progression to regular smoking compared to non-menthol cigarette use?" The protocol for this review was registered with the PROSPERO international prospective register of systematic reviews (Registration Number: CRD42019119301) on March 22, 2016 (updated January 10, 2019). The record is available at https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=119301

Literature Search Strategy

The literature searches were conducted by an information specialist. Search terms were developed using text words related to the associations between menthol cigarette use and cessation of cigarette smoking. The search strategy included using synonyms of search terms, truncation, wild card symbols, Boolean logic, proximity operators, and limits to focus the search towards the most relevant clinical literature (Supplemental Section 1: Literature Search Strategy).

We searched the following online databases for relevant articles from inception to October 15, 2021 (across 3 sequential literature searches): Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, MEDLINE, Embase and PsycInfo. The initial literature search (from inception to December 14, 2018) identified 853 potentially relevant articles, with 838 articles from online databases and 15 additional articles through other sources. The first literature search update (from January 1, 2018, to June 12, 2020) identified an additional 358 potentially relevant articles; however, 149 of these were duplicate articles across the searches due to a required overlap in search timeframes (searches are best conducted from the first of the year), resulting in 209 unique articles identified. The second literature search update (from January 1, 2020, to October 15, 2021) identified an additional 351 potentially relevant articles, of which 94 were duplicate articles across searches, resulting in 257 unique articles identified. Combined, this yielded a total of 1319 potentially relevant articles. After independent review of titles and abstracts by 2 members of the research team, 814 references were excluded, resulting in 505 articles being screened at the full-text level. An additional 355 articles were excluded at the full-text level (provided in Supplemental Section 2: Studies excluded at level 2 screening [with reason for exclusion]), resulting in 150 relevant articles eligible for inclusion for the larger systematic review of the association between menthol cigarette use and 3 smoking behaviors; 51 studies (3 of which were reported in paired studies) evaluated the association between menthol cigarette smoking and initiation and progression to regular smoking. The weighted overall kappa for inter-rater reliability at level-2 screening was 0.96 for the initial literature search, 0.95 for the first updated literature search, and 0.90 for the second updated literature search.

Figure 1
Literature Search Overview



Eligibility criteria. Eligibility criteria were developed according to the PICO framework and are presented in Table 1. Studies of solely non-US residents were excluded based on variations in national tobacco legislation limiting the generalizability of such studies to the US population.

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Table 1
Inclusion and Exclusion Criteria for Key Question (KQ)

	Inclusion Criteria	Exclusion Criteria
Population	• Youth and adults • Current or former smokers with explicit use of (or stated preference for) menthol or non-menthol cigarettes; studies of non-smokers were eligible if they reported a measure of initiation • United States residents	• Studies of never smokers who never initiated cigarette smoking at any time point • Studies of only non-United States residents
Comparisons	• Menthol versus non-menthol • Delivery of nicotine via traditional cigarettes	• Studies reporting only menthol or non-menthol or not directly comparing menthol with non-menthol • Studies of non-traditional tobacco delivery [a]
Outcomes	• Age at initiation • Initiation to or with menthol cigarettes • Switching between menthol and non-menthol cigarettes • Progression to regular smoking/increase in smoking over time	• Any other outcomes
Study Designs [b]	• Randomized and non-randomized controlled trials • Cross-sectional, case-control, and cohort studies • Letters and editorials containing original data not available elsewhere were eligible	• Reviews, case reports, editorials, and letters not containing original data

Note.
[a] For example, vaporizers, e-cigarettes, hookahs/water pipes.
[b] Reclassification of included trials as cross-sectional or cohort depending on the eligible data as follows: if only baseline data used from a trial, it was considered a cross-sectional study; if any post-baseline measurement data was used, it was considered a cohort.

Data Extraction

Data were extracted and managed through DistillerSR (Evidence Partners, Ottawa, ON, Canada). Articles were initially screened at the title/abstract level; full-text articles were obtained for studies not excluded based on the title/abstract alone. Two reviewers independently screened articles based on the inclusion/exclusion criteria. Any discrepancies between the 2 were resolved in a joint-reviewer decision. Any unresolved disagreements were settled by a third clinical reviewer; reasons for exclusions were documented.

Data were independently extracted by one research associate and checked by a second research associate. Discrepancies were resolved through discussion and included a third team member when necessary. Data extraction forms were created in DistillerSR.

Conceptual Framework

Smoking behaviors can vary across subgroups of the population, suggesting that both individual and environmental factors influence smoking.[12,13] It is essential that factors influencing smoking behaviors be considered to the extent possible based on available data. As applied to this review, the socio-ecological model[14] includes 3 main levels of factors that influence an individual's smoking behaviors: characteristics of the individual ("micro"); characteristics of the individual's social environment ("meso"); and characteristics of the systems-level environment in which the individual exists ("macro"). Examples of micro-level factors are age, race/ethnicity, gender, and education. Meso-level factors include living in a home where someone smokes, having friends who smoke, and whether someone lives in an urban or rural area, among others. Examples of macro-level factors include cigarette taxes, workplace cigarette smoking policies, and local or state tobacco control activities (eg, cigarette smoking bans)

Study Quality Assessment

Study quality rating. A random sample of approximately 15% of included studies was assessed independently by 2 members of the review team. The level of agreement between those researchers was evaluated based on the mean difference in scores between the 2 reviewers. The mean difference was 0.25 points (95% confidence interval [CI], -0.53 to 1.03), indicating that, on average, reviewers had a high level of agreement with 95% confidence that the true mean difference was no greater than one point on the scale. In addition, the difference in score across the sample of studies was distributed normally, indicating that there was no systematic bias, and that one reviewer was not consistently higher or lower than the other. Based on the high level of agreement, the ratings were not found to be subject to individual reviewer bias, and a single reviewer reviewed the remaining included studies.

Downs and Black checklist. The quality of the studies included in this systematic review was assessed at the study level using the Downs and Black checklist,[15] as recommended by the Cochrane Collaboration.[16] The instrument was used as reported in the original publication, with only one adaptation of the power question as to whether the study was adequately powered (yes/no). The maximum achievable score for a study was 28, and score ranges were grouped into the following 4 quality levels: "excellent" (26-28); "good "(20-25); "fair" (15-19); and "poor" (≤ 14). When data from a single study were reported in multiple references, all references were considered to determine an overall rating for the study.

Assessment of confounding. To evaluate confounding in this body of literature, the following steps were taken in accordance with Cochrane guidelines for systematic reviews.[16] During protocol writing, a list of potential confounding factors was identified *a priori* based on evidence and expert opinion from members of the research team and external advisors. During the systematic review process, the variables that individual study authors considered were recorded for additional *post hoc* consideration.

In this review, we assessed empirical evidence that controlled for confounding bias according to the pre-determined 3 confounders (age, race/ethnicity, and gender), through multivariable modeling, sample stratifications, or predefined study inclusion criteria. Those results minimized the potential for confounding bias and represented the "best evidence" and may be more likely to represent the "true" association of menthol cigarettes with smoking behaviors. Studies that also adjusted for additional potential meso- (eg, living with a smoker) or macro-level factors (eg, cigarette taxes), as defined per the applied conceptual framework, were flagged for inclusion in sensitivity analyses. Studies with potential overadjustment or adjustment for factors in the causal pathway also were flagged for further examination in sensitivity analyses.

Outcomes and Related Psychometrics

Included studies provided evidence on at least one of the following outcome measures: age at smoking initiation; smoking initiation with menthol cigarettes; switching between menthol and non-menthol cigarettes; and progression to regular smoking/increased smoking over time. Recognizing that not all the outcome measures are likely to be equally valid and reliable, we examined the following Contextual Question (CQ): "Have measures used to examine initiation and progression to regular smoking been psychometrically assessed as valid and reliable?" The following scoring approach was informed by the International Agency for Research on Cancer (IARC) Handbook on Cancer Prevention:[17] "Acceptable" – measures for which available empirical findings were identified in the reviewed studies demonstrating at least one criterion for reliability and at least one criterion for validity, in both gender and in the specific age group; or "Inconclusive" – measures either for which available empirical findings in the reviewed studies did not meet the required criteria above or for which insufficient empirical findings were identified by the methods employed herein.

Consideration was given to parsing the above levels of overall psychometric performance of each measure with greater granularity, such as, "Inconclusive," "Moderate," "Good," and "Superior." Such gradations could, theoretically, be predicated on further division of each individual criterion for reliability and validity, such as, for reliability coefficients: from 0.00 to 0.49 = Unacceptable; 0.50 to 0.69 = Borderline Acceptability; 0.70 to 0.79 = Good; and ≥ 0.80 = Excellent. Similarly, each statistical indication of convergent or criterion validity above a given threshold, or each independent study population in which a scale was shown to be valid, could contribute a "point" toward a "summed gradient of overall scale validity." Whereas this approach holds considerable appeal, it could introduce unwanted bias and was deemed to be beyond the scope of this CQ review. Instead, we elected to disclose all published information that was considered in this process so that readers could make their own conclusions about the relative strength of an "Acceptable" measure. The binary system of "Inconclusive" or "Acceptable" provides an indication of whether the available, published evidence related to each scale supports its overall psychometric suitability for use in the population-based research setting on which the KQ is based. Only studies for which the study population was at least partially US-based and the statistical measure for reliability or validity met acceptable values, are included.

Data Analysis

The strongest evidence to assess whether menthol compared to non-menthol cigarette use has a differential impact on initiation and progression to regular smoking would be expected to be provided by longitudinal analyses that adjusted or controlled for key confounding factors – age, race/ethnicity, and gender – by inclusion criteria, modeling, or stratification. Consequently, all studies that controlled for, at minimum, age, gender, and race/ethnicity were synthesized qualitatively.

Longitudinal analytic results were considered the highest available evidence and, as such, were weighed more heavily in the strength of evidence analysis and qualitative synthesis below. In the absence of longitudinal analytic results, the highest level of available evidence was synthesized according to studies that controlled for the predefined demographic factors.

Statistical significance. Estimates of the difference between menthol and non-menthol smokers are presented with the best measure of precision (ie, 95% CIs) or statistical significance (ie, p-value) reported in the included studies. The words "significant" and "significantly" are used herein to indicate statistical significance (ie, $p < .05$ and/or confidence interval that excludes 1.0). An "increase" or "decrease" that is not also described as "significant" is either not a statistically significant increase or decrease or statistical significance was not reported in the data source.

Meta-analysis. Literature search, study choices, and data extraction were completed according to the corresponding systematic review protocol. Standard guidelines were followed for conducting and reporting meta-analyses of observational studies.[18]

The generic inverse variance method was used, as described by DerSimonian and Laird.[19] This method combines adjusted odds ratios (AORs), resulting in pooled odds ratios (ORs) and 95% confidence intervals (CIs) with 2-sided p-values. Variations among pooled studies were assessed using Tau^2 and heterogeneity was quantified using Cochran's Q test and the inconsistency index I^2. Study authors were contacted to obtain missing data. All data were analyzed through Review Manager version 5.3 (The Cochrane Collaboration, Copenhagen, Denmark).

Strength of Evidence

Recognizing inherent limitations in assessing the confidence in empirical conclusions based on observational data,[20-23] the Agency for Healthcare Research and Quality (AHRQ) Evidence-Based Practice Center (EPC) approach, which is based largely on the methods developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group,[24] was deemed acceptable for this review.

Reporting bias is one of the specific strength-of-evidence (SOE) domains typically assessed, but the methods used to detect it are designed for use with controlled trials. Although observational studies may be susceptible to reporting bias, no comparable methods exist for assessing reporting bias for those study designs. As a result, reporting bias was not assessed for the purposes of this systematic review, which comprised only observational studies, in accordance with methodological recommendations.[25]

Measures with "Acceptable" reliability and/or validity were weighed more heavily than the "Inconclusive" measures (to minimize the impact of misclassification bias). The final SOE judgment was necessarily qualitative but reflected a sound, reasoned weighing of domain ratings. The overall strength of the body of evidence was assessed and graded as "high," "moderate," "low," or "Insufficient" using the Evidence-Based Practice Center (EPC) approach.

Sensitivity analysis. Additionally, 3 sensitivity analyses were conducted to evaluate the SOE, and included: limitation of the study pool to those that also adjusted for meso- and/or macro-level variables; exclusions of "poor" quality studies (according to the Downs and Black[15] study quality assessment); and exclusion of studies with potential overadjustment and/or inappropriate adjustment.

RESULTS

A total of 48 studies, from 51 unique references, evaluated the potential association between menthol cigarette use and initiation and progression to regular smoking. Adjusted studies were considered a higher level of evidence and, therefore, all subsequent analyses were restricted to studies adjusted for key demographic characteristics (age, gender, and race/ethnicity). A total of 16 studies, reported in 17 unique references, provided adjusted data for relevant smoking initiation and progression outcomes. Table 2 shows the complete study characteristics. The definitions of the specific outcome measures for initiation and progression to regular cigarette smoking applied across the adjusted studies are presented in Supplemental Section 3: Outcome Measures for Initiation and Progression to Regular Smoking across Adjusted Studies.

Table 3 contains a summary of the identified published assessments of the psychometric foundations of initiation and progression to regular smoking measures. Empirical data regarding reliability or validity qualified 2 of the 4 smoking initiation and progression measures (age at initiation and initiation to or with menthol cigarettes) as "Acceptable;" the remaining 2 measures (switching between menthol and non-menthol cigarettes and progression to regular smoking/increase in smoking over time) were "Inconclusive."

Table 2
Study, Dataset, and Sample Characteristics

First Author, Year, National survey name, Quality rating	Location; Funding; Study design / Duration	Sampling / Recruitment strategy [a]; Data collection period	Summary of inclusion criteria (including definition of "smoker")	Special population
Allen and Unger, 2007[28] None Fair	California; Govt & foundation; Cross-sectional	Fliers distributed to residents of southcentral Los Angeles on the campus of the King/Drew Medical Center, shopping malls, and other community sites, and given to previous participants to recruit additional participants through snowball sampling; Apr 2001-Sept 2001	Adult Black smokers age ≥ 18 who smoked ≥ 5 CPD for the past year, were willing to be interviewed and give breath and saliva samples, mentally able to provide informed consent, and had exhaled CO ≥ 7ppm.	Black
Azagba et al, 2020[36] NYTS Fair	National; NR; Cross-sectional	A nationally representative sample of students enrolled in grades 6 through 12. The sampling universe consists of public and private school students in the 50 states and the District of Columbia, 2017-2018	Middle school and high school students who were current cigarette users, defined as smoking at least one out of the past 30 days. Smoking frequency was derived from the question "During the past 30 days, on how many days did you smoke cigarettes?" with the following possible answers: "0 days," "1 or 2 days," "3-5 days," "6-9 days," "10-19 days," "20-29 days," and "All 30 days."	Middle school (grades 6 to 8) and high school (grades 9 to 12)
Cubbin et al, 2010[29] NHIS-CCS Good	National; NR; Cross-sectional	A supplement to the NHIS that assesses issues related to cancer-related behaviors, screening, and risk assessment, including tobacco use and control; 2005	Adults aged 25-64 who self-identified as black, non-Hispanic/Latino, Hispanic/Latino, or white non-Hispanic, smoked ≥ 100 lifetime cigs and currently smoke every day (current smoker) or do not currently smoke (former smoker).	None

First Author, Year, National survey name, Quality rating	Location; Funding; Study design / Duration	Sampling / Recruitment strategy [a]; Data collection period	Summary of inclusion criteria (including definition of "smoker")	Special population
Curtin et al, 2014[30] NHANES, NSDUH, NHIS, TUS-CPS Good	National; Industry; Cross-sectional	NHANES: Stratified multistage probability sample, civilian non-institutionalized US population; 1999-2010 NSDUH: Stratified multistage probability sample, civilian non-institutionalized US population; 2000-2009 NHIS: Cross-sectional household interview; stratified multistage area probability design; 2005 and 2010 TUS-CPS: Stratified multistage probability sample, civilian non-institutionalized US population; 2003, 2006-2007	NHANES: Youth aged 12-19 who ever tried cigarette smoking (even 1 or 2 puffs) and adults age ≥ 20 who smoked ≥ 100 lifetime cigs; NSDUH, NHIS: Adults aged ≥ 20 who ever smoked part or all of a cigarette; TUS-CPS: youth aged 15-19 and adults ≥ 20 who ever smoked part or all of a cigarette.	Some results stratified by age (youth)
Delnevo et al, 2015[39] NYAHS Good	National; Govt; Cross-sectional/ retrospective (12 months)	Stratified random-digit-dial cell phone survey representative of young adults in the US; 2011	Subsample of young adults aged 18-34 from the survey who smoked ≥ 100 lifetime cigs at the time of the survey.	Young adults aged 18-34
Fernander et al, 2010[31] TUS-CPS Fair	National; NR; Cross-sectional	Stratified multistage probability sample, civilian non-institutionalized US population; 2003, 2006-2007	Adult current smokers age ≥ 18 (≥ 100 lifetime cigarettes who were currently smoking every day or some days and at least once in the last 30 days).	None
Giovino et al, 2015[37] NSDUH Good	National; Foundation; Cross-sectional	Stratified multistage probability sample, civilian non-institutionalized US population; 2008-2010	US civilian non-institutionalized smokers (smoked all or part of a cigarette in the past 30 days) aged ≥ 12 years old.	None, but included age ≥ 12
Hyland et al, 2002,[26] Hyland and Rivard, 2010[27] None Good	2 sites in each of: New Jersey, California, New Mexico, New York, North Carolina, Canada; Govt; Prospective cohort (duration NA; only age at initiation reported)	Modified random-digit-dial method and geographic boundary screening used for the baseline prevalence survey; 1988-1993	Adult current smokers aged 25-64 who reported whether their current brand was mentholated or not in 1988 and had a known smoking status in 1993.	None
Kasza et al, 2014[33] ITC-4 (US data only) Fair	National; Foundation & Govt; Prospective cohort (9 years)	Random digit dialing to recruit adult smokers from the US, Canada, the United Kingdom, and Australia (US data only); 2002-2011	Adult smokers (≥ 100 lifetime cigarettes and smoked at least once in past 30 days).	None
Lawrence et al, 2010[32] TUS-CPS Good	National; Govt; Cross-sectional	Stratified multistage probability sample, civilian non-institutionalized US population; 2003, 2006-2007	Adult current smokers aged ≥ 18.	None
Nonnemaker et al., 2012[42] ALLTURS Good	7 communities in 5 states; Govt; Prospective cohort (3 years)	School-based survey of middle and high school youth conducted in 3 waves in 83 schools in 7 communities in 5 states, initially selected for a quasi-experiment that included matched communities; 2000-2002	Youth age <18 years who initiated smoking after baseline and before wave 3 and completed all 3 annual waves of the study.	Youth
Nonnemaker et al, 2019[40] ExPECTT Cohort Study Fair	National; Govt; Prospective cohort (3 years)	Address-based sampling to randomly select households clustered in US census block groups within 75 media markets; 2013-2016	Youth smokers that were either: Current, experimental smokers, defined as those who answered "yes" to "Have you ever smoked?" reported smoking fewer than 100 cigarettes in their lifetime, and reported smoking on one or more days in the past 30 days; Non-established smokers who answered "yes" to "Have you ever smoked?" and reported either smoking fewer than 100 cigarettes in their lifetime, not having smoked on 20 or more days in the past 30 days, or both	Youth (11-16 years)

First Author, Year, National survey name, Quality rating	Location; Funding; Study design / Duration	Sampling / Recruitment strategy [a]; Data collection period	Summary of inclusion criteria (including definition of "smoker")	Special population
Odani et al, 2019[38] TUS-CPS Fair	National; None; Cross-sectional	A multistage and stratified sample of approximately 72,000 households were selected each month. Households were scientifically selected based on mailing address, to represent the nation as a whole, individual states, and other specified areas; 2014-2015	Current cigarette smokers were those who had smoked at least 100 cigarettes during their lifetime, and smoked "every day" or "some days" at the time of interview	Adults (≥ 18 years)
Rath et al, 2015[34] LYAC Fair	National; Govt; Prospective cohort (6 months)	An online panel of adults aged 18 or older that covers both the online and offline populations in the US. Recruited via address-based sampling, a probability-based sampling method that provides statistically valid representation of the US population, including cell phone only households. Black and Hispanic young adults were oversampled; 2011-2012	Adults aged 18-34 who completed the first 3 surveys and either remained current smokers across all 3 time points or initiated cig smoking at Time 2 and remained cigarette smokers at Time 3. Current smokers used ≥ 1cigarettes in the past 30 days.	Young adults
Sidney et al, 1989[35] None Fair	California; Govt; Prospective cohort (7 years)	Patients at Kaiser Permanente Medical centers in Oakland and San Francisco. Data collected as part of a multiphasic health checkup; 1979-1986	Black current smokers aged 15-40 years.	Black HMO medical center patients aged 15-40

Abbreviations: ALLTURS=American Legacy Longitudinal Tobacco Use Reduction Study; CO=carbon monoxide; COMMIT=Community Intervention Trial for Smoking Cessation; CPD=cigarettes per day; cigs=cigarettes; Govt=government; HMO=health maintenance organization; ITC-4=International Tobacco Control Four Country Survey (US data only); LYAC=Legacy Young Adult Cohort; NHANES=National Health and Nutrition Examination Survey; NHIS=National Health Interview Survey; NHIS-CCS=National Health Interview Survey Cancer Control Supplement; NR=not reported; NSDUH=National Survey on Drug Use and Health; NYAHS=National Young Adult Health Survey; NYTS=National Youth Tobacco Survey; ppm=parts per million; TUS-CPS=Tobacco Use Supplement to the Current Population Survey; US=United States.

Table 3
Overview of Psychometric Findings for Measures of Smoking Initiation and Progression

Scale or Measure	Statistical reliability indicator ≥ 0.70?			Statistical Validity Indicator? [Criterion, Predictive, Convergent]		External (Population) Validity?			Overall Psychometric Rating
	Both Genders	By Age				Both Genders	By Age		
		Adults	Youth	Behavioral	Bio-chemical		Adults	Youth	
Age at initiation	**Yes** Brigham et al, 2008,[43] Soulakova et al, 2013,[44] Soulakova et al, 2012),[45]	**Yes** Brigham et al, 2009,[46] Grant et al, 2003,[47] Johnson and Mott, 2001,[48]	**Yes** Johnson and Mott, 2001,[48] Eppel et al, 2006,[49]	**Yes** Hwang and Park, 2014,[50] Kendler et al, 2013,[51]	**No**	**Yes** Hwang and Park, 2014,[50] Kendler et al, 2013,[51]	**Yes** Kendler et al, 2013,[51]	**Yes** Hwang and Park, 2014,[50]	A
Initiation to or with menthol cigarettes	**No**	**No**	**No**	**No**	**No**	**No**	**No**	**No**	I
Switching between menthol or non-menthol cigarettes	**No**	**No**	**No**	**No**	**No**	**No**	**No**	**No**	I
Progression to regular smoking/increase in smoking over time	**Yes** Colby et al, 2012,[52] Grant et al, 2003,[47] Blank et al, 2016,[53] Borland et al, 2010,[54] Huerta et al, 2005,[55] Ramo et al, 2011,[56] Weinberger et al, 2007,[57]	**Yes** Brigham et al, 2009,[46] Brigham et al, 2010,[58] Colby et al, 2012,[52] Grant et al, 2003,[47] Huerta et al, 2005,[55] Ramo et al, 2011,[56]	**Yes** Brener et al, 2002,[59] Stanton et al, 1996,[60]	**Yes** Eppel et al, 2006,[49] (Stanton et al, 1996,[60] Abrams et al, 1987,[61]	**Yes** Abrams et al, 1987,[61] Stanton et al, 1996,[60] Rostron et al, 2019,[62]	**Yes** Eppel et al, 2006,[49] Abrams et al, 1987,[61] Stanton et al, 1996,[60] Rostron et al, 2019[62]	**Yes** Stanton et al, 1996,[60] Abrams et al, 1987[61]	**Yes** Eppel et al, 2006,[49]	A

Synthesis of the Best Available Evidence

Summaries of the best available evidence, controlling for age, race/ethnicity, and gender, are presented by outcome measure below. Outcome measures are presented with a corresponding overview table for each outcome in the following order: age at initiation; initiation to or with menthol cigarettes; switching between menthol and non-menthol cigarettes; and progression to regular smoking/increase in smoking over time. The complete data extraction for all included adjusted studies appear in Supplemental Section 4: Evidence Tables, Modeled / Adjusted Results.

Age at initiation. Seven studies, 2 reporting on the same COMMIT trial and counted as one study throughout this review,[26,27] provided adjusted analyses that assessed age at smoking initiation;[26-32] sample sizes ranged from 432 to 66,145 participants. Four studies were rated "good" quality [26,27,29,30,32] and 2 were rated "fair."[28,31]

Three studies analyzed data from the 2003 and 2006/2007 Tobacco Use Supplement to the Current Population Survey (TUS-CPS).[30-32] The smoking frequencies in the TUS-CPS, as defined by Curtin et al,[30] were as follows: (1) past-month smokers, or individuals who had smoked part or all of a cigarette on ≥ 1 day during the month preceding participation in the survey; (2) regular smokers, or those who had smoked on ≥ 10 days during the month prior to the survey; and, (3) daily smokers, or those who had smoked on all 30 days prior to the survey.

Curtin et al[30] reported that menthol smokers report significantly older ages of initiation compared to non-menthol cigarette smokers. Specifically, adult daily menthol smokers reported a mean age of smoking initiation of 15.7 years compared with 15.4 years for non-menthol smokers (p < .001); and, 15.8 years for regular menthol smokers compared to 15.6 years for non-menthol smokers (p < .001). Curtin et al[30] further reported that among past-month, regular, and daily smokers, those who smoked menthol cigarettes reported a significantly older age for smoking a whole cigarette for the first time, compared with non-menthol smokers (past-month: 12.3 vs 11.6 years, p < .0001; regular: 11.9 vs 11.1 years, p = .004; daily: 11.1 vs 10.3 years, p = .03). These analyses used a continuous age variable, which may explain the difference in findings compared to earlier studies described below.

Reporting on data from the same time periods in the TUS-CPS, Fernander et al[31] found that the odds of being a menthol smoker ("Is your usual cigarette brand menthol or non-menthol?") was only marginally associated with age of initiation (adjusted odds ratio [AOR] = 1.01, 95% CI: 1.00 to 1.01; p = .0007; age of initiation ≥ 18 versus age of initiation < 18). Lawrence et al[32] found that smokers who began smoking regularly before the age of 15, and those who began smoking regularly between ages 15 and 17, had the same odds of being a menthol smoker compared to smokers who started smoking regularly at age 18 or older (age of 15: AOR = 0.99, 95% CI: 0.90 to 1.09; and, between ages 15 and 17: AOR = 0.95, 95% CI: 0.89 to 1.02).

In similar analyses of data from the 2000-2009 National Survey on Drug Use and Health (NSDUH), Curtin et al[30] found that past-month and regular menthol (M) smokers reported significantly older ages at initiation of daily smoking compared to non-menthol (NM) smokers (M: 16.16, Standard Error [SE] = 0.07, 95% CI: 16.01 to 16.30 vs NM: 16.00 years, SE = 0.07, 95% CI: -0.30 to -0.01, p = .03; and, M: 16.17, SE = 0.08, 95% CI: 16.02 to 16.32 vs NM: 16.00 years, SE = 0.08, 95% CI: -0.33 to -0.01, p = .03, respectively) .

According to analyses of the 1999-2010 National Health and Nutrition Examination Survey (NHANES), Curtin et al[30] reported that past-month menthol smokers were older at the start of regular smoking, compared with non-menthol smokers (M: 15.5 years old, SE = 0.20, 95% CI: 15.1 to 15.9 vs NM: 15.4 years old, SE = 0.18, 95% CI: -0.41 to 0.29). This difference was not statistically significant. In the reported analyses of the 2005 and 2010 National Health Interview Survey (NHIS, Curtin et al[30] reported that past-month menthol smokers were not significantly older at the start of regular smoking, compared with non-menthol smokers (M: 15.8, SE = 0.15, 95% CI: 15.51 to 16.09 vs NM: 15.7 years, SE = 0.13, 95% CI: -0.36 to 0.14). Similarly, in an analysis of the 2005 NHIS-Cancer Control Supplement (CCS) data, Cubbin et al[29] reported no significant differences in age at initiation between menthol and non-menthol smokers of any race/ethnicity-gender combination.

Analyses of data from 3 smaller survey studies, again 2 reporting on the same COMMIT trial,[26,27] examined age at initiation for menthol versus non-menthol cigarette use.[26-28] Specifically, Allen and

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Unger[28] found no difference in age at initiation between current menthol and non-menthol female (AOR = 1.04, 95% CI: 0.98 to 1.11) or male (AOR = 1.03, 95% CI: 0.97 to 1.09) smokers. The analysis by Hyland et al[26,27] found that, compared with smokers who started smoking at or younger than age 15, those who started smoking between the ages of 16 and 19, and those who began smoking at 20 years or older, were no different in their odds of being menthol smokers (AOR = 0.92, 95% CI: 0.82 to 1.02, and AOR = 0.89, 95% CI: 0.78 to 1.01, respectively).

Overall, analyses of adult menthol smokers suggested that they have the same or an older age at initiation compared to non-menthol smokers, regardless of current smoking frequency. Although the data are limited, one analysis among youth suggested that menthol smokers were younger at initiation of "fairly regular" smoking;[30] however, other studies found no difference or slightly older age at initiation of "regular" smoking in youth.[26-29,31,32]

Initiation to or with menthol cigarettes. No adjusted studies reported results for smoking initiation to or with menthol cigarettes.

Switching between menthol and non-menthol cigarettes. Three prospective cohort studies reported a measure of switching cigarette type for both menthol and non-menthol smokers and adjusted for key confounders, and all 3 were rated "fair" quality.[33-35]

Rath et al[34] analyzed data from 267 smokers ages 18 to 34, and found that current menthol cigarette use was significantly associated with initiation with menthol cigarettes (vs initiating with non-menthol cigarettes), across 3 models with increasing number of covariates controlled for: Model 1, OR = 11.98 (95% CI: 6.03 to 23.8); Model 2, OR = 12.33 (95% CI: 6.12 to 24.84); and Model 3, OR = 8.50 (95% CI: 3.93 to 18.39). This led the authors to conclude that young adults tend to remain with the product they first initiated with.

Kasza et al[33] examined switching between menthol and non-menthol cigarettes in a cohort of 3118 adult smokers in the US. AORs for likelihood of switching were adjusted by age, race/ethnicity, and gender. Among participants who initially reported smoking menthol cigarettes, Blacks were significantly less likely than Whites to switch to non-menthol cigarettes (AOR = 0.57, 95% CI: 0.33 to 0.99). However, no difference was observed in switching from menthol cigarettes to non-menthol cigarettes (AOR = 1.11, 95% CI: 0.74 to 1.67), or for switching from non-menthol to menthol (AOR = 0.88, 95% CI: 0.59 to 1.32) by gender. There was also no difference between Hispanics and Whites in the odds of switching to non-menthol cigarettes (AOR = 1.94, 95% CI: 0.90 to 4.17). Among participants who initially reported smoking non-menthol cigarettes, both Blacks (AOR = 11.93, 95% CI: 6.30 to 22.58) and Hispanics (AOR = 3.16, 95% CI: 1.37 to 7.29) were significantly more likely to switch to menthol cigarettes compared with Whites. Adults 25 years and older were significantly less likely to switch to menthol cigarettes, compared with adults aged 18 to 24 (AORs ranged from 0.26 to 0.47, respectively).

Sidney et al[35] analyzed data from 1688 black smokers under the age of 40 and concluded that the odds of non-menthol cigarette smokers' switching to menthol cigarettes were significantly higher than the odds of menthol smokers' switching to non-menthol (hazard ratio = 4.2, 95% CI: 2.8 to 6.4).

Progression to regular smoking/increase in smoking over time. Ten studies presented results for progression to regular smoking or increase in smoking over time. Six of these studies were cross-sectional studies comparing daily versus non-daily smoking.[30-32,36-38] The other 4 studies were longitudinal cohort studies reporting on increasing smoking over time (progression to daily smoking or becoming an established smoker).[39-42] Of the 6 cross-sectional studies, 3 studies were rated "good,"[30,32,37] and 3 were "fair."[31,36,38] Of the 4 longitudinal studies, 3 were rated "good,"[39,41,42] and one was rated "fair."[40]

Giovino et al[37] studied data from more than 40,000 smokers at least 12 years of age in the 2008-2010 NSDUH. The investigators found no difference in the odds of being a past-30-day menthol, versus non-menthol, smoker when comparing 1 to 5 days, and 6 to 29 days, to daily smoking (AOR = 1.01, 95% CI: 0.91 to 1.13; p = .82, AOR = 1.02, 95% CI: 0.92 to 1.12; p = .73, respectively).

Curtin et al[30] analyzed adjusted data from 4 data sets, 3 that included adults only (2000 to 2009 NSDUH, 1999 to 2010 NHIS, and 2003 and 2006/07 TUS-CPS), and one that provided data for both adults and youth (1999 to 2010

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NHANES). Among adults, the findings were mixed in the NHANES and the NSDUH data sets. When evaluating the odds of daily smoking for non-menthol smokers (ie, menthol use is the reference group), the difference in the NSDUH analysis was significant (AOR = 1.07, 95% CI: 1.01 to 1.12, p = .011), whereas the difference in the NHANES analyses was not (AOR = 1.21, 95% CI: 1.00 to 1.46, p = .05). In both the NHIS and TUS-CPS, adult non-menthol smokers were not different in their likelihood of smoking daily compared to menthol smokers (NHIS: AOR = 0.94, 95% CI: 0.81 to 1.09, p = .39; TUS-CPS: AOR = 0.99, 95% CI: 0.96 to 1.01, p = .22). Among youth, both the NHANES analysis found that non-menthol smokers were no more likely than menthol smokers to smoke daily (AOR = 0.72, 95% CI: 0.49 to 1.05, p = .09).

Odani et al[38] analyzed data 2014 to 2015 data from the TUS-CPS, and found that daily smokers had higher odds of being a menthol smoker, compared with non-daily smokers (AOR = 1.13, 95%CI: 1.03-1.35, p < .05). Analyzing data from the 2003 and 2006/07 TUS-CPS, Lawrence et al[32] found a nonsignificant association in the odds of daily smokers being menthol smokers, compared with non-daily smokers (AOR = 1.06, 95% CI: 0.94 to 1.19). These results did not change if smokers were women or men or Hispanic. Fernander et al[31] also analyzed data from the 2003 and 2006/07 TUS-CPS, and found similar results to Lawrence et al[32] for likelihood of daily smokers being menthol smokers (AOR = 1.06, 95% CI: 0.99 to 1.14).

Using NYTS youth data from 2017 and 2018, Azagba et al[36] found that menthol cigarette users were not significantly more likely to smoke cigarettes daily (vs non-daily) in the past 30 days compared with non-menthol cigarette smokers, in the overall youth sample (AOR = 1.35, 95% CI: 0.92 to 1.98; p ≥ .05), as well as in both of their stratified analyses of middle school (AOR = 2.74, 95% CI: 0.68 to 11.13; p ≥ .05) and high school (AOR = 1.26, 95% CI: 0.88 to 1.82; p ≥ .05) students.

Of the 4 longitudinal studies, Delnevo et al[39] found that among young adult lifetime smokers, current menthol cigarette smokers had significantly increasing odds of transitioning from non-daily to daily smoking over a period of one year, from smoking on some days to smoking daily (AOR = 1.87, 95% CI: 1.06 to 3.30). Nonnemaker et al[42] found that, among high school students between the ages of 12 to 17, non-established smokers who initiated to menthol cigarettes were at higher risk of becoming established smokers over time than those who initiated to non-menthol cigarettes (adjusted relative risk ratio = 1.80, 95% CI: 1.02 to 3.16).

In another publication of the same ALLTURS high school sample, Nonnemaker et al[41] found that youth who initiated to menthol cigarettes and remained menthol smokers were more likely to progress to daily smoking at wave 3, compared with youth who initiated to non-menthol cigarettes and remained non-menthol smokers. The authors reported analyses both including youth who participated in all 3 waves and excluding youth who initiated smoking at wave 3. A significant difference for progression to daily smoking was indicated when youth who initiated at wave 3 were included (AOR = 2.12, 95% CI: 1.44 to 3.12); however, the association was not significant with their exclusion (AOR = 1.51, 95% CI: 0.67 to 3.42). The authors noted that youth that initiated smoking at the last of the 3 waves were excluded from analysis to ensure that regression model estimates examined the impact of menthol versus non-menthol cigarette use prior to and not concurrent with the smoking outcome.

Finally, in a third publication by Nonnemaker et al[40] — this time using data from the ExPECTT Cohort Study— a number of analyses (and sensitivity analyses) results in mixed findings. Current experimental smokers progressing to current established use of cigarettes were significantly more likely to be menthol users versus non-menthol users in both analytic models (Model 2: AOR = 1.91, 95% CI: 1.07 to 3.42, p < .05; Model 3: AOR = 1.85, 95% CI: 1.03 to 3.33, p < .05). A first sensitivity analysis categorizing menthol use (vs non-menthol use) in terms of use at the previous wave resulted in a continued significant association with Model 2 (AOR = 1.80, 95% CI: 1.00 to 3.25, p < .05); however, this sensitivity analysis rendered Model 3 nonsignificant (AOR = 1.74, 95% CI: 0.96 to 3.16, p < .10). A second sensitivity analysis categorizing menthol use in terms of prior use but not at the last wave rendered both models nonsignificant (Model 2: AOR = 0.38, 95% CI: 0.05 to 3.02, p = NS; Model 3: AOR = 0.38, 95% CI: 0.05 to 3.05, p = NS). A third sensitivity analysis adjusted the model to include those in the risk pool whose prior-wave menthol status was unknown, ie, when unknown used their current wave status (same wave as event) as a proxy for the respondent's "prior" menthol use. In this analysis Model 2 remained significantly association with menthol use (AOR = 1.53, 95% CI: 1.00 to 2.35, $p < .05$), while Model 3 became nonsignificant (AOR = 1.51, 95% CI: 0.98 to 2.34, $p < 0.10$). The third sensitivity analysis, however, should be interpreted with caution because temporality between exposure and outcome cannot be determined.

When applying the same analyses as previously described, except measuring transitions from non-established smoking to regular established smoking, Nonnemaker et al[40] found no significant association with menthol cigarettes in either model (Model 2: AOR = 1.56, 95% CI: 0.80 to 3.03, p = NS; Model 3: AOR = 1.51, 95% CI: 0.76 to 2.97, p = NS) of their main analysis. Similarly, the results remained nonsignificant across all 3 sensitivity analyses: categorizing menthol use in terms of use at the previous wave (Model 2: AOR = 1.44, 95% CI: 0.73 to 2.83, p = NS; Model 3: AOR = 1.39, 95% CI: 0.70 to 2.78, p = NS); categorizing menthol use in terms of prior use but not at the last wave (Model 2: AOR = 0.38, 95% CI: 0.05 to 3.06, p = NS; Model 3: AOR = 0.39, 95% CI: 0.05 to 3.12, p = NS); inclusion of those in the risk pool whose prior-wave menthol status was unknown (Model 2: AOR = 1.39, 95% CI: 0.81 to 2.37, p = NS; Model 3: AOR = 1.38, 95% CI: 0.80 to 2.39, p = NS).

Together, one analysis found that adult menthol smokers were significantly less likely to be daily (vs non-daily) smokers, compared with non-menthol smokers.[30] Four analyses found a non-significant association between menthol use and non-daily smoking.[30,36-38] The t3 overlapping analyses of the adult TUS-CPS sample all found that menthol smokers were no more likely to be daily smokers, as did analyses of the NHIS adult sample.[30-32] Of the 2 analyses of youth,[30] both found that non-menthol smokers were no more likely than menthol smokers to smoke daily. Across 3 of the 4 longitudinal analyses, menthol smokers were significantly more likely than non-menthol smokers to increase smoking (quantity or frequency) over time, although 2 of the study samples included overlapping participants; however, none of the studies truly assessed menthol use at smoking initiation. In the fourth longitudinal analyses, transitioning from experimental to current establishing smoking was generally significant; however, various sensitivity analyses that applied different temporal definitions of e-cigarette use results in some models becoming non-significant. Moreover, this study found a non-significant association between menthol use and transition from non-established to regular-established smoking, across all models and sensitivity analyses.

Sensitivity Analyses

Three sensitivity analyses were planned to test whether the results differed after more stringent inclusion and exclusion criteria were applied. Four studies were included in the sensitivity analyses by adjusting for meso- (sociocultural and physical) and macro-level (policies, government, and industry) variables in addition to age, race/ethnicity, and gender.[26,31,32,40] The sensitivity analysis of these studies yielded no difference. Details are provided in Supplemental Section 5: Sensitivity Analyses (Adjusted Results).

Results of Meta-analyses

Pooled data for the meta-analyses were extracted from 2 studies[30,38] reporting on results that adjusted for age, race/ethnicity, and gender. Both studies evaluated data from nationally representative datasets, with Curtin et al[30] evaluating 4 separate datasets that evaluated adults (2000 to 2009 NSDUH, 1999 to 2010 NHIS, and 2003, 2006/07 TUS-CPS, and 1999 to 2010 NHANES), and Odani et al[38] evaluating TUS-CPS adult data. Definitions applied in the included studies are provided in Supplemental Section 6: Definitions applied in Included in the Meta-Analysis.

Adjusted odds of reporting daily versus non-daily smoking – adults. The main analysis was comprised of studies that adjusted for demographic variables. Whereas the study by Curtin et al[30] provided estimates from multiple models adjusting for different factors, only those that adjusted for demographic covariates were pooled for this analysis as they were closest to the variables used by the study of Odani et al.[38] As Figure 2 presents, no significant association was observed between non-menthol cigarette use, compared to menthol cigarette use, and daily cigarette smoking (AOR = 1.00, 95% CI: 0.93 to 1.08, p = 1.00, $I^2 = 76\%$).

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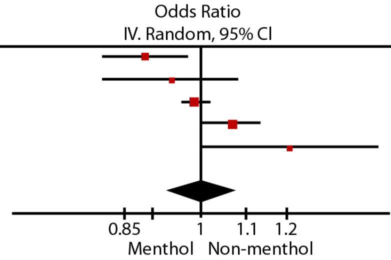
Figure 2
Meta-analysis for Odds of Reporting Daily Versus Non-Daily Smoking by Non-menthol Versus Menthol cigarette use - Controlling for Demographics

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV. Random, 95% CI
Odani 2019 - TUS-CPS (2014/15), adults	-0.1222	0.0473	20.8%	0.88 [0.81, 0.97]
Curtin 2014 - NHIS (2005 & 2010), adults	-0.0619	0.0759	13.6%	0.94 [0.81, 1.09]
Curtin 2014 - TUS-CPS (2003 & 2006/07), adults	-0.0101	0.0157	29.6%	0.99 [0.96, 1.02]
Curtin 2014 - NSDUH (2000 - 2009), adults	0.0677	0.0294	26.1%	1.07 [1.01, 1.13]
Curtin 2014 - NHANES (1999 - 2010), adults	0.1906	0.0973	10.0%	1.21 [1.00, 1.46]
Total (95% CI)			100.0%	1.00 [0.93, 1.08]

Heterogeneity. $Tau^2 = 0.00$; $Chi^2 = 16.88$, df = 4 (P = 0.002); $I^2 = 76\%$
Test for overall effect: Z = 0.00 (P = 1.00)



Sensitivity analyses. To explore the variations in exposure definitions and outcome measures, a series of sensitivity analyses were conducted. First, due to its different measure of daily (vs non-daily) smoking between the studies from Curtin et al[30] and Odani et al[38] a sensitivity analysis included only the 4 surveys from Curtin et al,[30] thereby excluding the results from Odani et al;[38] no difference in the likelihood of non-menthol smokers reporting daily (vs non-daily) use compared to menthol smokers (AOR = 1.03, 95% CI: 0.96 to 1.11, p = .41, I^2 = 69%), as Figure 3 shows.

Second, adjusted odds ratios from the random effects models were calculated according to the likeness in survey items on menthol preference. Datasets from Curtin et al[30] that analyzed NHIS and TUS-CPS data were combined, and odds ratios pooled among those that adjusted for demographics, and those that controlled for significant demographic factors and dependence variables. No association was found between non-menthol cigarette use (compared to menthol cigarette use) and reporting daily versus non-daily smoking when controlling for demographics (AOR = 0.99, 95% CI: 0.96 to 1.02, p = .43, I^2 = 0%), as Figure 4 shows, nor when controlling for significant demographic variables and dependence measures (AOR = 0.91, 95% CI: 0.81 to 1.03, p = .12, I^2 = 42%), as Figure 5 shows.

When investigating the pooled estimates from the NSDUH and NHANES data (which applied similar definitions of exposure groups) and excluding Odani et al[38] (due to its differing definition of the outcome measure), results again found no association between non-menthol cigarette use and daily cigarette smoking when controlling for demographics (AOR = 1.10, 95% CI: 1.00 to 1.21, p = .06, I^2 = 32%), as Figure 6 shows. However, results showed a significant association between non-menthol cigarette use and daily cigarette smoking when controlling for significant demographic variables and dependence measures (AOR = 1.08, 95% CI: 1.03 to 1.13, p = .002, I^2 = 0%), as Figure 7 shows.

Figure 3
Meta-analysis of Odds of Reporting Daily Versus Non-Daily Smoking by Non-menthol Versus Menthol cigarette use (excluding Odani et al.) - Controlling for Demographics

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV. Random, 95% CI
Curtin 2014 - NHIS (2005 & 2010), adults	-0.0619	0.0759	15.1%	0.94 [0.81, 1.09]
Curtin 2014 - TUS-CPS (2003 & 2006/07), adults	-0.0101	0.0157	40.4%	0.99 [0.96, 1.02]
Curtin 2014 - NSDUH (2000 - 2009), adults	0.0677	0.0294	34.0%	1.07 [1.01, 1.13]
Curtin 2014 - NHANES (1999 - 2010), adults	0.1906	0.0973	10.6%	1.21 [1.00, 1.46]
Total (95% CI)			100.0%	1.03 [0.96, 1.11]

Heterogeneity. $Tau^2 = 0.00$; $Chi^2 = 9.82$, df = 3 (P = 0.02); $I^2 = 69\%$
Test for overall effect: Z = 0.82 (P = 0.41)

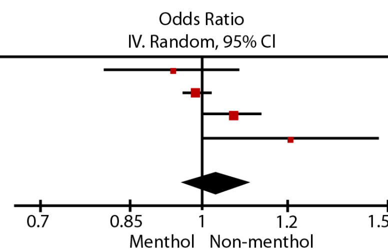


Figure 4
Meta-analysis of Odds of Reporting Daily Versus Non-Daily Smoking by Non-menthol Versus Menthol cigarette use (TUS-CPS and NHIS) - Controlling for Demographics

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV. Random, 95% CI
Curtin 2014 - NHIS (2005 & 2010), adults	-0.0619	0.0759	4.1%	0.94 [0.81, 1.09]
Curtin 2014 - TUS-CPS (2003 & 2006/07), adults	-0.0101	0.0157	95.9%	0.99 [0.96, 1.02]
Total (95% CI)			100.0%	0.99 [0.96, 1.02]

Heterogeneity. Tau² = 0.00; Chi² = 0.45, df = 1 (P = 0.50); I² = 0%
Test for overall effect: Z = 0.80 (P = 0.43)

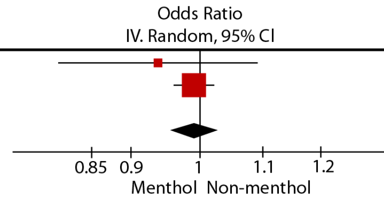


Figure 5
Meta-analysis of Odds of Reporting Daily Versus Non-Daily Smoking (TUS-CPS and NHIS) - Controlling for Significant Demographic Variables and Dependency Measures

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV. Random, 95% CI
Curtin 2014 - NHIS (2005 & 2010), adults	-0.2107	0.1123	22.1%	0.81 [0.65, 1.01]
Curtin 2014 - TUS-CPS (2003 & 2006/07), adults	-0.0619	0.0165	77.9%	0.94 [0.91, 0.97]
Total (95% CI)			100.0%	0.91 [0.81, 1.03]

Heterogeneity. Tau² = 0.00; Chi² = 1.72, df = 1 (P = 0.19); I² = 42%
Test for overall effect: Z = 1.54 (P = 0.12)

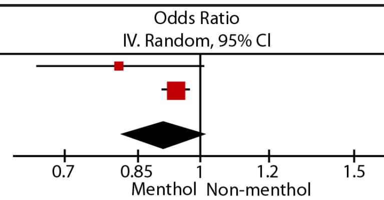


Figure 6
Meta-analysis of Odds of Reporting Daily Versus Non-Daily Smoking by Non-menthol Versus Menthol cigarette use (NSDUH and NHANES) - Controlling for Demographics

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV. Random, 95% CI
Curtin 2014 - NSDUH (2000 - 2009), adults	0.0677	0.0294	78.5%	1.07 [1.01, 1.13]
Curtin 2014 - NHANES (1999 - 2010), adults	0.1906	0.0973	21.5%	1.21 [1.00, 1.46]
Total (95% CI)			100.0%	1.10 [1.00, 1.21]

Heterogeneity. Tau² = 0.00; Chi² = 1.46, df = 1 (P = 0.23); I² = 32%
Test for overall effect: Z = 1.86 (P = 0.06)

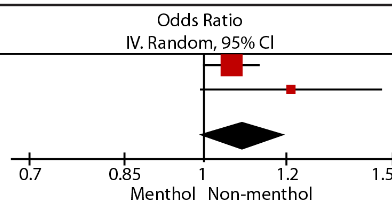
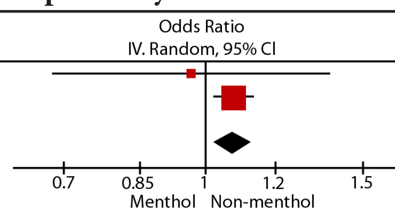


Figure 7
Meta-analysis of Odds of Reporting Daily Versus Non-Daily Smoking (NSDUH and NHANES) - Controlling for Significant Demographic Variables and Dependency Measures

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV. Random, 95% CI
Curtin 2014 - NHANES (1999 - 2010), adults	-0.0305	0.1812	1.8%	0.97 [0.68, 1.38]
Curtin 2014 - NSDUH (2000 - 2009), adults	0.077	0.0242	98.2%	1.08 [1.03, 1.13]
Total (95% CI)			100.0%	1.08 [1.03, 1.13]

Heterogeneity. Tau² = 0.00; Chi² = 0.35, df = 1 (P = 0.56); I² = 0%
Test for overall effect: Z = 3.13 (P = 0.002)



Strength of Evidence (SOE)

Table 4 provides the SOE for the outcomes used in the current review to examine the association between menthol cigarette use and initiation and progression to regular smoking. Measures were "indirect" and limited by the varying and/or undefined measures of initiation and/or progression.

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As Table 5 presents, the overall strength of evidence across outcomes for an association between menthol cigarette use and initiation and progression to regular smoking was graded as "low" based on indirectness and inconsistency. Measures were "indirect" and at risk of measurement error because of the use of a surrogate measure for menthol cigarette use at initiation. Most included studies used current cigarette type as a surrogate measure for type at initiation, assuming that participants did not switch cigarette types during the period between initiation and data collection (which was decades in some studies).

Table 4
Strength of Evidence Assessment by Measure (Adjusted Analyses)

Measure	Study limitations	Directness	Consistency	Precision	SOE	CQ assessment
Age at initiation						
	Low	Indirect	Inconsistent	Precise	Low	Acceptable
Initiation to or with menthol cigarettes						
	NA	NA	NA	NA	Insufficient	Inconclusive
Switching between menthol and non-menthol cigarettes						
	Medium	Indirect	Inconsistent	Imprecise	Insufficient	Inconclusive
Progression to regular smoking/increase in smoking over time						
	Low	Indirect	Consistent	Precise	Low	Acceptable

Note.
CQ = Contextual Question; SOE = Strength of Evidence

Table 5
Overall Strength of Evidence Assessment (Adjusted Analyses)

Measure	CQ Assessment	Measure SOE	Overall SOE
Age at initiation	Acceptable	Low	Low
Initiation to or with menthol cigarettes	Inconclusive	Insufficient	
Switching between menthol and non-menthol cigarettes	Inconclusive	Insufficient	
Progression to regular smoking/increase in smoking over time	Acceptable	Low	

Note.
CQ = Contextual Question; SOE = Strength of Evidence

DISCUSSION

This qualitative synthesis examined literature that compared menthol to non-menthol smokers according to age at smoking initiation; smoking initiation with menthol cigarettes; switching between menthol and non-menthol cigarettes; and progression to regular smoking/increased smoking over time. Overall, direct information from longitudinal cohort studies on smoking initiation with menthol cigarettes and progression to regular or daily smoking is lacking, and consequently, there is currently insufficient evidence to support an association between menthol cigarette use and smoking trajectories.

Age at initiation was one of 2 measures of initiation/progression to regular smoking rated with "acceptable" reliability and validity according to the psychometric evidence. In addition to the inconsistent findings across the body of evidence for this outcome, the ability to draw any solid conclusions was further limited due to most studies measuring initiation to menthol as a proxy for menthol status at initiation.

No studies included evaluated initiation to or with menthol cigarettes and controlled for key demographic founders. The absence of adjusted studies prevented a qualitative analysis for this outcome measure; however, it does illustrate the lack of available data on true cigarette smoking initiation, as it relates to menthol cigarettes, which this review has identified as a key limitation of the body of available literature.

In terms of switching between menthol and non-menthol cigarettes (a measure rated "inconclusive" according to the psychometric evidence), a significant association between initiation with menthol cigarettes and current use of menthol cigarettes among young adults was reported,[34] as well as a significantly lower likelihood of older adults switching to menthol cigarettes comparted to young adults.[33] These findings suggest that preference is established early in individual smoking trajectories. This is consistent with the findings of Smith et al[10] who also found minimal switching among becomes even less likely as users age. Findings from a single study indicate that while switching product type does not appear to be influenced by gender, it may be influenced by race ethnicity—specifically, both black and Hispanic non-menthol smokers may be more likely to switch to menthol cigarettes compared to white non-menthol smokers, and black menthol smokers were less likely to switch the non-menthol cigarettes compared to white menthol smokers.[33]

Among 4 longitudinal studies examining progression to regular smoking in youth and young adult populations,[39-42] there was insufficient evidence to support an association between menthol cigarettes and initiation and progression to regular smoking. Specifically, the findings for youth were consistent with previously-reported findings that suggested that the prevalence of youth menthol and non-menthol smokers at different stages and trajectories of smoking progression—defined as increasing quantities and frequencies of past month cigarette use—did not differ significantly.[2] These findings contradict Villanti et al,[8] who concluded that the "strength and consistency of the associations in these studies support that the removal of menthol from cigarettes is likely to reduce youth smoking initiation [...] and in turn, benefit public health." However, none of the studies included in this study for this outcome measure truly assessed menthol use at smoking initiation. Although the samples included relatively new initiators, empirical data on switching cigarette type support the theory that if switching occurs, it occurs early in the smoking trajectory.[34] Therefore, studies on progression to regular smoking suffered from the same issues of temporality as the studies of age at smoking initiation and provide insufficient evidence to support an association.

To provide a higher level of evidence, data were appropriately pooled for meta-analyses evaluating daily versus non-daily cigarette smoking. Understanding the issues of temporality in the evidence base, the meta-analyses informed on the outcome of daily versus non-daily smoking with a higher level of evidence according to pooled results. Consistent with the majority of cross-sectional studies evaluating menthol use and daily cigarette smoking, results of a meta-analysis of government survey data from 2 studies[30,38] suggested menthol and non-menthol cigarette smokers were not significantly different in their odds of reporting daily smoking, for both adults and youth. Consistent with the main analysis, the sensitivity analyses to isolate studies with similar definitions of exposure groups and outcome measures were generally non-significant, with the exception of one analysis—controlling for dependency measures—which found that non-menthol use was significantly associated with daily (vs non-daily) smoking.

Limitations

This systematic review was conducted according to established methodological standards and with inherent limitations. For example, the variation in the definitions of several outcome measures made it challenging to summarize results, which limited the authors' ability to draw definitive conclusions.

Most of the smoking behavior data were self-reported. However, any impact of self-reported data in this review is expected to be minimal.

The Downs and Black[15] checklist has limitations when applied across a variety of study designs. Furthermore, a study's quality score on the Downs and Black[15] checklist may reflect the quality of reporting rather than the quality of the study itself.

Finally, the conclusions in this review are based on studies conducted in the US and may not be generalizable to other countries due to the potential impact of important influences, such as cultural norms, smoking policies, and taxes on smoking behaviors outside of the US.

Conclusions

The body of available evidence suggests that there is no significant, differential association between menthol smoking and reporting daily versus non-daily, smoking, compared to non-menthol smoking. However, the overall strength of evidence is insufficient to draw clear and confident conclusions about the relationship between menthol (versus non-menthol) cigarette use and initiation and progression to regular smoking.

Human Subjects Approval Statement

Preparation of this paper did not require original data collection involving human subjects.

Conflict of Interest Disclosure Statement

Dr. Kim serves as full-time employee of RAI Services Company, a wholly owned subsidiary of Reynolds American Inc. Dr. Curtin is a retired employee of RAI Services Company.

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ABBREVIATIONS

Abbreviation	Definition
AHRQ	Agency for Healthcare Research and Quality
ALLTURS	American Legacy Longitudinal Tobacco Use Reduction Study
AMSTAR	A measurement tool to assess systematic reviews
AOR	Adjusted odds ratio
CI	Confidence interval
COMMIT	Community Intervention Trial for Smoking Cessation
CQ	Contextual Question
DANDY	Development and Assessment of Nicotine Dependence in Youths Study
EPC	Evidence-Based Practice Center
ExPECTT	Evaluation of Public Education Campaign on Teen Tobacco
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IARC	International Agency for Research on Cancer
KQ	Key Question
LYAC	Legacy Young Adult Cohort Study
M	Menthol
NA	Not Applicable
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NHIS-CCS	National Health Interview Survey Cancer Control Supplement
NM	Non-menthol
NSDUH	National Survey on Drug Use and Health
PICO	Population, Intervention/exposure, Control group, Outcomes
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SE	Standard error
SOE	Strength of Evidence
TPSAC	Tobacco Products Scientific Advisory Committee
TUS-CPS	The Tobacco Use Supplement to the Current Population Survey
US	United States

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