

Appendix B
**Sample Review Forms/
Quality Rating Forms**

Title Abstraction Form

1. Original research (no editorials, letters to the editor) published in English after 1980 or a Cochrane review?

- Yes
- No
- Cannot determine

2. Study located in any of the following countries: USA, Canada, United Kingdom, Western Europe, Australia, New Zealand

- Yes
- No
- Cannot determine

3. Addresses one or more of the following (check all that apply):

- Population and Community based interventions for preventing tobacco use (KQ1)
- Strategies for increasing consumer demand for and use of individually oriented cessation treatments (KQ2)
- Strategies for increasing the implementation of population-level cessation strategies (KQ3)
- Effects of smokeless tobacco product marketing and use on population harm (KQ4)
- Effectiveness of interventions in populations with co-morbidities and risk behaviors (KQ5)
- Future research (KQ6)
- Cannot determine by the title or abstract
- None of the above

4. Study design is one of the following:

- RCT (n>30)
- RCT (n=?)
- Meta-analysis

- Observational Study (n=?)
- Observational Study (n>100)
- Case series
- Case report
- Cannot be determined
- Observational Study (n<99)
- Model or simulation study
- None of the above designs (Flag this response)
- Cochrane systematic review

5. If an **RCT** is excluded because of **small sample** size check here:

- Yes

6. Use for background ? If Yes, check here and **flag** article.

- Yes

Full Text Review Form

1. Is this article

a) referenced in a systematic review, or an editorial or comment?

b) Cochrane systematic review or meta analysis?

Yes

No

2. Study is located in any of the following countries:

USA, Canada, United Kingdom, Western Europe, Australia, New Zealand

Yes

No

3. The study is one or more of the following:

KQ1 - Population and community based interventions for preventing tobacco use in adolescents and young adults (RCTs published Jan 2000 & later only) or refers to tobacco industry and product restriction (1980 to present)

KQ2 - A 6mo or longer intervention designed to increase the number of tobacco users (i.e. adults/diverse pops) who seek individually-oriented treatments or increase use of proven intervention strategies {i.e., counseling, behavioral, & Pharmo} (published Jan 1999 & later only)

KQ3 - A 6 mo or longer study of strategies to increase the implementation & use of proven pop-level tobacco cessation interventions, particularly those in communities & healthcare settings (published Jan 1999 & later only)

KQ4 - Influence of smokeless tobacco marketing on initiation & use, and the effects on population harm

KQ5 - 6 mo or longer study of effectiveness of cessation interventions in pops with co-morbidities & risk factors

KQ6 - Future research

None of the above

4. Study design is one of the following:

RCT (n>30)

- Cohort Study (n>100) - Smokers & non-smokers followed over time to compare outcomes
- Case Control (n>100) - Subjects who have a certain condition are compared with people who don't
- Cross Sectional (n>100) - Like case-control studies, but more than two categories (such as just "smoker" & "non-smoker")
- None of the above (please flag if meta-analysis or systematic review)
- Cochrane Systematic review or meta analysis

5. If an RCT is excluded because of sample size <30, please check here and flag:

- Yes

6. Use for background? If yes, please check & flag (write background in flag box)

- Yes

Abstraction Form for Systematic Review or Meta-analysis

1. Is this a systematic review of meta-analysis?

- Systematic Review
- Meta-analysis

2. Author et al, date

3. Geographic Area

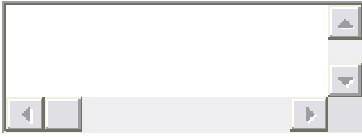
- United States
- Canada
- United Kingdom
- Western Europe
- Australia
- New Zealand

4. Funding Source


5. Aim of Review

6. Time Period Covered


7. Inclusion Criteria

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8. Population

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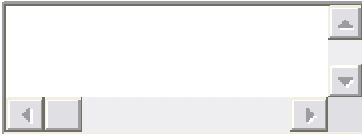
9. Characteristics of studies (Interventions)

An empty rectangular text box with a thin border. On the right side, there are two small square buttons with upward and downward arrows. At the bottom, there are two small square buttons with leftward and rightward arrows.

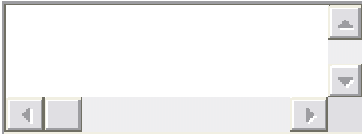
10. Method of Review

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11. What studies are included in the Meta analysis?

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12. Study Design

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13. Main Results

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14. Adverse Events

No

Yes

Not Applicable

15. Quality Rating

Good

Fair

Poor

Comments:

Abstraction Form for Articles

1. Abstractor Initials

2. If the article should have been excluded in level 2 exclude and provide reason in text box...otherwise include.

Exclude

Include

3. Key Question

KQ1

KQ2

KQ3

KQ4

KQ5

KQ6

4. Author/Year

5. Geographic Area

United States

Canada

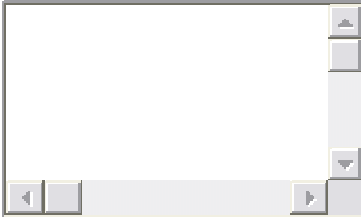
United Kingdom

Western Europe

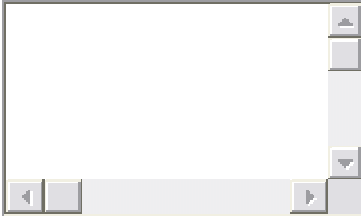
Australia

New Zealand

6. Funding Agency



7. Study Objective



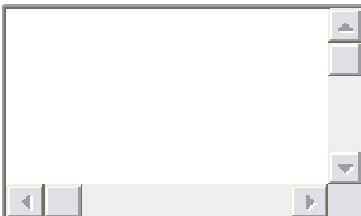
8. Population

- Adolescents,
- Young Adults,
- Adults,
- Men (only),
- Women (only),
- Pregnant women,
- African Americans,
- American Indians,
- Latino,
- Low SES,

Describe



9. Risk Behavior(s)



10. Psychiatric condition(s)

11. Study Setting

- School-based
- Community-based
- Population-based
- Hospital
- Worksite
- Practice/provider settings

Describe

12. Study Design

- RCT with simple randomization
- RCT with systematic randomization
- RCT with stratified randomization
- RCT with cluster randomization
- Cohort Study
- Case Control
- Before and after study
- Time series
- Control trial
- Cross-sectional

13. Describe study design

14. Sampling Technique

15. Sample Size

Total sample

I1

I2

I3

C1

16. Inclusion Criteria:

17. Exclusion Criteria:

18. Intervention Methods

- Self-Help
- Individual Counseling by Health Professional
- Individual Counseling by non Health Professional
- Group Counseling
- Telephone Counseling
- Computer-based Program

- Social Support
- Video
- Media Campaign
- Pharmaceuticals
- Parent involvement
- Extra-curricular activities
- Classroom instruction
- Community-Activities

Describe

19. Intervention

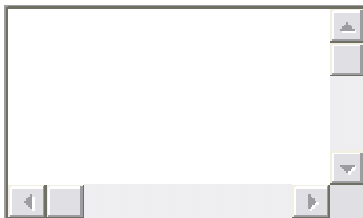
I1

I2

I3

C1

20. Method of Assessment



21. Definition of Smoking

Cigarettes

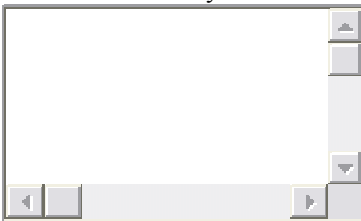
Smokless tobacco

NR

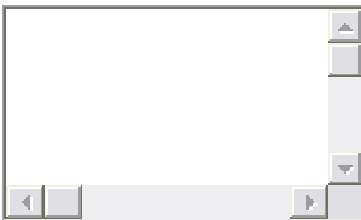
22. Baseline Data



23. Statistical Analysis



24. Data verification



25. Results

Dependent Variables

Outcome measures

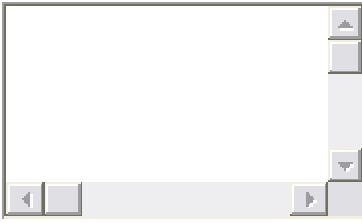
26. Adequate Randomization

Yes

No

NR

27. Attrition Rates



28. Quality Rating

- Good
- Fair
- Poor
- Comments

Quality Review Form for RCT Studies

1. Is this a drug study?

- Yes
- No

2. Was randomization adequate?

- Yes
- No
- Not Randomized
- NR

3. Was allocation of concealment adequate?

- Yes
- No
- Not randomized
- NR

4. Are the groups similar at baseline?

- Yes
- No
- NR

5. Was the eligibility criteria specified?

- Yes
- No

6. Was blinding adequate?

- Yes

- No
- Yes, but method not described
- NR
- NA

7. The outcome assessor (Researcher) was blind to the study participants.

- Yes
- No
- Yes, but method not described
- NR

8. Are participants blind to the study treatment?

- Yes
- No
- Yes, but method not described
- NR

9. Reporting of crossovers, adherence, and contamination.

Yes

No

10. Was attrition less than 25%? Please report percentage.

Yes

No

Not

Reported

Percentage

11. Was the differential attrition less than 15%?

Yes

No

NR

Percentage

12. Was a power analysis calculated for the study?

Yes

No

NR

13. Did the study use Intention To Treat analysis (impute missing responses)?

Yes

No

14. Did post randomization of exclusions occur in the study?

Yes

No

Unable to determine

NR

15. What is the quality rating for this study? Please provide a rationale in the comment box.

Good

Fair

Poor

comments:

Quality Assessment for External Validity

16. The control group standard of care was described?

Yes

No

Comments:

17. Is the study population representative of the population of interest?

Yes

No

Comments:

Quality Assessment for Adverse Events

The next questions are for drug studies only.

18. Non-bias selection?

Yes

No

Not clear

19. Low overall attrition at follow-up (less than 25%)?

Yes

No

Not clear

20. The adverse events were pre-specified and defined?

Yes

No

Comments:

21. Ascertainment techniques (instruments) were non-biased and adequately described?

Yes

No

Comments:

22. Statistical analysis of potential confounders?

Yes

No

Comments:

23. Was there adequate duration of follow-up (at least 6 months)?

Yes

No

Comments:

24. What is the overall adverse event assessment quality?

Good

Fair

Poor

Comments:

Quality Review Form for NonRCT Studies

Study quality is evaluated using six categories (Descriptions, Sampling, Measurement, Analysis, Interpretation of Results, and other). Some problems with a study can be included under several of the categories. Use your best judgement to list the problems under the most appropriate category.

Answer the questions based on the quality of execution of the study's design.

Always provide comments for limitations.

External Validity (Generalizability of the Study Results)

1. Was the study population well described? (Study should describe both intervention and comparison populations and all relevant characteristics such as age, gender, SES)

Yes

No

NR

Limitations:

2. Was the intervention well described? (What was done?, how was it delivered?, who was targeted?, and where it was done?)

Yes

No

NA

NR

Limitations:

3. Did the authors specify the sampling frame or universe of selection for the study population?

Yes

No

NR

NA

Limitations:

4. Did the authors specify the screening criteria for study eligibility?

- Yes
- No
- NR
- NA
- limitations:

5. Was the population that served as the unit of analysis the entire eligible population or a probability sample?

- Population
- Probability
Sample
- Limitations:

6. Are there other selection bias issues not identified above? (This might include a very low participation rate (or a high refusal rate), a volunteer sample (as opposed to a convenience sample selected by the investigators), an inappropriate control or comparison group, or extremely restricted sampling inappropriate for measuring the effectiveness of the intervention being studied.)

- Yes
- No
- NA
- Limitations:

Internal Validity and Reliability

7. Did the authors attempt to measure exposure to the intervention? (observation, interviews, self administered questionnaire, Record review, lab test)

- Yes
- No
- NA

Limitations:

8. Was the exposure variable valid? (i.e., measured exposure in different ways, consistency checks for self-reports)

Yes

No

NA

limitations:

9. Was the exposure variable reliable? (measures of internal consistency were used, Cronbach's alpha, inter rater reliability)

Yes

No

NA

Limitations:

10. Were the outcome and other (or predictor) variables valid?

Yes

No

NA

NR

Limitations:

11. Were the outcome and other (or predictor) variables reliable?

Yes

No

NA

NR

Limitations:

12. Did the authors conduct appropriate statistical testing by: (Select all that apply)

Conducted statistical testing when appropriate.

Reported which statistical test were used.

Controlled for design effects in the statistical model.

Controlled for repeated measures in populations that were followed over time.

Controlled for differential exposure to the intervention.

Used a model designed to handle multi-level data when they included group-level and individual covariates in the model.

Describe other problems with the data analysis.

13. Was the attrition greater than 25% (if a survey, please write in the response rate)?

Yes

No

NA

Survey response rate

14. Did the author assess whether the unit of analyses were comparable prior to exposure to the intervention?

Yes

No

NA

15. Did the author correct for controllable variables or institute study procedures to limit bias appropriately (e.g., randomization, restriction, matching, stratification, or statistical adjustment)?

Yes

No

NA

16. Based on your overall impression of the study please rate quality of article. Important issues: who are the participants and how are they selected, are good instruments used to measure the results, are the results analyzed using appropriate methods. Finally can the results be replicated and are the outcomes generalizable...if not, this study may have a fatal flaw.

Good studies (an outstanding study, one to two minor limitations)

Fair studies (limitations but mostly minor limitations)

Poor studies (the study had fatal flaws in sampling, assessment measures, or statistical analysis)


Good

Fair

Poor

Comment

17. New Text Box Question



Quality Review Form for Systematic Reviews and Meta-analysis

1. Is this a systematic review or meta-analysis?

- Systematic Review
- Meta-analysis

2. Is the systematic review based on a focused question of research?

- Yes
- No
- Not reported

3. Are the eligibility criteria for the studies clearly described?

- Yes
- No
- Not reported

4. Did the search strategy employ a comprehensive, systematic literature search?

- Yes
- No
- Not reported

5. Did at least 2 people independently review studies?

- Yes
- No
- Not reported

6. Did the authors use a standard method of critical appraisal before including studies?

- Yes
- No

Not reported

These questions are for meta-analysis only

7. Was publication bias assessed?

Yes

No

Not reported

8. Was heterogeneity assessed and addressed?

Yes

No

Not reported

9. Did statistical analysis maintain trials as the unit of analysis?

Yes

No

Not reported

10. What is the quality rating for this study? Please provide rationale for response.

Good

Fair

Poor

Rational: