NIH NATIONAL CANCER INSTITUTE

EBCCP Case Studies for Teaching

Student's Guide

Evaluation of Research for Implementation

EBCCP Evidence-Based Cancer Control Programs

Teaching Case Study
Student's Guide: Research Methodology

Overview

The Evidence-Based Cancer Control Programs (EBCCP) website is a searchable database sponsored by the National Cancer Institute (NCI) that aims to increase knowledge and utilization of cancer control programs in community and clinical settings. The EBCCP website was created and is maintained by the Implementation Science team in the Office of the Director at NCI's Division of Cancer Control and Population Sciences. The EBCCP website exemplifies the mission of the team: to develop and apply the implementation science knowledge base to improve the impact of cancer control and population science on the health and health care of the population, and foster rapid integration of research, practice, and policy.

The website currently features more than 200 cancer-related programs in the following areas: breast cancer screening, cervical cancer screening, colorectal cancer screening, diet/nutrition, HPV vaccination, informed decision-making, obesity, physical activity, prostate cancer screening, public health genomics, sun safety, survivorship/supportive care, and tobacco control. Additional topical areas and new programs are being added regularly.

Purpose and Competencies Addressed

The purpose of this teaching case study is to provide students with an opportunity to apply their research methodology and evaluation skills. This assignment requires students to closely examine 16 research integrity criteria: (1) theory/hypothesis-driven measure selection, (2) reliability, (3) validity, (4) intervention fidelity, (5) nature of comparison condition, (6) comparison fidelity, (7) assurances to participants, (8) participant expectations, (9) standardized data collection, (10) data collector bias, (11) selection bias, (12) attrition, (13) missing data, (14) analysis meets data assumptions, (15) hypothesis-driven selection of analytic methods, and (16) anomalous findings.

Upon completion of this case study, students will have applied strategies for examining a program theory and 15 other research methodology areas within a health-related evidence-based intervention.

The following competencies from the Council on Education for Public Health's accreditation criteria are addressed with this assignment:

- **D1.6:** Explain the critical importance of evidence in advancing public health knowledge.
- **D2.4:** Interpret results of data analysis for public health research, policy, or practice.
- **D2.11:** Select methods to evaluate public health programs.
- **D2.12:** Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence.
- **D3.1:** Explain qualitative, quantitative, mixed methods, and policy analysis research and evaluation methods to address health issues at multiple levels (individual, group, organization, community, and population).
- **D3.6:** Integrate knowledge, approaches, methods, values, and potential contributions from multiple professions and systems in addressing public health problems.
- **D3.16:** Integrate scientific information, legal and regulatory approaches, ethical frameworks, and varied stakeholder interests in policy development and analysis.

The Assignment

1. Read the Nutrition Pathfinders program summary on the EBCCP website.
   a. Identify the program's primary outcome(s).
2. Locate the program's publication, which is linked in the "Publications" section of the program summary.
3. Read the publication.
4. Complete the below sections in this guide, following the instructions provided:
   a. Program Review Packet: Nutrition Pathfinders
   b. Reflection Questions
5. Debrief the assignment and your responses to the reflection questions with your instructor.

Support

Ask your instructor for clarification on the assignment. For technical support or to provide feedback, email Jasmine Douglas, Ph.D., at jasmine.douglas@icfnext.com, or Aubrey Villalobos, Dr.PH., M.P.H., M.Ed., health scientist at NCI, at aubrey.villalobos@nih.gov.

Program Review Packet: Nutrition Pathfinders Instructions

1. Review the "Research Integrity Rating Criteria and Evidence Notes" section—it lists the 16 evaluation criteria with ratings, definitions, and considerations relevant to each criterion.
2. Rate each criterion by choosing low, moderate, or high evidence, and provide any comments justifying your rating in the "Evidence Notes" sections.
3. Respond to the two reflection questions.
4. Refer to communication from your instructor for assignment submission details.

Research Integrity Rating Criteria and Evidence Notes

LIST THE PRIMARY OUTCOME MEASURE(S) FOUND IN THE PRIMARY PUBLICATION	
PRIMARY OUTCOME(S)	**MEASURE(S)**

1. THEORY- OR HYPOTHESIS-DRIVEN MEASURE SELECTION

Outcome measures should be supported by literature related to the study theories and/or hypotheses.

Low = The measure is not related to the study theories and/or hypotheses.

Moderate = The relationship of the measure to the study theories and/or hypotheses is questionable and/or unclear.

High = The measure is well related to the study theories and/or hypotheses.

Considerations:

- Detail of explanation, or how well defined the measure is
- Goodness of conceptual fit and sequential flow from theory to hypothesis to measure
- Whether the measure is extraneous to theories/hypotheses
- Primary vs. secondary outcome measures
- Whether the measure has any theoretical basis
- How well established the field is
- Other

Evidence Notes:

2. RELIABILITY

Outcome measures should demonstrate evidence of reliability (consistency of the measure).

Low = No evidence of measure reliability **or** evidence that is presented is poor.

Moderate = Reliability estimates are at fair levels.

High = Reliability estimates are at excellent levels.

Considerations:

- Types of reliability tests used (e.g., test-retest, internal consistency)
- Number of reliability tests used
- Levels of reliability coefficients
- Nature of measure (e.g., survey, administrative records, observations)
- Number of items in measure
- Nature of response options
- Use of a well-known instrument normed on study population
- Use of a well-known instrument normed on study population and also with the sample participating in the study
- Measure not well known/developed for the study
- Reliability established by the study evaluator vs. independent investigator
- Measure adapted from an instrument with known reliability but reliability not established with new measure
- Demonstration that the new study measure was pilot-tested
- Other

Evidence Notes:

3. VALIDITY

Outcome measures should demonstrate evidence of validity (how accurate the measure is).

Low = No evidence of measure validity **or** evidence that is presented is poor.

Moderate = Validity estimates are at fair levels.

High = Validity estimates are at excellent levels **or** the measure is objective and observable.

Considerations:

- Types of validity examined (construct, concurrent, predictive)
- If no mention of validity, does the measure have face validity?
- Nature of measure (e.g., survey, administrative records, observations)
- Use of a well-known instrument normed on study population
- Measure not well known/developed for the study
- Measure adapted from an instrument with known validity but validity not established with new measure
- Other

Evidence Notes:

4. INTERVENTION FIDELITY

The "experimental" intervention should be implemented as intended or modified as appropriate as the study progresses.

Low = There is no evidence the intervention was implemented with appropriate fidelity **or** there is evidence the intervention was not implemented with appropriate fidelity.

Moderate = There is fair evidence the intervention was implemented with appropriate fidelity.

High = There is excellent evidence the intervention was implemented with appropriate fidelity.

Considerations:

- Clearly articulated/documented intervention protocol
- Training/supervision of intervention implementers
- Dosage
- Adherence to guidelines
- Use of a fidelity checklist
- Use of a psychometrically sound fidelity instrument
- Data reported from fidelity checklist
- Observations (by investigator or third party)
- Qualitative/narrative data
- Quantitative data
- Modifications appropriate and documented
- Other

Evidence Notes:

5. NATURE OF COMPARISON CONDITION

A study's comparison condition should be an appropriate contrast to the experimental intervention.

Low = The comparison condition provides a poor contrast to the experimental intervention.

Moderate = The comparison condition provides a fair contrast to the experimental intervention.

High = The comparison condition provides an excellent contrast to the experimental intervention.

Considerations:

- Adequacy of the description
- Clarity as to the purpose of the comparison condition (e.g., placebo, attention control, no-treatment or wait-list control, alternative active intervention)
- Appropriateness of the comparison condition
- Multiple comparison conditions
- Other

Evidence Notes:

6. COMPARISON FIDELITY

The "comparison" condition(s) should be implemented as intended or modified as appropriate as the study progresses.

Low = There is no evidence the comparison condition was implemented with fidelity **or** there is evidence the comparison condition was not implemented with fidelity.

Moderate = There is fair evidence the comparison condition was implemented with fidelity.

High = There is excellent evidence the comparison condition was implemented with fidelity.

Considerations:

- Whether comparison group is a no-treatment or wait-list control group
- Whether comparison group participants received interventions that were very similar or identical to intervention participants
- Potential for contamination across comparison/intervention groups
- Training/supervision of implementers
- Dosage
- Adherence to guidelines
- Use of a fidelity checklist
- Use of a psychometrically sound fidelity instrument
- Data reported from fidelity checklist
- Observations
- Qualitative/narrative data
- Quantitative data
- Modifications appropriate and documented
- Other

Evidence Notes:

7. ASSURANCES TO PARTICIPANTS

Confidentiality and assurances that participants' standard of care will not be affected by study participation are likely to result in more accurate responses.

Low = There is no evidence that participants were assured confidentiality and that participation would have no effect on services.

Moderate = There is fair evidence that participants were assured confidentiality and that participation would have no effect on services.

High = There is excellent evidence that participants were assured confidentiality and that participation would have no effect on services **or** data were not collected directly from participants.

Considerations:

- Setting (e.g., institutional vs. non-institutional settings)
- Institutional review board approval
- Consent and assent forms
- Confidentiality and privacy forms
- HIPAA-related documents (Health Insurance Portability and Accountability Act)
- Voluntary nature of participation
- Whether service provider was also the data collector
- Other

Evidence Notes:

8. PARTICIPANT EXPECTATIONS

Participants can be biased by how an intervention is introduced to them and by an awareness of their study condition. Information used to recruit and inform study participants should be carefully crafted, if possible, to equalize expectations.

Low = There is no evidence that participant expectations were equalized.

Moderate = There is fair evidence that participant expectations were equalized.

High = There is excellent evidence that participant expectations were equalized.

Considerations:

- Possible effects that knowledge of the study condition had on outcomes
- How participant bias might be minimized (e.g., information used to recruit and inform study participants)
- Other

Evidence Notes:

9. STANDARDIZED DATA COLLECTION

All outcome data should be collected in a standardized manner. Data collectors trained and monitored for adherence to standardized protocols provide the highest-quality evidence of standardized data collection.

Low = Investigator did not use standardized data collection protocols.

Moderate = Data were collected by individuals who were trained in the use of a standardized protocol.

High = Data collection was standardized, and to ensure adherence to the protocol, data collectors were monitored and retrained as needed.

Considerations:

- Appropriateness of the data collection procedures
- Training
- Who monitored data collection
- Nature of data collection (computer-assisted telephone interviewing/random-digit-dialing, self-report, administrative records/database)
- Other

Evidence Notes:

10. DATA COLLECTOR BIAS

Data collector bias is most strongly controlled when data collectors are not aware of the conditions to which study participants have been assigned (i.e., blinded or masked). When data collectors are aware of specific study conditions, their expectations should be controlled for through training and/or statistical methods.

Low = Data collectors were not masked to participants' study conditions.

High = Data collectors were masked to participants' conditions **or** data were not collected directly from participants.

Considerations:

- Data collectors also the service providers?
- Attempts made to reduce possible bias (e.g., data collector training, statistical control)?
- Other

Evidence Notes:

11. SELECTION BIAS

There should be baseline equivalence across study conditions on key variables, and any baseline differences should be appropriately controlled for in statistical analyses.

Low = The evidence is poor or weak that the groups were equivalent at baseline through assignment and/or statistical adjustment.

Moderate = The evidence is fair that the groups were equivalent at baseline through assignment and/or statistical adjustment.

High = The evidence is excellent that the groups were equivalent at baseline through assignment and/or statistical adjustment.

Considerations:

- Random assignment
- Matching
- Other sampling approaches
- Variables examined for equivalence
- Regression continuity design
- Statistical approaches to equalize key baseline variables
- Other statistical procedures
- Bias related to self-selection across conditions
- Other

Evidence Notes:

12. ATTRITION

Study results can be biased by participant attrition; therefore, efforts are required to account for attrition.

Low = Attrition was so extensive that statistical methods were unable to provide adequate correction.

Moderate = Attrition was an issue and was inadequately addressed statistically.

High = Attrition was taken into account effectively **or** there was no attrition needing adjustment.

Considerations:

- Extent of attrition
- Study setting and population
- Differential attrition between treatment and control groups
- Baseline differences between attriters and study completers
- Methods used to account for attrition (e.g., crudely estimating data, modeling missing data/observations/participants)
- Other

Evidence Notes:

13. MISSING DATA (OTHER THAN MISSING DATA RESULTING FROM ATTRITION)

Study results can be biased by missing data; therefore, efforts are required to account for missing data.

Low = Missing data were so extensive that statistical methods were unable to provide adequate correction.

Moderate = Missing data were an issue and were inadequately addressed statistically.

High = Missing data were adequately addressed statistically **or** missing data were not an issue.

Considerations:

- Extent of missing data
- Methods used to account for missing data (e.g., mean replacement, last point carried forward, modeling or imputation)
- Other

Evidence Notes:

14. ANALYSIS MEETS DATA ASSUMPTIONS

The appropriateness of statistical analyses is a function of the properties of the data being analyzed and the degree to which data meet statistical assumptions.

Low = Analyses were inappropriate to the data collected; severe violations of assumptions make analysis uninterpretable.

Moderate = There were violations of statistical assumptions, casting doubt on the interpretation of results.

High = There were no major violations of assumptions for any analysis.

Considerations:

- Nature of data (e.g., interval, ratio)
- Distribution of the data
- Adjustments for multiple comparisons, clustering
- Other

Evidence Notes:

15. HYPOTHESIS-DRIVEN SELECTION OF ANALYTIC METHODS

Data analytic approaches should be consistent with study hypotheses rather than being ex post facto data-driven.

Low = There is no evidence that data analytic approaches are consistent with study hypotheses **or** there is evidence to the contrary.

Moderate = There is fair evidence that data analytic approaches are consistent with study hypotheses.

High = There is excellent evidence that data analytic approaches are consistent with study hypotheses.

Considerations:

- Fit between data analyses and logic model
- Adjustments for multiple comparisons, clustering
- Analysis of scale/factor vs. individual items
- Evidence of "fishing expeditions"
- Other

Evidence Notes:

16. ANOMALOUS FINDINGS

Findings that contradict the theories and hypotheses underlying an intervention suggest the possibility of confounding causal variables and limit the validity of study findings.

Low = There were anomalous findings suggesting alternative explanations for findings reported, and they were explained inadequately.

Moderate = There were anomalous findings, and some effort was made to explain them.

High = There were no anomalous findings **or** researchers explained anomalous findings in a way that preserved the internal validity of results reported.

Considerations:

- Circumstances that could have affected the outcome (e.g., environmental, historical)
- Adverse effects
- Unexpected differential outcomes across subgroups
- Sensitivity of the measure to change
- Other

Evidence Notes:

REFLECTION QUESTIONS

1. After reviewing the evaluation approach for the Nutrition Pathfinders program, what might you have done differently if you had been leading the evaluation design and implementation?
2. If you were responsible for implementing the Nutrition Pathfinders program in a new setting or with a new population, what do the evaluation findings suggest might be important considerations for implementation or adaptation?

Evidence Notes: