Best Practices in the Evaluation of Consumer Food Safety Interventions

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http://norocore.ncsu.edu/cms/
Introduction

- Worldwide, food safety is an important and pressing public health issue.
- The 2010 Global Burden of Disease report ranks diarrheal disease as the 4th most prevalent malady in the world, after heart disease, pneumonia, and stroke. (Murray et al. 2013).
- Most cases of diarrheal disease are from contaminated food or water.
1. **Food Laws and Regulations** – relevant, science-based, enforceable food laws and regulations.

2. **Food Control Management** – coordination of policies and operations at the national level.

3. **Inspection** – food laws and regulations that use qualified, trained, and honest food inspection service.

4. **Food Monitoring/Epidemiological Data** – laboratory facilities run by qualified analysts.

5. **Information, Education, and Communication** – delivery of balanced, factual information, education, and communication to groups across the farm-to-table continuum.
Critics of Food Safety Education

- Critics suggest many education efforts to raise awareness of food safety are not approached in a systematic, scientific, and theoretically and pedagogically sound fashion.

- In the *IFT Expert Report on Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century* (IFT 2002), the authors acknowledge food safety education as a control strategy, but are unconvinced of its effectiveness.
Aim of Food Safety Education

- Globally, pursued as a means to decrease the burden of illness from foodborne disease.
- Governments, industry, colleges, and universities have developed countless food safety education interventions.
- But . . . How effective are they, particularly at changing safe food handling practices?
Typical Outcome Measures

- Improved knowledge, presumably because one assumes practices will improve as knowledge increases.
- Knowledge, as well as positive attitudes, about an intended behavior are important prerequisites to taking action, but they do not guarantee action.
- **Implementation** of safe food handling practices is the action that reduces the burden of illness.
Two Systematic Literature Reviews

- **Egan et al. (2007) Food Control**
  - Summarizes results of studies that reported effectiveness of training in commercial food industry.
  - Conclude scant empirical evidence that documents the effectiveness of education at improving practices.
  - Most evidence is fair to poor by scientific standards.

- **Viator et al. (2015) Journal of Food Protection**
  - Current state of evaluation is not sufficiently rigorous to support development of an evidence-based literature.
Suggested Reasons

- Educators trained to deliver information not to evaluate it.
- Educators might not understand research methods.
  - Medeiros et al. (2001) evaluated 12 food safety curricula targeting consumers.
  - Only 50% of the evaluation instruments reviewed had been tested for reliability and/or validity and then to varying extents.
- More rigor is needed in the development and pretesting of evaluation instruments if educators are to have confidence in the outcomes they report.
Moving Forward

- Scientific community is just beginning to gather empirical evidence to prove the effectiveness of food safety interventions.
- When substantially high quality, empirical evidence is collected and analyzed, a decisive judgment of the effectiveness of food safety education at reducing the burden of illness from foodborne disease can then be made.
- Much more work needs to be done to prove food safety education is effective.
Guidance on research design
- Counterfactual condition
- Measures to avoid threats to validity
- Alternatives to randomized designs

Specification of outcome measures
- SMART measures
- Quantifiable terms
- Primary and secondary outcomes

Development and testing of impact instruments
- Seven guidelines
- Cognitive testing
- Translation
The experimental method

Three goals

- **Causation.** It allows the experimenter to make causal inferences about the relationship between independent variables and a dependent variable.

- **Control.** It allows the experimenter to rule out alternative explanations due to the confounding effects of extraneous variables (i.e., variables other than the independent variables).

- **Variability.** It reduces variability within treatment conditions, which makes it easier to detect differences in treatment outcomes.
What Do We Mean By Cause And Effect?
What Do We Mean By Cause And Effect?

THE FAMILY CIRCUS

"I wish they didn't turn on that seatbelt sign so much! Every time they do, it gets bumpy."
Rules for demonstrating a causal relationship

- **Temporal Precedence**
  - The observed effect must occur after the assumed cause

- **Co-variation**
  - The observed effect must be associated with assumed cause beyond chance association

- **Plausibility**
  - We must be able to rule out alternative explanations for the observed effect
The Null Hypothesis

Statistical Test
Logic of statistical hypothesis testing

- Hypothesis -- A testable statement about the relationship between two factors
  - Theory-driven
  - Include researchers belief about direction and magnitude
  - Operationalizable
  - Falsifiable
Logic of statistical hypothesis testing

- **Hypothesis Test** – Inferential procedure using samples drawn from a population to evaluate a hypothesis about that population.
- Does the observed difference reflect a *real* population difference?
  - 2 possibilities:
    - Real statistical difference (samples not from the same population)
    - Chance variation (random difference, but same population)
What Do We Mean By Validity?
What is validity?

- Validity refers to the approximate truth of an statement
  - Does the evidence support the statement?
  - What is the source of the evidence?
  - What other information is available?

- Validity of the property of an inference, not a design
What is validity?

- Experimental studies are designed to identify a set of practices and strategies that improve food safety.
- Resources are limited—want to use the opportunity wisely.
- If we draw incorrect inferences about what works or what doesn’t work, may make bad decisions about allocation of time and resources.

*Bad decisions can ultimately fail to benefit—and may even do harm to—those we are seeking to serve.*
Today, we will discuss internal validity and statistical conclusion validity.
Internal validity

- Do our conclusions about observed covariation between a treatment, intervention, or program and a behavior the program is designed to affect reflect a causal relationship?

- Have we controlled for or measured factors that could also covary with our program or the outcome?
Threats to internal validity

- Selection
- History
- Maturation
- Regression artifacts
- Attrition
- Instrumentation
Statistical conclusion validity

- Did the measured outcome covary with the application of the program?
- What was the magnitude of covariation?
- Was the observed covariation greater than expected by chance alone?

How confident can we be regarding the conclusions we draw about our hypotheses?
Threats to statistical conclusion validity

- Violated assumptions of the test statistic
- Low statistical power
- Inaccurate effect size estimation
- Unreliability of measures
- Extraneous variation in the experimental setting
- Unreliability of treatment implementation
- Error rate problem
Experimental Designs

Randomization and alternative designs
Randomization isn’t all that random

- Randomization is the single best and most efficient method of eliminating measurable sources of bias.

- It is one of the only methods of eliminating unmeasurable sources of bias.

- AND…it’s not random in the common sense of the word

- Randomization uses a known mechanism for assignment treatments to persons.
Benefits of randomization

- Estimates of effect from randomized experiments are unbiased: the expectation equals the population parameter.
  - So the average of many randomized experiments is a good estimate of the parameter (e.g., Meta-analysis)

- Estimates from randomized experiments are consistent: as the sample size increases in an experiment, the sample estimate approaches the population parameter.
  - So large sample sizes are good
What randomization is NOT

- Random assignment is not random sampling
  - Random sampling is rarely feasible in experiments

- Random assignment does not require that every unit have an equal probability of being assigned to conditions
  - You can assign unequal proportions to conditions

- Random assignment does not compensate for poorly designed experiments
Different approaches to randomization

- Simple random assignment
  - Assigns units to conditions with a non-zero probability
Alternatives to randomization
Alternatives to randomized design

- Not always possible to randomly assign treatment to participants
- Practical issues
  - Logistics
  - Timing
  - Recruitment/enrollment procedures
- Legal and ethical issues
  - Distribution of scarce resources
  - Participants may have a right to receive treatment
  - Ethics of withholding beneficial treatment
Logic of quasi-experimental designs

- Identification of plausible threats to internal validity
  - What other factors could account for the observed association?
  - How do the participants in one group differ from the participants in the other group?
  - Differences in place? Differences in time?

- Primacy of control by design
  - Matching
  - Stratification
  - Multiple baseline measures

- Coherent pattern matching
  - Complex predictions allow for fewer alternative explanations
  - Interactions
  - Mediating factors
Alternatives to randomized design

- Regression discontinuity
  - Assignment based on cut-off score prior to the implementation of the program or treatment
  - Internal validity may be as strong as randomized design

- Non-equivalent comparison group design
  - Assignment is not random and most likely based on
  - Can rule out many plausible alternative explanations

- Interrupted time series (we will not discuss this further)
  - Requires a large number of time points
  - Researcher must know the exact time with policy or program is enacted
Assigns participants to treatment or control based on whether the fall above or below a determined cut-off score on an assignment variable.

Assignment variable can be any continuous measure taken prior to treatment.

Assignment variable does not have to be correlated with the outcome variable.

The power of the design is maximized when the cut-off value is the mean of the assignment variable.
Regression discontinuity compared with randomized design

Posttest \((Y2)\)

Cutting Point

Selection Variable \((S)\)

Δ
Non-equivalent comparison (NCG) group designs

- One of the most commonly used QE designs in public health and public policy research
- There are NCG designs that rely strictly on post-test data
- Our focus is on NCG designs with pre-test and post-test data
  - Repeated measures on same participants in most cases
  - General design plus augmented designs
Logic of the NCG design

- Retains control of a treatment of intervention applied to one set of participants, withheld from another.
- With baseline measures, researchers can examine similarity across conditions on outcomes measures and other factors that could be correlated with treatment outcomes.
- Careful design and consideration allows researchers to eliminate many potential validity threats.
Untreated control group with pre-test and post-test

- One of the most commonly used QE designs in public health and public policy research
- Closely mirrors RCT (minus randomization)
- Eliminates many validity threats
NCG with additional pre-test measure

- Provides a more dynamic view of change
- Excellent design to use when outcome is modeling a developmental process

### NEC design with Multiple Pre-tests and one Post-test measure

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![Graph showing Trx Group and Comp Group](graph.png)
NCG with additional comparison group

- Can reduce eliminate some selection factors
- Excellent design to help rule out maturation, history

NEC design with Multiple Pre-tests and one Post-test measure

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- Many other NCG designs are possible
- Creative and logical thinking can compensate for most challenges and threats to internal validity
An outcome measure is the desired benefit, improvement, or achievement of a specific program goal or objective.

More specifically, it is the amount of change expected in an individual, a group of people, or population that is associated with a program or intervention activity within a given time frame (Posavac & Carey, 1997).
Identify Key Outcomes First

- Engage key stakeholders.

- Develop logic model to outline at minimum the program’s
  - Inputs, activities, or processes;
  - Outputs;
  - Outcomes or impacts; and
  - External factors that may influence program’s inputs, activities, or outcomes.
OUTCOME ≠ OUTPUTS

- Outputs describe the number of individuals served by a program.
- Outcomes record the results of the program’s interactions with the individual.
Outcome measures quantify the desired achievements and should be clearly defined and be “SMART” (Meyer, 2003):

- **Specific**
- **Measurable**
- **Achievable**
- **Relevant**
- **Time bound**
Specific: Clearly state your desired outcome, achievement, or accomplishment by addressing the 5 Ws: Who, What, When, Where, and Why.

**Good example:**
- Specific outcome: At least 85% of the teen participants will wash all fruit before eating by the end of the 6-week intervention.

**Bad example:**
- Nonspecific outcome: To get teens to wash fruit.
Outcome Measures Should Be **Measurable**

- **Measurable**: Identify the level or amount of change expected as a result of program activity.
- Include numeric or descriptive measures that define quantity, quality, cost, etc.
- Measurable outcomes guide evaluation design, track progress, and document success.

**Good example:**
- Measurable outcome: To increase food thermometer usage among program participants by 25% by June 2015.

**Bad example:**
- Nonmeasurable objective: To ensure that participants in the program use a food thermometer.
Achievable: Intended behaviors should be realistic, feasible, and attainable.

Good example:

✓ Achievable objective: By end of semester, increase the percentage of college males who always wash countertops with soap and hot water after preparing a meal at home from 40% to 50%.

Bad example:

✗ Nonachievable objective: Increase the percentage of college males who always wash countertops with soap and hot water after preparing a meal at home to 90% in 1 month.
Outcome Measures Should Be Relevant and Time Bound

- **Relevant**: Align outcomes with organization’s mission and goals.
- **Time bound**: Clearly state a definitive date when the desired behavior will be achieved (e.g., within 6 months).
Express Evaluation Measures in Quantifiable Terms

If outcome measures are not expressed in quantifiable terms, it is hard to know if the program failed to observe desired changes because of implementation failures or statistical/measurement issues.

- Examine measures from prior program implementations (i.e., what is realistic and achievable).
- Review published literature.
- If no prior estimates available, consider whether it is appropriate to move forward with full impact evaluation or if a smaller pilot study is more appropriate.
Primary and Secondary Outcome Measures

- Include secondary outcome measures.
- Secondary outcomes link intervention to your outcomes to create a clear snapshot of program’s impact on behaviors.
- Secondary outcomes capture complex nature of behavior change process, include mediating factors and short-term outcomes.
- Changes in short-term outcomes may influence primary outcome.
Mediating Factors

- **Predisposing factors** include the knowledge and attitudes of an individual as they relate to the motivation to act.
- **Enabling factors** include the skills and resources needed to engage in intended behavior.
- **Reinforcing factors** include factors that help reinforce intended behavior.
For More Information on Selecting and Defining Outcome Measures

- Davidson, E. J. (2013). *Actionable evaluation basics: Getting succinct answers to the most important questions*. Auckland, New Zealand: Real Evaluation Ltd.
Questions
# Developing Effective Evaluation Instruments

<table>
<thead>
<tr>
<th>Step 1:</th>
<th>Use multiple measures and/or data sources</th>
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<tbody>
<tr>
<td>Step 2:</td>
<td>Include only important variables</td>
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<td>Step 3:</td>
<td>Use valid and reliable measures</td>
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<td>Step 4:</td>
<td>Use existing instruments…don’t reinvent the wheel</td>
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<tr>
<td>Step 5:</td>
<td>Use measures that are sensitive to change</td>
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<td>Step 6:</td>
<td>Use measures that are appropriate for audience’s literacy level</td>
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<tr>
<td>Step 7:</td>
<td>Follow guidelines for writing original questions</td>
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</table>
By using multiple measures of the same underlying construct that are assessed in different ways and drawn from different sources, you can arrive at conclusions that can greatly strengthen your overall evaluation effort (Posavac, 2010).

Two or more data sources will provide a clearer picture of intended behavior than just one source on its own. If resources permit, this is a good approach to use.
STEP 2: Include Only Important Variables

- Resist the “kitchen sink” approach. Ask yourself what questions truly need to be answered. Which variables are essential to the evaluation?

- If respondents perceive questions to be unimportant or off-track, they may become inattentive and less willing to complete the survey accurately.

- Asking nonessential questions can weaken your results if respondents do not answer particular questions or decline to complete the survey.

A good rule of thumb: Limit interviewer-administered surveys to 15 to 20 minutes and self-administered surveys to 5 to 10 minutes
Reliability
- Reliability of a survey item or instrument is shown by the extent to which it produces the same result when applied to the same person under the same conditions.
- Often assessed using test-retest method.

Validity
- Survey items or instruments are considered to be valid when they accurately measure the activity, behavior, or opinion they’re intended to assess.
- Validity applies not to the survey items themselves but rather to the purpose for which they are being used.
Use Reliable and Valid Measures (continued)

- Reliability refers to the consistency of measures.
- Validity refers to the accuracy of measures.
- Example…
  - Let’s say your scale is off by 5 pounds. Everyday, it reads your weight as being 5 pounds higher than it actually is.
- Although the reliability (consistency) of this scale is very good because it consistently reports the same weight every day, it is not valid (accurate) because you actually weigh 5 pounds less.
Reliability = consistency of measure

<table>
<thead>
<tr>
<th>Type of Reliability</th>
<th>Description</th>
<th>Statistical Test</th>
</tr>
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<tbody>
<tr>
<td>Test-retest</td>
<td>Indicator of the stability of responses over time that is measured by having the same set of respondents complete the survey (a single item or group of items or scale within an instrument) at two different time points.</td>
<td>Correlation coefficient or r value is calculated to compare the two sets of responses.</td>
</tr>
<tr>
<td>Internal Consistency</td>
<td>Indicator of how well a group of items in a scale measures the same characteristic or concept.</td>
<td>Measured by calculating Cronbach’s coefficient $\alpha$, a statistic that reflects the homogeneity of the scale.</td>
</tr>
<tr>
<td>Interobserver or inter-rater</td>
<td>Indicator of how well two or more interviewers agree in their assessment of a variable; should be used whenever there is a subjective component in the measurement of an external variable.</td>
<td>Measured as a correlation coefficient between different data collectors.</td>
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### Types of Validity

Validity = accuracy of measure

<table>
<thead>
<tr>
<th>Type of Validity</th>
<th>Description</th>
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<tbody>
<tr>
<td>Face</td>
<td>Casual review of how good an item or group of items appears as assessed by individuals with no formal training in the subject matter of interest.</td>
</tr>
<tr>
<td>Content</td>
<td>Formal expert review of how good an item or series of items appears, usually assessed by individuals who are experts in the subject matter of interest.</td>
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<tr>
<td>Concurrent criterion</td>
<td>Measures how well the item or scale correlates with the “gold standard” measure of the same variable. For example, for measuring dietary intake, the “gold standard” would be 24-hour dietary recalls.</td>
</tr>
<tr>
<td>Predictive criterion</td>
<td>Measures how well the item or scale predicts expected future observations.</td>
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<tr>
<td>Construct</td>
<td>Theoretical measure of how meaningful a survey instrument is and is usually determined after years of experience by numerous investigators (more like hypothesis testing than calculation of correlation coefficients).</td>
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Examples of Reliable and Valid Food Safety Measures/Instruments


For More Information on Measuring Survey Reliability and Validity

Do not reinvent the wheel.
Whenever possible, use existing instruments that have been previously demonstrated to be **valid** and **reliable** for measuring the outcomes of interest.
- See examples on previous slide
- FDA Food Safety Survey at [http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm259074.htm](http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm259074.htm)
- Others
STEP 5: Use Measures that are Sensitive to Change

- The term “sensitivity” refers to the ability of a measure to detect variation associated with the measured outcome before and after the intervention.
- Continuous measures of an outcome (e.g., a 5-point Likert scale) are more sensitive to detecting change than dichotomous (yes/no) measures.

<table>
<thead>
<tr>
<th>Dichotomous Measure</th>
<th>Continuous Measure</th>
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<tr>
<td>Do you use a food thermometer to check the doneness of hamburgers?</td>
<td>How often do you use a food thermometer to check the doneness of hamburgers?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>□ Almost never □ Often □ Once in a while □ Almost always □ Sometimes</td>
</tr>
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STEP 6: Use Measures that are Appropriate for Audience’s Literacy Level

- Make sure your audience understands the questions asked in your survey.
- Questions should be easily understood by low-literacy and limited-resource audiences.
- For best results, use existing instruments that have been tested for literacy, especially ones that have been used with limited-resource audiences.
- If developing new questions, conduct tests to assess ease of reading and literacy grade level.
A variety of tests are available to assess reading ease and grade level.
- Flesch Reading Ease test (Flesch, 1948)
- Flesch–Kincaid Grade Level Formula (Kincaid et al., 1975)
- Gunning Fog index (Gunning, 1968)
- Coleman–Liau index (Coleman & Liau, 1975)
- Fry Test (Fry, 1968)
- Automated Readability Index (ARI) (Senter & Smith, 1967)

This website can perform several different tests: http://www.readability-score.com.

Microsoft Word can conduct Flesch tests.
Example: Results of Readability Testing

Harder to Read
How confident are you in your ability to wash your hands using soap and warm water before preparation of a meal every single day of the week?
- Flesch Reading Ease (higher score indicates easier to read): 51.0
- Flesch–Kincaid Grade Level Formula: 12.9

Easier to Read
How sure are you that every time you prepare a meal you can first wash your hands with soap and warm water?
- Flesch Reading Ease: 84.5
- Flesch–Kincaid Grade Level Formula: 6.9
STEP 7: Follow Guidelines for Writing Original Questions

- Begin by asking questions that clearly relate to the program’s topics and goals to build face validity and engage respondents.
  - Ask about specific domains (e.g., printed materials, hands-on activities) before asking general summary questions.
  - Ask sensitive items near end of questionnaire.
  - Conclude with demographic questions.
  - Thank participants.

- Consider whether respondents are willing or able to answer all the questions you would like to ask them.
  - For example, respondents may not be able to accurately report behaviors of household members.
Guidelines for Writing Original Questions (continued)

- Avoid open-ended questions whenever possible.
  - Low-literacy populations can find writing challenging and their handwriting may be difficult to read or interpret.
  - Written text takes longer to code and quantify.

- Avoid numerous, wordy, or complicated questions that involve many skips and changes in topic.

- Write questions that address one subject at a time; avoid double-barreled questions.
  - Use response items that are mutually exclusive.
Guidelines for Writing Original Questions (continued)

- Avoid complicated syntax, technical jargon, or advanced vocabulary.
- Word questions neutrally to avoid response bias.
  - For example, mix positively and negative worded questions in attitude scales.
- Be specific about reference periods.
  - For example, use “in the past 7 days” instead of “in the past week.”
Guidelines for Writing Original Questions (continued)

- Explain survey data will be handled confidentially.
  - Use unique case IDs.
  - Report data in summary form.

- Ask colleagues to review draft questions to get a fresh perspective.
  - Read questions aloud.
  - Obtain estimate of how long survey will take to complete.
Cognitive interviews can provide useful information on the
- manner and degree to which respondents understand questions,
- how respondents recall information and appropriate cues to help aid recall,
- cognitive complexity of questions and the strategies used by respondents to answer the questions,
- extent to which respondents are answering questions as intended,
- ability of respondents to make any calculations and judgments, and
- whether any important responses are missing from the list of responses.
How to Test Evaluation Instruments (continued)

- Two approaches to conducting cognitive interviews:
  1. The respondent reads aloud from the draft survey (especially if the instrument will be self-administered) or
  2. You (the interviewer) read the questions aloud to the respondent

- Use a “think aloud” method in which you ask a respondent to describe his/her thought process while answering the survey questions.

- Use follow-up “probes” to learn how respondents understand the meaning of questions.
  - Concurrent versus retrospective probing
Sample Follow-Up Probes for Cognitive Interviews

- “How would you put that into your own words?” for instructional text, complex questions, or technical terms
- “How far back did you think when answering that question?” for a question asking about past behavior
- “What response options should be added there?” for a question asking respondents to select one or more responses
- “How does that make you feel?” for a sensitive question
- “Where would you go next in the survey?” for a skip instruction
For More Information on Developing Effective Evaluation Instruments


Translating Survey Instruments

The focus of translation should be cross-cultural and conceptual rather than linguistic (literal equivalence).

- Steps in forward translation
  - Conduct forward translation using native-speaking translation professionals.
    - Provide translator with instructions on translation approach, emphasizing conceptual rather than literal translations and the need to use natural and acceptable language for the broadest audience.
  - Edit revised documents (second person).
  - Conduct cognitive interviews to test translation.
  - Finalize translated documents.
The World Health Organization (WHO) Guidelines for Forward Translation

1. Translators should always aim at the conceptual equivalent of a word or phrase, not a word-for-word translation (i.e., not a literal translation). They should consider the definition of the original term and attempt to translate it in the most relevant way.

2. Translators should strive to be simple, clear, and concise in formulating a question. Fewer words are better. Long sentences with many clauses should be avoided.

3. The target language should aim for the most common audience. Translators should consider the typical respondent for the instrument being translated and what the respondent will understand when s/he hears the question.

4. Translators should avoid the use of any jargon. For example, they should not use
   a. technical terms that cannot be understood clearly and
   b. colloquialism, idioms, or vernacular terms that cannot be understood by common people in everyday life.

5. Translators should consider issues of gender and age applicability and avoid any terms that might be considered offensive to the target population.

For More Information on Translating Survey Instruments

Questions