Getting Your Measures Right in Dietetic Outcomes Research

SUMMARY NOTES AND WORKSHEETS

CONTENTS:

Key Points: Outcomes Research

- Outcomes research is defined as "any investigation that measures the result of an intervention provided to a patient (or community)". Outcomes research is distinguished from other types of research by *purpose* rather than any special methods or approaches.
- Key methodologic issues in conducting outcomes research are:
- Outcomes studies include measures which capture aspects of the intervention, the desired outcomes as well as other variables which may be related to the intervention or outcome
- Measures of the **intervention** must be specified carefully so that the key predictor variables are those which are likely to induce or have induced change in the study subjects
- The **outcome measures** should be selected or developed systematically, be well defined and operationalized prior to initiation of data collection
- Other possible **(intervening or confounding) variables** that vary within and between interventions include care provider characteristics and patient characteristics (such as severity of illness, health beliefs, age, sex, SES) should be measured, especially for non-randomized outcome studies
- The time interval between the intervention and the outcome must be chosen carefully
- The endpoints for outcomes research now go beyond crude mortality and morbidity. More comprehensive and informative indicators are now used to determine the results of health interventions, such as functional status, quality of life and satisfaction with care
- Outcomes should be selected carefully, such that they reflect improvement in the health problem, but also the broader experience of the patient/subject/participant, outcomes that go beyond the patient him or herself may also be appropriate to measures such as impact on the family or caregivers

In Worksheet A, on the following page, add other examples that you can think of from your own work setting and/or from your own proposed or planned outcomes study.

WORKSHEET A:
OUTCOME MEASURES FOR DIETETIC RESEARCH - EXAMPLES

Outcomes Indicator Class	General Examples	Dietetic Examples	Your Study
Mortality	death rates	death due to CVD, anorexia nervosa, or GSD hypoglycemia	
Morbidity	complications, symptoms, sequelae	episodes of hypoglycemia, kidney failure	
Physiology	blood pressure, pulse	hemoglobin A1C levels, cholesterol, weight gain, calorie intake	
Behavior	compliance, competence, motivation	healthy food choices, breast feeding, self-monitoring	
Knowledge	knowledge of treatment or health condition	knowledge of disease, diet, risk factors	
Resource Utilization	supplies, ER visits, admissions, length of stay	G-tube equipment, supplements use, days on TPN	
Financial	cost of treatment, costs of episode of care, cost of lost work time, other opportunity costs	cost for special formulas, costs of travel to dietetic counseling, staffing costs for multidisciplinary feeding team	
Functional Status (physical)	self-dressing, independent ambulating, symptom control	self-feeding, swallowing,	
Functional Status (mental)	coping, attitude, mood	body image, anxiety about NG tube feedings	
Functional Status (social)	activities of daily living communications, return to work	eating behaviors among peers, school days lost due to anorexia nervosa exacerbations	
General health and well-being	general health rating susceptibility, resistance	growth/development and global health status after diet change	
Quality of Life (general or health-related)	SF-36, Sickness Impact Profile, ComQol	SF-36 etc. after dietary intervention	
Quality of Life (disease specific)	QL (any disease)	tools specific to Diabetes, Eating Disorders, CF QL etc.	
Family/Caregiver Outcomes	caregiver burden, social support, parenting stress	caregiver burden etc. after dietary intervention	
Satisfaction	general satisfaction with care (patient or family) VSQ, PSS	satisfaction with dietetic counseling, satisfaction with G-tube surgery care	

NOTE: some examples are actual measures/instruments and others are hypothetical; some examples are general and some are more specific, some measures, depending on your study question may also be predictor or intervening variables

**adapted from Lang and Marek (1991), also thanks to Dr. M. Reimer

Key Points: Attributes of a Good Outcomes Research Question

- The first step in operationalization of your study variables is specifying and refining the research question/topic of the study
- A good outcomes research question/study topic should be specific as to WHAT (both intervention provided and outcomes expected), WHO (the study population) and WHERE (the institutions or geographic area)
- In your proposal you will be even more specific about WHAT (as you define and operationalize your intervention and outcome variables) and WHO (including specific inclusion and exclusion criteria such as ages, clinical condition, etc.)
- The WHY of the study, i.e. the theoretical or underlying reasons for the variable associations will usually be explained in your study literature review and rationale and later in the discussion section of your manuscript.
- The WHEN is also usually specified in the study methods section, as the results of the research question are usually assumed to generalize to all contemporary time periods unless there is some specific when issue related to the subjects' experience i.e. "after childbirth" or "during surgery"
- The research question should be concise and clear and go beyond a "yes" or "no" answer
- All terms in the question should be precisely defined in the study
- Don't use unnecessary phrases such as "a study of" or "the relationship between"…
- The question occasionally may include a descriptor of the study design

Example of a poor research question*:

How effective is nutrition counselling?
Too vague - there could be multiple answers to this question ("how" is too broad a question)
- what is effectiveness?
- what is it that is unique about the nutrition counselling that you provided?
- what individuals are you most interested in?

What about medical condition, age, sex, employment, education, etc.?
Where? - to which population/geographic region would the results generalize?

Examples of good research questions:

Satisfaction with peer group food and nutrition skills training among adolescent females at risk for eating disorders

A randomized controlled trial of menu selection and dietary nutrient intake among urban seniors on a Meals Delivery Program

* with thanks to K. Hauchecorne

In this Worksheet, write in the specifics of your study idea for each research question component. Then combine the details into a single, descriptive research study title in the box below the table. Your "question" doesn't actually have to be formatted as a question, just a topical statement.

WORKSHEET B:
REFINING THE RESEARCH QUESTION

Use the following table to develop a specific outcomes research question for your study problem.

Question Component	Examples	Your Study:
What - the intervention	"antenatal diet counselling" "nutrient intake monitoring"	
What - the outcome	"satisfaction with dietetic referral services" "knowledge of dietary sources of Calcium" "health related quality of life" "compliance with enzyme supplements"	
Who - (the population to which results can be generalized)	"pediatric nephrology patients"… "adolescent boys" "lactating mothers"	
Where - (the geographic area or organization to which results can be generalized)	"tertiary referral centre" "urban pre-schoolers" "long-term care facilities"	
How - (optional, necessary only when the design is of particular importance)	"a randomized controlled trial" "qualitative analysis of"	

Your complete research question:

NOTE - after working through the operationalization of the variables in your study and reviewing the logistics of getting your study subjects you may have to re-visit and modify your question.

Key Points: Elements of the Study Design

Every outcomes study has the following design elements:

- **TIME** - variables are measured at a single point in time, or longitudinally over a time period the latter may be prospective (forward-looking) or retrospective (backward-looking)
- **GROUPS** - subjects are grouped together according to their intervention or treatment (predictor) variable or according to their outcome status
- **RANDOMIZATION** - the allocation of subjects to groups is random (by chance) or not

randomization greatly increases the likelihood that the groups compared on the intervention are similar on other/confounding variables aside from the intervention variable, which decreases bias

- **CONTROL/COMPARISON** - the investigator's ability to control interfering and irrelevant variation in the study; may include control of the environment, treatment given, etc. Often a control group is used wherein subjects are similar to the intervention group except for the intervention itself, but comparison groups on the outcome may also be used
- **INTERVENTION/MANIPULATION** - the investigator actively influences the subjects' experiences by providing the treatment, or, (in the case of a natural experiment) the investigator measures the impact of an intervention provided by others
- **Analytic** designs are distinguished from descriptive designs by an explicit comparison of groups to determine whether or not the outcome differs on the basis of the intervention
- By definition, outcomes studies are analytic designs but they can be either **observational** designs (case-control or cohort) wherein the investigator observes the natural course of events, or **experimental** designs (including quasi-experimental) wherein the investigator manipulates the exposure then follows the subjects to observe for outcome

Analytic Design	Dietetic Example	Pros	Cons
case-control - (subjects grouped on outcome and compared on intervention)	pre-term infants are grouped according to "good" outcome (100% oral feeding) or poor (tube feeding) and compared on amount and type of feeding team intervention	relatively small, quick and inexpensive because reviewing information retrospectively; well suited to outcomes which occur a long time after the intervention; can look at multiple aspects of the intervention for a single outcome	temporal relationships may be difficult to establish (did the intervention cause the outcome or vise-versa?) tough to select appropriate control/comparison group; groups may differ on selection into the study or ability to recall events
cohort - (subjects are grouped on intervention and compared on outcome)	new diabetics are grouped according to the amount of dietary education they have received and are followed for hemoglobin A1C levels in the first 6 months	well-suited to infrequent interventions; can examine multiple outcomes of a single intervention; can establish the proper temporal relationship	prospective cohort studies are expensive and time-consuming; loss to follow-up is a problem; in retrospective cohort studies there is less control over subject selection and intervention measures
experimental - (subjects receive an explicit intervention and are compared on outcome	pregnant women are randomized to receive folate supplements or not and are followed for NTDs in their infants	provides the strongest and most direct evidence about existence of a cause-effect relationship	study question restricted; difficult to design and conduct (ethics, feasibility, costs); outcomes may be too rare; may not be generalizable

WORKSHEET C: STUDY DESIGN DIAGRAM

Characterize your study according to each of the following design elements:

time	❍ single point ❍ longitudinal retrospective ❍ longitudinal prospective
groups	grouped according to ❍ outcome or ❍ intervention
randomization	❍ randomized to group ❍ no randomization, just observation
control/comparison	❍ single group ❍ two or more comparison groups
intervention/manipulation	❍ intervention actively provided ❍ subjects just grouped on intervention

Describe your study design in one or two sentences:

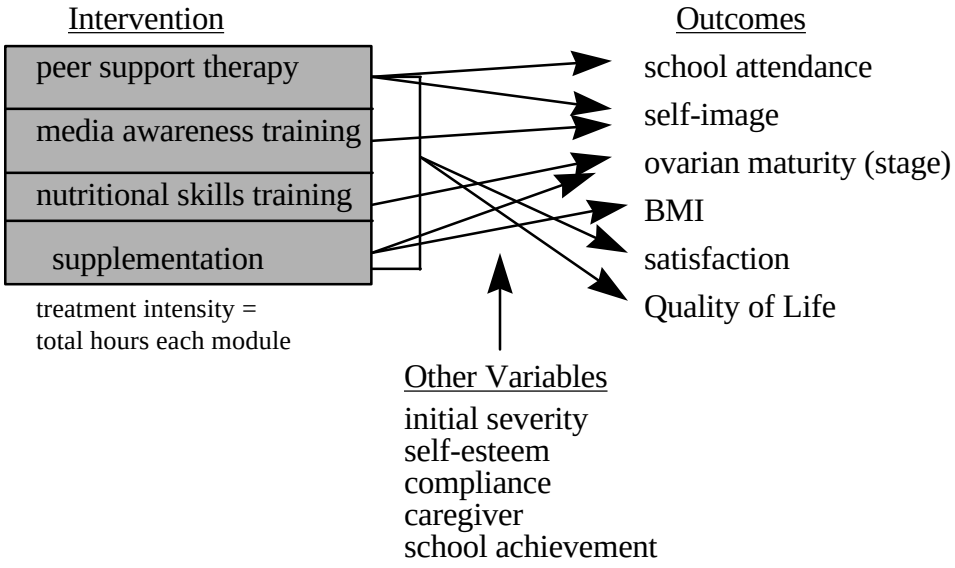
Draw a diagram of your proposed study design using boxes to represent study groups. Identify on the box(es) whether the subjects are grouped according to the intervention or the outcome. Include the expected number of subjects, dates of follow-up of groups, an I to identify the point of intervention, and an R to identify randomization (if present).

Key Points: Operationalization of Variables

- A variable is defined as an "attribute or characteristic that can vary"
- Many variables and their "values" make up a dataset
- All variables can be classified into one of four levels of measurement (LOM):
  nominal - "values just unrelated names or labels"
  ordinal - "values in rank order; no meaningful intervals"
  interval - "values have order and equal, real intervals"
  ratio - "values have order, equal intervals and true zero"
- These can be further collapsed into **categorical** or **continuous** LOM
- The level of measurement of a variable in a study is the single most important aspect which determines the strategies for statistical analysis
- The hypothesized relationship among variables is also crucial to study design/analysis
- Terms for variables which specify their hypothesized relationships include:
  independent variable(s) (IDV) = predictor variable(s)
  dependent variable(s) (DV) = outcome variable(s)
  other variable(s) = intervening variables = confounders
- The units of measurement (UOM) for continuous variables and categories for categorical variables should be specified in advance
- The concepts of validity and reliability apply to individual variables, instruments and questionnaires, as well as the overall study
- **Reliability** is the extent to which it, if repeatedly administered, the item or instrument gets the same result; it can be assessed as test re-test, alternate form, split-half, intra-observer and inter-observer reliability
- **Validity** is the extent to which the item or instrument measures what it was intended to measure; establishment of validity requires comparison with independent information (often referred to as a "gold standard"); types of validity include face, content and criterion-related validity
- **Responsiveness** is the instrument's ability to detect change

WORKSHEET D: VARIABLE RELATIONSHIPS DIAGRAM

Hypothetical Example:



Your Study Idea:

WORKSHEET E: VARIABLES CONCEPTUALIZATION TABLE

General Concept	Indicator(s)	Measure
Example: Socioeconomic Status (SES) relative position in society based on tangible resources occupational prestige, knowledge and power	education occupation income	- number of years of completed education (not including kindergarten) with Canadian equivalents for post-secondary - mean Blishen occupational prestige scores for all employed family members - Statistics Canada income categories
Dietetic Example: Low-Fat Diet Compliance	reduced intake of prohibited foods increased intake of allowed foods	observed intake of foods with > 40% fat calories in grams (food diary (spouse)) reported intake of foods with > 40% fat calories (standard 24 hour recall questionnaire) observed intake of foods with < 40% fat calories (food diary (spouse)) reported intake of foods with < 40% fat calories (24 hour recall questionnaire to be developed)
Your Study Variables:		

WORKSHEET F: STUDY VARIABLES SPECIFICATION TABLE

Using the following tables, specify the main study variables for your study idea. Examples are based on the research question **"adherence (compliance) with pancreatic enzyme therapy leads to improved growth, nutritional status and lung function among CF patients and may also vary with age and sex of the child and SES of the parents"**

Predictor Variables:

Variable/Indicator:	Definition:	UOM or Categories	LOM
Example: Enzyme Adherence	capsules dispensed in a year as % of minimum prescribed dose compliance groupings	percent EA Good = 80%+/Poor = <80%	continuous categorical
Your Predictor Variables:			

Outcome Variables:

Variable/Indicator:	Definition:	UOM or Categories	LOM
Example: growth/health	one year change in weight parent report of perceived wellness	weight Z scores 3 point wellness scale	continuous categorical
Your Outcome Variables			

Other/Intervening/Confounding Variables

Variable/Indicator:	Definition:	UOM or Categories	LOM
Example: Age	age last birthday	years and months	continuous
Your Other Variables:			

Key Points: Data Collection Tools and Methods

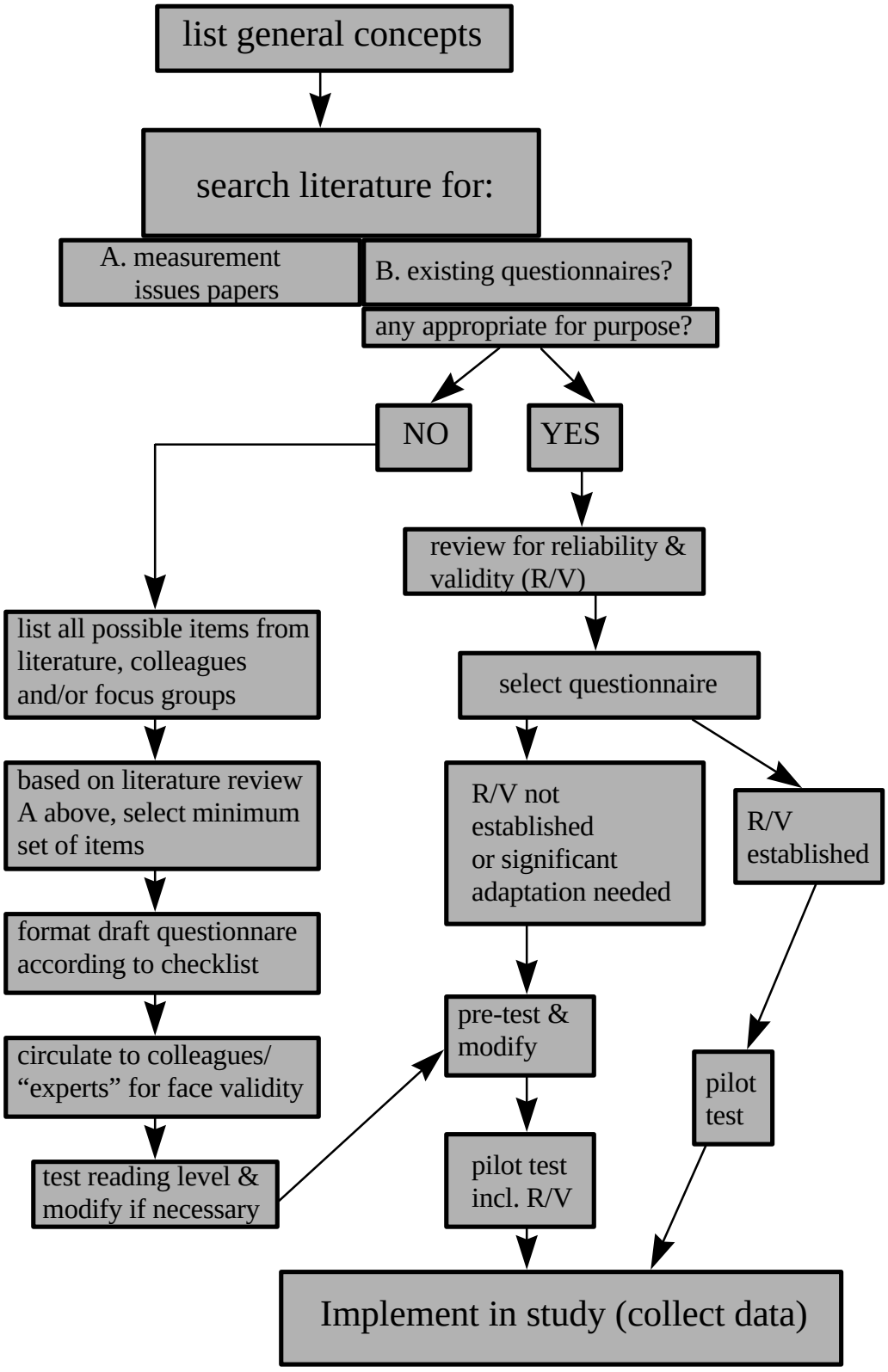
- Data can be collected from records (via standard forms), the subjects themselves or surrogates/proxies (via interview or self-completed questionnaire)
- Whenever possible use "gold standard" information (information with best known reliability and validity)
- Relying on the subjects themselves to provide information may be less accurate if a long period of recall is required, but this is not always the case; reporting accuracy depends on many factors
- A questionnaire is defined as a series of pre-determined questions
- In general, self-completed questionnaires (in-person or by mail) are less expensive, may elicit more honest responses (because of anonymity), may be quicker and more convenient, easier to administer to large groups and across geographic distance, and avoid interviewer bias. However, they may provide less accurate and complete information, especially for subjects with lower literacy skills or special problems
- Interviews (either in-person or by telephone) may be more time-consuming and costly but may result in a greater response and more complete information, can elicit more complex information through the assistance of the interviewer, and, for in-person interviews can provide an opportunity for observation of behavior which may supplement or corroborate the questionnaire data
- Pre-testing a questionnaire includes review by colleagues/experts for gross errors or problems, and administration to volunteers who are similar to the proposed study subjects for acceptability, comprehension, interpretability, recall etc.
- Pilot-testing is the implementation of the instrument under conditions as close to the actual study protocol/field conditions as possible, and can include establishment of reliability, validity as well as permit estimates of response rates and value ranges for variables
- Follow-up strategies such as those recommended in the Dillman Total Survey Design method should always be used to maximize response for surveys using distributed or mailed out self-completed questionnaires
- When questionnaires are being interviewer-administered, a systematic training program based on cognitive interviewing techniques should be used
- Questionnaires and interview schedules for dietary assessment are well developed relative to other health behavior measurement tools. Self-completed dietary assessment questionnaires include food frequency questionnaires, weighed food records, and food diaries. Interviewer-administered questionnaires include standardized dietary histories and 24-hour recall of food intake. Photos of types of foods and food portion models may assist respondents with estimating and reporting intake

WORKSHEET G: QUESTIONNAIRE DEVELOPMENT CHECKLIST

If you will be developing questionnaires for data collection in your study, use the following checklist of recommendations culled from questionnaire design textbooks and articles to ensure you address all design and formatting issues.

- ❍ the title is large, bold, eye-catching, clear, and descriptive
- ❍ all questions and sub-parts are numbered
- ❍ the question stems are placed first, followed by instructions, then response choices
- ❍ lengths of the stems are as short as possible without losing meaning
- ❍ response choices are presented horizontally (3 or fewer) or as vertical lists (4+)
- ❍ boxes are placed consistently to the right or the left and in line within a question
- ❍ response categories are mutually exclusive and exhaustive
- ❍ instructions (respondent or interviewer) are in bold and italics and are placed consistently
- ❍ questions are cast in the positive voice; there are no double-negatives or double-barreled items
- ❍ responses i.e. YES, NO are capitalized
- ❍ *don't know*, *unsure* or *other* response choice is included for all appropriate items
- ❍ open-ended questions are at a minimum especially for self-completed questionnaires (except of course if the study is qualitative)
- ❍ vague or "jargony" terms are removed or defined in parentheses
- ❍ type is clear and there is lots of white space on the page
- ❍ the length of the questionnaire and total number of pages is kept to minimum
- ❍ the number of skips is at an absolute minimum and they are very simple (many errors are made on skips in all of response, coding and analysis)
- ❍ long questionnaires have encouraging transition statements/pictures as reinforcement
- ❍ items are ordered or grouped according to some logic, i.e. temporally
- ❍ no question is split across a page
- ❍ the questionnaire starts with an easy, close-ended, interesting question
- ❍ items are ordered to progress from more general to more specific content
- ❍ sensitive questions (e.g. income and other sociodemographics) are placed near the end
- ❍ space is provided at the end for comments
- ❍ there are clear instructions at the beginning for completion
- ❍ there are clear instructions at the end for return
- ❍ there is a thank-you statement at the end for the respondent's time/assistance
- ❍ if possible the questionnaire is printed in a booklet format with title, date, authors' names and an eye-catching logo on the front
- ❍ items have been checked for order and context effects (the impact of adjacent questions on each other)
- ❍ the overall questionnaire has been checked for smooth flow of introduction, transition statements and ending
- ❍ the reading level has been measured and adjusted if necessary
- ❍ the questionnaire has been pre-tested for item comprehension, interpretation, recall, acceptability etc. as well as completion time

WORKSHEET H: QUESTIONNAIRE DEVELOPMENT FLOWCHART



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I would most appreciate feedback from anyone who uses any or all of these worksheets to develop a research study, so that I can improve them in subsequent versions. Please e-mail your comments to: ceadair@acs.ucalgary.ca or write to: C. Adair, 43 Scimitar Pt. NW, Calgary, Alberta T3L 2B3