

Linkage of Question to Design for Diabetes Translation

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Outline

- Study Design
 - ☐ Should be closely linked to the purpose of the evaluation
 - ☐ Should build on a theoretical framework of behavioral change
 - ☐ Non-randomized designs or designs where the unit of randomization is other than the participant may be the most appropriate for translation research questions

Study Design Selection

- Builds on theoretical, qualitative, and modeling work
- Should be closely linked to the purpose of the evaluation
- Goal is to minimize bias and maximize generalizability

Eccles M, et al. *Qual Saf Health Care* 2003;12:47-52

Study Design Selection

- Challenge is translation research is that the interventions are usually complex (multifaceted with simultaneous changes in different parts of the organization)
- Researcher has variable control over how the intervention is implemented

Eccles M, et al. *Qual Saf Health Care* 2003;12:47-52

Critical Steps in the Research Plan Before the Definitive Study

- Development of a theoretical basis for the intervention
- Define the components of the intervention
- Exploratory studies of observational data + qualitative research to further refine the intervention and planned evaluation
- Definitive evaluation

Eccles M, et al. *Qual Saf Health Care* 2003;12:47-52

Qualitative Designs

- Results from qualitative studies can provide critical information in the translation of interventions to real world settings that have been shown to be effective in clinical trials
- Most frequently used methods are focus groups and cognitive interviews
 - both use structured scripts grounded in theory and what is known about the topic

Qualitative Research Example

- Goal: To modify and implement an existing empowerment intervention designed to enhance self management skills among older African Americans and Latinos with diabetes
- Research Questions:
 - Are the content areas relevant to the population of interest?
 - What are the primary barriers to participation and are these modifiable?

Sarkisian et al. Submitted 2003

Qualitative Research Example

- Method: 11 focus groups with providers & patients
- Results:
 - Older African Americans and Latinos desired more dietary information, and identified coping with disability as an important missing content area
 - Barriers included: transportation, language, family influences, and competing family demands

Qualitative Methods

- A method to identify ways to enhance the acceptability, cultural and age appropriateness of interventions that need to be translated to community settings.
- Can identify structural, cultural, and personal barriers to participation in an intervention

Quantitative Non-experimental Designs

- Cross-sectional designs
- Uncontrolled before and after (longitudinal observational cohort studies)
- Controlled before and after
- Time series analyses
- In translation research there can be political, practical, and ethical barriers to randomized designs and these are our best options

Quantitative Non-experimental Designs

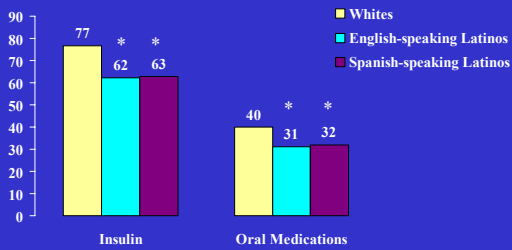
- May have little control over the implementation of the intervention...
 - Strength ... very “real world”
 - Weakness ... hard to know what really happened or which “outcomes” are likely to have changed
 - Researcher should document implementation across heterogeneous settings
- Lack of randomized controls is always a threat to internal validity but this trade-off must be placed in the context of the research question and goals of the study

An Example from the TRIAD Study

- Research Question:
 - Do Latinos and Whites in managed care settings self monitor blood glucose at similar rates and are their HbA1cs similar?
- Design: Observational Cohort Study
- Sample: 4685 persons with diabetes cared for in 8 health plans from various regions in the US

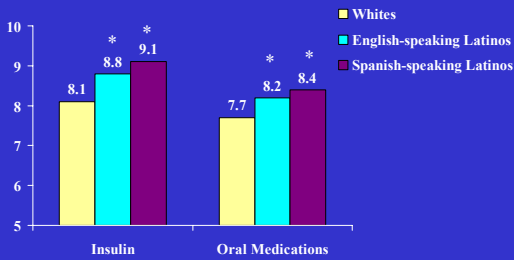
Brown et al AJPH 2003

Ethnic Differences in Self-Monitoring Blood Glucose



*p < 0.05 in comparison to whites
Adjusted for clinical and sociodemographic characteristics and health plan clustering

Ethnic Differences in mean % HbA1c Levels



*p < 0.05 in comparison to whites
Adjusted for clinical and sociodemographic characteristics and health plan clustering

Uncontrolled Before and After

- Simple to conduct
- Secular trends make it difficult to attribute changes to the intervention
- Probably over-estimate the benefit from quality improvement interventions

Controlled Before and After

- A control population with similar characteristics is identified
- Baseline and post-intervention data are collected on both the control and intervention populations
- Protects against secular trends
- Even in well matched groups, baseline characteristic can differ

Controlled Before and After

- Looking at the significance of within group change is not appropriate
- Analyses of these data need to account for clustering by site especially if the intervention is delivered at the organizational level.

Time Series Designs

- Does the intervention improve care more than the observed secular trend?
- Requires the collection of data multiple times both before and after so that you understand the magnitude of the secular trend.
- Analysis must account for the auto-correlation of data collected at multiple time points
- Strength is that you do not need a control group. Weaknesses are that you need to collect data multiple times and the design does not protect against other events occurring at the same time as the intervention.

Most Interventions Are:

- Randomized or quasi-randomized trials
- Interrupted time series (ITS)
 - defined intervention
 - 3 points in time before and after
- Non-randomized studies with controls at a second site
 - data collected before and after the intervention
 - key to interpretation hinges on comparability of the sites
- Most are evaluations within systems rather than between systems

Quantitative Experimental Designs

- Individual patient-level randomized controlled trials
- Cluster randomized controlled trials
- Strongest designs to establish a causal relationship
- But often times not appropriate for health plan or other system level interventions.

Randomized Controlled Trials

- Considered to be the gold standard
 - randomly allocated to either intervention or control group
 - best way to insure that both known and unknown factors that may influence the effectiveness of the intervention are balanced in the 2 comparison groups
- Time consuming, expensive, complex, may require a large number of clusters, tight inclusion criteria limit generalizability
- Unlikely to tell you whether an intervention will improve routine practice

Cluster Randomization

- Many QI interventions are at the provider or system level and if you randomize at the individual patient level it is likely that there will be *contamination*.
- Randomization at a higher level will reduce contamination but you pay a high price with regard to *power* and the ability to detect clinically meaningful differences in outcomes. Additionally the risk for *bias* is much higher.
- Randomize at a higher level but collect data at the patient level

Level of Randomization

- Patient
- Health Care Professional
- Practice/Hospital
- Provider group
- Health Plan
- Community

LOW LEVEL \longrightarrow \uparrow CONTAMINATION
HIGH LEVEL \longrightarrow \downarrow POWER, \uparrow LOGISTICS

Level of Randomization

- At higher levels of randomization measurement of pre-intervention characteristics is critically important
- Consider stratification on baseline characteristics that are likely to influence the effectiveness of the intervention
- Cluster randomization is likely to violate the assumption of independence of observations within a cluster...2 patients in the same practice are likely to be more similar than 3 from different practices...need to be able to estimate the intracluster correlation coefficient (ICC)

Analysis of Cluster Randomization

- Analysis at the cluster level ...uses the cluster as the unit of randomization and the unit of analysis ...each cluster is treated as one data point (inefficient!)
- Patient level analyses that are adjusted for the cluster
- Patient level analyses that allow for the correlation between clusters is explicitly modeled. The hierarchical nature of the data is accounted for in the analysis.
- Unit of randomization must be accounted for in all analyses

Challenges Inherent in Real World Settings

- Corporate restructuring and fluidity of the health care market
- Heightened sensitivity to patient confidentiality
- Difficulty changing the behavior of providers

Weinberger et al. *HSR* 2002;37:4

“...we need to embrace and study the complexity of the world, rather than attempting to ignore or reduce it by studying only isolated (and often unrepresentative) situations”

Glasgow et al. *AJPH*, 2003;93:1261-1267
