Strategies for Addressing Data Collection Challenges in a Complex Community-Based Health Evaluation

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Purpose of this Presentation

This presentation will discuss strategies for managing data collection challenges, and implications for analyses, conclusions, and replication.
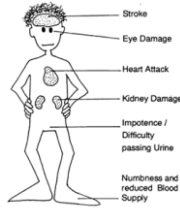
- Challenges
- Strategies
- Lessons Learned

Project Overview

Hawaii Demonstration to Maintain Independence and Employment (HI-DMIE):

- Funding: $$$ CMS
- Partners: UH, HBHC, HI-DHS
- Objective:
  - *Can a program of medical assistance and other supports forestall or prevent the loss of an individual's employment and independence due to potentially disabling complications arising from their diabetes*
- Independent Evaluation

Stroke
Eye Damage
Heart Attack
Kidney Damage
Impotence / Difficulty passing Urine
Numbness and reduced Blood Supply

Project Overview

Participants

Eligibility at baseline:
- Between 18 – 62 years
- Hawaii resident
- Diagnosis of diabetes or $HbA1_c > 6.5$
- Work > 40 hours/month
- Minimum wage

Random Assignment:
Treatment : Control ratio of 2 : 1

Hypotheses

H 1: Intervention group participants will work more hours per week

H 2: Intervention group participants will significantly increase their health status

H 3: Intervention group participants will remain independent of SSDI or SSI

Project Overview

Control Participants

- "Business as Usual"
- No intervention
- Data will be compared with Treatment Group
- $$ Compensation

Treatment Participants

- Pharmacist
- Life Coach
- Other support services
  - CDE
  - Nutritionist
  - Fitness Membership
  - Support Groups
  - Diabetes Resources
  - Laptop and internet access
  - Medical copayments related to diabetes

Participant Data Requirements

Activity	Timeline	Description
Health Assessment	Months: 0, 6, 12, 18	Physician reported HbA1c, Cholesterol, triglycerides, BMI, blood pressure
Monthly Work Calendar	Every month	Self-reported daily hours worked
Work Productivity Survey	Months: 0, 3, 6, 9, 12, 15, 18	Work Productivity and Activity Impairment Diabetes Specific: Self reported ability to work and perform regular activities
6-month Assessment • Demographics • WHO-QOL BREF • SF-12 • DES-SF	Months: 0, 6, 12, 18	Self reported: • Participation in government assistance • Quality of Life • Health and Well Being • Diabetes Empowerment
Satisfaction Survey	Months: 6, 12	Self reported: • Satisfaction • Effectiveness Treatment participants only

Factors Affecting Data Collection

Participant data collection may be affected by:

- Lack of time and logistical barriers
- Expenses related to participation
- Accessibility of locations for implementation and/or data collection
- Residence instability
- Participant psychosocial issues such as self-efficacy, distress, or readiness to change
- Presence or absence of timely incentive payments
- Participant attitudes toward the scientific and medical community

    - Yancey, Ortega & Kumanyika, 2006

- Complexity and stringency of protocol
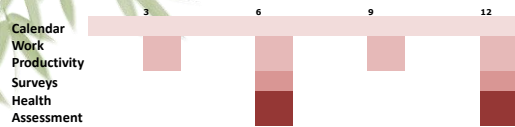- Dislike of randomization
- Physician attitudes toward intervention

    - Mills et al., 2006

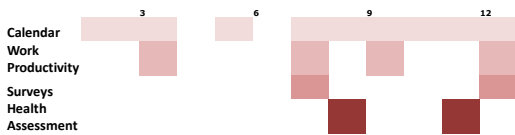
Participant Data Collection Challenges

Issue	Influences
Disenrollment	• Participant motivation • External life events
Missing data	• Participant motivation • Number of required items • Overall demands of project on participant • Physician data refusal
Completeness	• Participant motivation • Attention to detail
Timeliness	• Awareness of deadlines • Participant and physician diligence • Health assessment deadlines incongruent with typical physician appointments
Accuracy	• Social desirability bias • Recall bias and reliability

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Timeliness

Ideal Timeline

	3	6	9	12
Calendar				
Work Productivity				
Surveys				
Health Assessment				

Sample Timeline

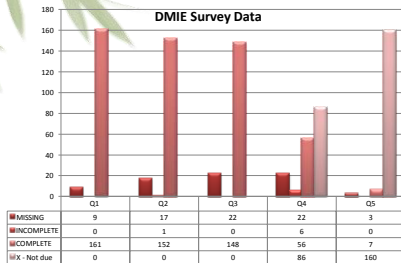|	3	6	9	12
Calendar				
Work Productivity				
Surveys				
Health Assessment				

Efforts to Improve Data Collection

Coordinated Incentive Payments
- Contingent on submission of monthly calendars, quarterly surveys & semi-annual health assessments

Individual Tracking and Follow-up
- Reminders prior to deadlines
- Follow-up re: missing items
- Follow-up re: incomplete items

Current Status of Data Collection

DMIE Survey Data

	Q1	Q2	Q3	Q4	Q5
MISSING	9	17	22	22	3
INCOMPLETE	0	1	0	6	0
COMPLETE	161	152	148	56	7
X - Not due	0	0	0	86	160

Treatment Staff Data Requirements

Activity	Timeline	Description
Session logs	Each session	Pharmacist and Life Coach self reported: • Session duration • Focus of meeting • Referrals • Reflections • Meeting format (life coach only)
Session recordings	Each session	Digital audio recording of entire session
Project specific requirements	Each session	Pharmacists: Database tools • Quality Assessment Prescription (QARX) or Digital Outcomes Communication System (DOCS) Life Coaches: Online Coaching tool • Case notes/session summaries/participant messages

Factors Affecting Data Collection

Data collection by treatment staff in community settings:

May be adversely affected by the following:
- Research needs are secondary to treatment/clinical needs
- Insufficient training, monitoring, or administrative support
- Lack of motivation, incentives, or recognition
- Ethical issues (confidentiality, consent)
- Clinical features (research skills, beliefs about merit of research)
- Political factors (collaboration, competing research agendas)
  - Boyd et al., 2007
- Systemic barriers (caseload, tasks, $)   - Butler, Little, & Grimard, 2009

May be reluctant to engage in data collection due to the following:
- Ambivalence
- Competing work demands
- Questionable evidence supporting outcome measures
- Fear about how data will be used   - Meehan et al., 2006

Treatment Staff Data Challenges

| Issues	Possible influences
Data Refusal	• Political/ethical/clinical issues • Fear of how data will be used
Missing Data	• Other job responsibilities/ double reporting • Recording errors/downloads • Change in database tool
Incomplete Data	• Motivation/incentive • Training/monitoring • Time constraints • Recording/hardware errors
Inaccurate Data	• Low motivation/ambivalence • Recall bias • 3rd party data entry

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Efforts to Improve Data Collection

Administrative support	• P.I. letter on use and intent of session recordings • Supervisor mediation • Project IT data collection
Additional in-service training	• Pharmacists – Month 3 • Life Coaches – Month 6
Pharmacist follow-up	• Follow-up re: missing items • Follow-up re: incomplete items
Payment incentive	• Payment contingent on submission of data
Reduced data obligations	• Only first page of session logs • No session recordings • 3rd party data entry (supervisor)

Current Status of Data Collection

Pharmacist Missing Data:

Before
- No log: 125 (34%)
- No recording: 163 (44%)

After
- No log: 16 (4%)
- No recording: 163 (44%)
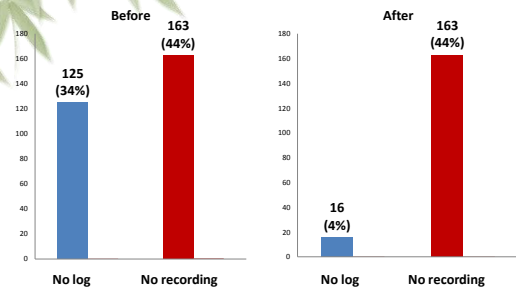
Implications for Analyses

Missing Data (Specific Items, Complete Subjects)

1. A Potential Source of Bias

2. Impacts the Ability to Interpret Results

3. Influences the Certainty With Which Conclusions are Drawn
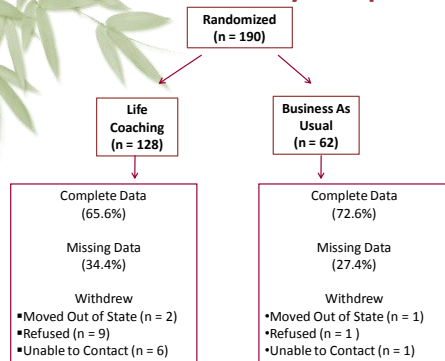

Analysis Strategy:
"As Randomized…. So Analyzed"*

Use All Randomized Participants -Regardless of Withdrawal, Non-Compliance, etc.

- Preserve Sample Size, Power

- Deviation can Contaminate Treatment Comparison

- Compliant Participants Have Better Outcomes, Regardless of Group Assignment

- LaValley (2003)
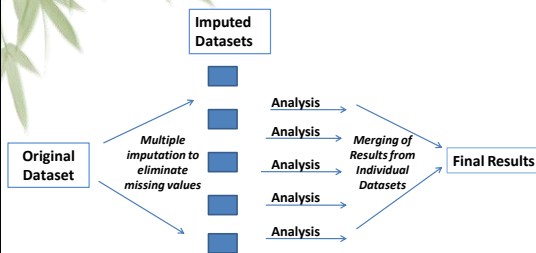
Flowchart- Study Sample


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Randomized
(n = 190)

Life                    Business As
Coaching                Usual
(n = 128)               (n = 62)

Complete Data           Complete Data
(65.6%)                 (72.6%)

Missing Data            Missing Data
(34.4%)                 (27.4%)

Withdrew                Withdrew
▪Moved Out of State (n = 2)   •Moved Out of State (n = 1)
▪Refused (n = 9)              •Refused (n = 1 )
▪Unable to Contact (n = 6)    •Unable to Contact (n = 1)
```

Analysis Strategies

Multiple Imputation (MI)

• A Range of Plausible Values are Generated that Approximate Each Missing Value

• Allows for the Inclusion of All Subjects in the Analysis

• Less Bias, More Statistical Efficiency, Straightforward

Multiple Imputation Process


```
Original          Multiple                      Imputed
Dataset           imputation to                 Datasets
                  eliminate
                  missing values    Analysis
                                    Analysis    Merging of
                                    Analysis    Results from    Final Results
                                    Analysis    Individual
                                    Analysis    Datasets
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Missing Data in Health Interventions

• Goal to Minimize Bias

• Method for Handling Data Should Provide Conservative Estimate of the Treatment Effect

• Pragmatic Approach- Determine Utility of Intervention for Practice and Dissemination

• Need to Make Appropriate Conclusions

Lessons Learned

1. Pre-specify in protocol strategies to minimize amount of missing data and how missing data will be handled

2. Pre-service training with community partners on merits of research and data collection

3. Continued data monitoring, feedback, and re-training

4. Clearly defined contractual agreements regarding data collection, payment of incentives

5. Staff resources to follow-up on missing data

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Diabetes complications: http://www.crossfitbalboa.com/uploads/balboa/image/07_diabetes_problems.gif
Stomach on strike: http://www.doctorsecrets.com/your-medicine/diabetes-causes-picture.gif
Diabetes clinic: http://comps.fotosearch.com/comp/IMZ/IMZ123/diabetes-clinic-b_~ski0007.jpg
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