Theoretically Speaking…
Pre-Clinical or Theoretical Phase
Matt Crowley, MD | Leah Zullig, PhD, MPH
September 22, 2017

Agenda

Why use a theory, model, or framework?

What’s the difference?
theories, models, & frameworks

What are some well-known frameworks?

How to apply a framework?
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What's the difference? theories, models, & frameworks

What are some well-known frameworks?

How to apply a framework?

Theory of change

“What if we don’t change at all ... and something magical just happens?”
Few Studies Use Theory


Why Do We Need Theory?

- Required for good science
- Convinces funders
- Identifies where to focus interventions
- Justifies outcome selection
- Helps us identify constructs to focus on
- Ensures reproducibility
- Explains mechanisms of action

Why Use Theoretical Frameworks

- States assumptions and enables critical evaluation
- Provides a basis for hypotheses and choice of research methods
- Identifies limits to generalizations


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What are some well-known frameworks?

How to apply a framework?
Theory

• Set of analytic principles designed to structure observation and understanding

• Comprised of definitions of variables and domains

• Explain relationships and events

Model

• Simplifies a phenomenon or a specific aspect

• Need not be completely accurate

• Descriptive
Framework

- Conveys a structure or system consisting of various descriptive categories


Theory
- Provides analytic principles
- Defines variables & relationships
- Explanatory & descriptive

Model
- Simplifies a phenomenon
- Focuses narrowly
- Descriptive

Framework
- Conveys structure
- Doesn’t explain how/why
- Categories variables

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  - theories, models, & frameworks
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Health Belief Model

- Modifying Variables
  - Perceived Benefits vs. Perceived Barriers
- Perceived Seriousness
- Perceived Susceptibility
- Perceived Threat
- Self-Efficacy
- Cues to Action
- Likelihood of Engaging in Health-Promoting Behavior
Theory of Planned Behavior

Figure 1. The Theory of Planned Behavior (Ajzen) as it applies to reducing cost-related non-adherence to oral anticancer medications.

<table>
<thead>
<tr>
<th>BARRIERS</th>
<th>BEHAVIORAL INTENT</th>
<th>BEHAVIOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>KNOWLEDGE “Where do I go for financial assistance?”</td>
<td>Intention to take medications</td>
<td>Adherence to oral cancer medications</td>
</tr>
<tr>
<td>ATTITUDE “Lowering costs might harm my care”</td>
<td>Intention to seek financial assistance</td>
<td>Use of financial resources</td>
</tr>
<tr>
<td>SUBJECTIVE NORMS “My doctor doesn’t want to talk about my costs”</td>
<td>Intention to discuss costs</td>
<td>Discussion of costs</td>
</tr>
<tr>
<td>PERCEIVED BEHAVIORAL CONTROLS “There is no way to lower my costs”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Chronic Care Model

The Chronic Care Model

Community
- Resources and Policies
- Self-Management Support

Health Systems
- Organization of Health Care
- Delivery System Design
- Decision Support
- Clinical Information Systems

Improved Outcomes
- Informed, Activated Patient
- Prepared, Proactive Practice Team
- Productive Interactions
Cycle of Complexity Model

Social System of Diffusion

Adoption Factors

- Relative Advantage
- Compatibility
- Complexity or Simplicity
- Trialability
- Observability

Innovation Adoption Curve

Innovation Adoption Curve

Innovation Adoption Curve


BRAND CAMP by Tom Fishburne

NEW PRODUCT ADOPTION

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Find a Framework

Dissemination & Implementation Models in Health Research & Practice

This interactive website was designed to help researchers and practitioners to select the DBI Model that best fits their research question or practice problem, adapt the model to the study or practice context, fully integrate the model into the research or practice process, and find existing measurement instruments for the model constructs. The term "Models" is used to refer to both theories and frameworks that enhance dissemination and implementation of evidence-based interventions more likely.

Select
Search, view, and select DBI Models

Adapt
Read strategies for adapting D&I Models to research or practice context

Integrate
Read strategies for incorporating D&I Models into the full spectrum of your project

Measure constructs
Find a list of constructs and links to measurement tools associated with the D&I Models

http://dissemination-implementation.org/index.aspx
A Case Study
Persistent poorly-controlled diabetes mellitus

- In comparison to other chronic diseases, diabetes management (especially self-management) is complex
- Some patients with diabetes do not thrive under clinic-based care
- We have defined **persistent poorly-controlled diabetes mellitus (PPDM)**, as maintenance of an HbA1c continuously ≥8.5% for >1 year despite engagement with clinic-based diabetes care

**Who has PPDM in VHA?**

- In 2012, approximately 12% of Veterans with type 2 diabetes met PPDM criteria
- Relative to well-controlled patients, Vets with PPDM are:
  - Younger
  - More likely to be Black or Hispanic/Latino
  - More likely to have key comorbidities (including depression)
  - Prescribed more medication for their diabetes, especially complex insulin regimens

### Variable OR for PPDM (95% CI)

<table>
<thead>
<tr>
<th>Demographics</th>
<th>OR for PPDM (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (ref 60-70)</td>
<td></td>
</tr>
<tr>
<td>&lt;40</td>
<td>3.53 (3.22, 3.88)</td>
</tr>
<tr>
<td>40-50</td>
<td>2.85 (2.73, 2.99)</td>
</tr>
<tr>
<td>50-60</td>
<td>1.83 (1.77, 1.88)</td>
</tr>
<tr>
<td>70-80</td>
<td>0.60 (0.58, 0.62)</td>
</tr>
<tr>
<td>≥80</td>
<td>0.56 (0.53, 0.59)</td>
</tr>
<tr>
<td>Black or African-American race</td>
<td>1.44 (1.40, 1.49)</td>
</tr>
<tr>
<td>Hispanic or Latino/a ethnicity</td>
<td>1.45 (1.38, 1.53)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>OR for PPDM (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (ref 18-24)</td>
<td></td>
</tr>
<tr>
<td>30-34</td>
<td>1.07 (1.02, 1.11)</td>
</tr>
<tr>
<td>35-39</td>
<td>1.09 (1.04, 1.14)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.97 (0.94, 1.00)*</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>1.06 (1.02, 1.09)</td>
</tr>
<tr>
<td>Depression</td>
<td>1.06 (1.03, 1.09)</td>
</tr>
<tr>
<td>Tobacco abuse</td>
<td>1.07 (1.04, 1.10)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication use</th>
<th>OR for PPDM (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biguanide</td>
<td>1.15 (1.11, 1.18)</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>2.52 (2.44, 2.60)</td>
</tr>
<tr>
<td>Insulin Use Category (ref no insulin)</td>
<td></td>
</tr>
<tr>
<td>Basal insulin</td>
<td>8.59 (8.26, 8.93)</td>
</tr>
<tr>
<td>Pre-mixed insulin</td>
<td>11.32 (10.80, 12.29)</td>
</tr>
<tr>
<td>Prandial insulin</td>
<td>20.33 (19.25, 21.47)</td>
</tr>
</tbody>
</table>

* = not statistically significant, all others p<0.001
Complications and utilization in PPDM

- Veterans with PPDM use most VA services at a higher rate than well-controlled Veterans

- Veterans with PPDM experience higher rates of most diabetes complications

<table>
<thead>
<tr>
<th>2013 Utilization</th>
<th>Rate ratio a/w PPDM (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Care office visits</td>
<td>1.08 (1.07, 1.09)</td>
</tr>
<tr>
<td>Primary Care telephone visits</td>
<td>1.17 (1.15, 1.19)</td>
</tr>
<tr>
<td>Endocrinology/Diabetes visits</td>
<td>2.21 (2.15, 2.28)</td>
</tr>
<tr>
<td>Home Telehealth</td>
<td>1.49 (1.46, 1.53)</td>
</tr>
<tr>
<td>Mental Health visits</td>
<td>0.92 (0.90, 0.94)</td>
</tr>
<tr>
<td>ED visits</td>
<td>1.15 (1.13, 1.18)</td>
</tr>
<tr>
<td>≥1 Inpatient stay</td>
<td>1.03 (1.01, 1.05)*</td>
</tr>
</tbody>
</table>

*OR a/w having at least 1 inpatient stay (not rate ratio)

<table>
<thead>
<tr>
<th>2013 Complications</th>
<th>OR a/w PPDM (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic retinopathy</td>
<td>1.83 (1.76, 1.87)</td>
</tr>
<tr>
<td>Diabetic nephropathy</td>
<td>1.42 (1.34, 1.49)</td>
</tr>
<tr>
<td>Diabetic neuropathy</td>
<td>1.33 (1.30, 1.37)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>1.12 (1.09, 1.15)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>1.17 (1.13, 1.22)</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>0.95 (0.91, 0.98)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>1.10 (1.06, 1.14)</td>
</tr>
</tbody>
</table>

What to draw from this?

- Veterans meeting PPDM criteria have greater morbidity than those with well-controlled type 2 diabetes

- More standard VHA care does not solve PPDM

- More medication (particularly more insulin) does not solve PPDM

- How can we leverage VHA’s natural advantages to deliver care differently in practice – and thereby potentially improve outcomes?
Comprehensive telehealth for PPDM in VHA

- Needs to address factors that contribute to PPDM
- Needs to be tolerable to Veterans – so that they engage with the intervention
- Needs to be amenable to practical delivery within VA system

Advanced Comprehensive Diabetes Care (ACDC)

- ACDC targets factors that contribute to ongoing poor control in PPDM:

<table>
<thead>
<tr>
<th>Problem in PPDM</th>
<th>ACDC Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unreliable/unavailable blood glucose data</td>
<td>1) Telemonitoring</td>
</tr>
<tr>
<td>Suboptimal medication adherence</td>
<td>2) Self-management support</td>
</tr>
<tr>
<td>Complex medication regimens</td>
<td>3) Medication management</td>
</tr>
<tr>
<td>Comorbid depression</td>
<td>4) Depression management</td>
</tr>
</tbody>
</table>

- Critically, ACDC was designed for delivery by existing VA Home Telehealth nurses, making it amenable to practical delivery within VA system
- We examined ACDC in a diabetes QUERI-funded (RRP 12-458) pilot study
- 50 Veterans with PPDM, randomized to intervention vs. usual care
ACDC pilot results

- ACDC lowered HbA1c by 1.0% on average vs. UC
  - Nearly 2.0% among the subgroup of ‘engaged’ Veterans
- Our qualitative work helped us understand factors that may affect engagement

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>PREDICTED MEAN (SE)</th>
<th>PREDICTED MEAN DIFFERENCE ACDC VERSUS UC (95% CI)</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>ACDC INTERVENTION</td>
<td>UC</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>105.9 (2)</td>
<td>105.9 (2)</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>92 (4)</td>
<td>102 (4)</td>
<td>-10.3 (-17, -2.8)</td>
</tr>
<tr>
<td>6 months</td>
<td>92 (4)</td>
<td>102 (4)</td>
<td>-10.3 (-26, -1.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ENGAGED PATIENTS (≥5 STUDY ENounters)</th>
<th>NONENGAGED PATIENTS (≤3 STUDY ENounters)</th>
<th>USUAL CARE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>N</td>
<td>MEAN</td>
</tr>
<tr>
<td>Baseline</td>
<td>16</td>
<td>102</td>
</tr>
<tr>
<td>3 months</td>
<td>16</td>
<td>87</td>
</tr>
<tr>
<td>6 months</td>
<td>16</td>
<td>87</td>
</tr>
</tbody>
</table>

HbA1c: hemoglobin A1c; SD: standard deviation.

Qualitative analysis

- Participants with <1% improvement reported that competing demands interfered with their engagement
- Participants with ≥1% improvement reported increased capacity to self-manage as a result of engaging with the intervention
How to use these data?

- Wanted to use our pilot data to inform the choice of a theoretical model to inform our study of a 'next generation' version of ACDC
  - **PRACTICE-DM** (Practical Telemedicine to Improve Control and Engagement for Veterans with Clinic-Refractory Diabetes Mellitus)

- In light of:
  - The clinical importance of supporting patient engagement
  - Our qualitative observations regarding competing demands and capacity

...We identified the **Cumulative Complexity Model** and adapted it for our purposes
Benefits of using model

- Enhances our understanding of how patients may engage with the intervention
- Suggests ways to tweak the intervention to support engagement
- Guides our selection of analytic outcomes
- Informs secondary analyses to look at model constructs as moderators and mediators of intervention effect
- Improves our chances of getting funded!
Thank You

Please contact us with questions and comments:
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