

Applying an Implementation Science Approach to Genomic Medicine

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Research

“the move from considering an adoption to successfully routinizing it is generally a nonlinear process characterized by multiple shocks, setbacks, and unanticipated events”

Greenhalgh, T et al. (2004). Diffusion of innovations in service organizations: Systematic review and recommendations. *Milbank Quarterly*, 82(4), 581–629.

Is Genomics Any Different?

- Answer is probably yes and no, depending
- Some may be
 - Return of results to patients & family members
 - Interpretation of genomic specific data
 - Reimbursement
- Others likely not
 - Changing physician, health system workflow
 - Decision support
 - Reimbursement
 - Evidence base

Implementation should be done in a rigorous and evaluable manner: early, mid-term, and endpoint evaluations

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- Program Benefits**

Type III error:
Attributing poor outcomes to a failed/ineffective intervention when, actually, it was a result of poor implementation

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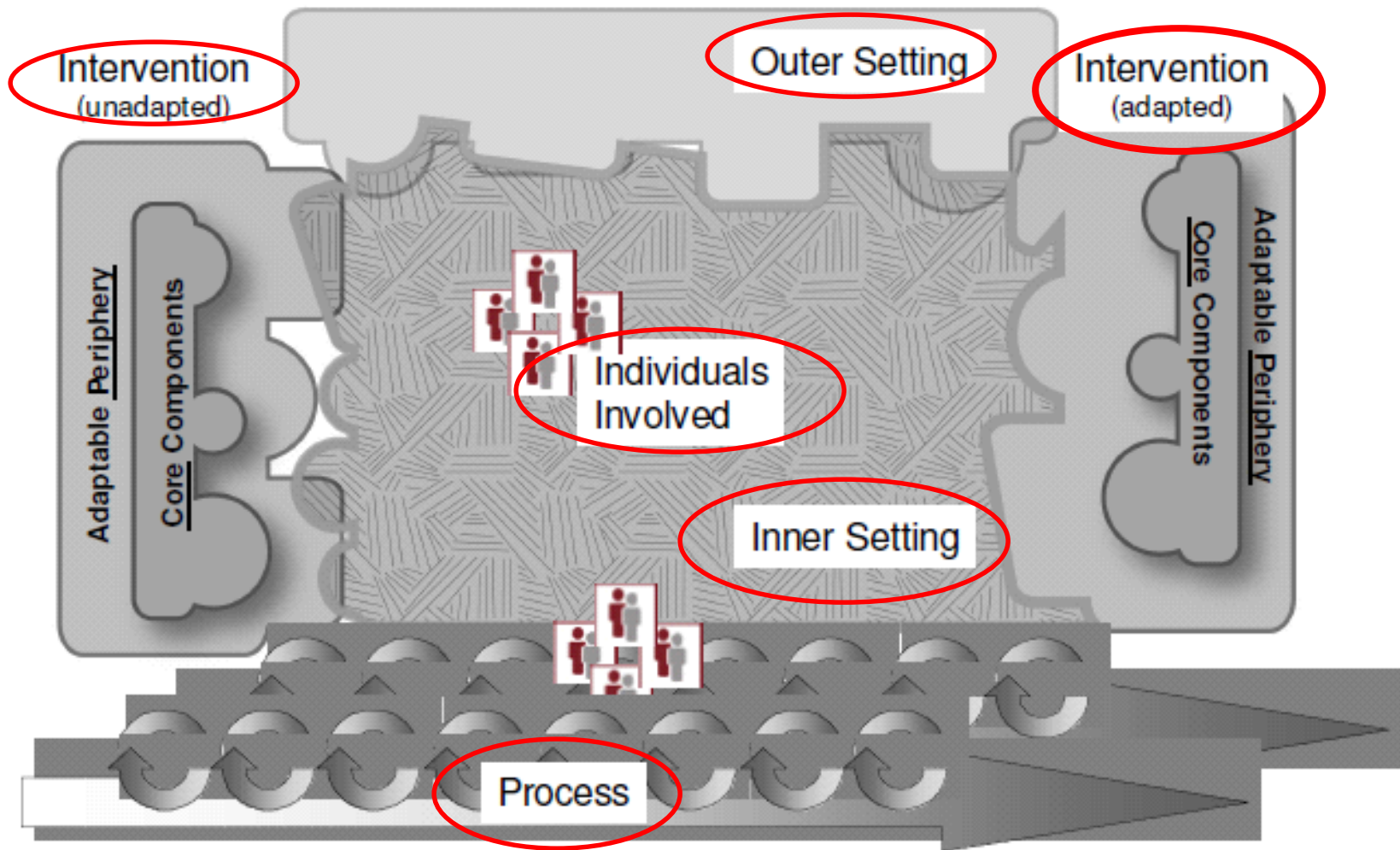
graph LR
    A[Explainable Behaviors  
e.g., user click] --> D[User Profiling]
    B[Demographic & Environmental Variables] --> D
    D --> C[Self-Monitoring]
    C --> E[Small Changes in Movement/State Behavior]
    E --> F[Inter-ventor Effectiveness  
Short-term & Long-term weightings]
  
```

Consolidated Framework for Implementation Research (CFIR)

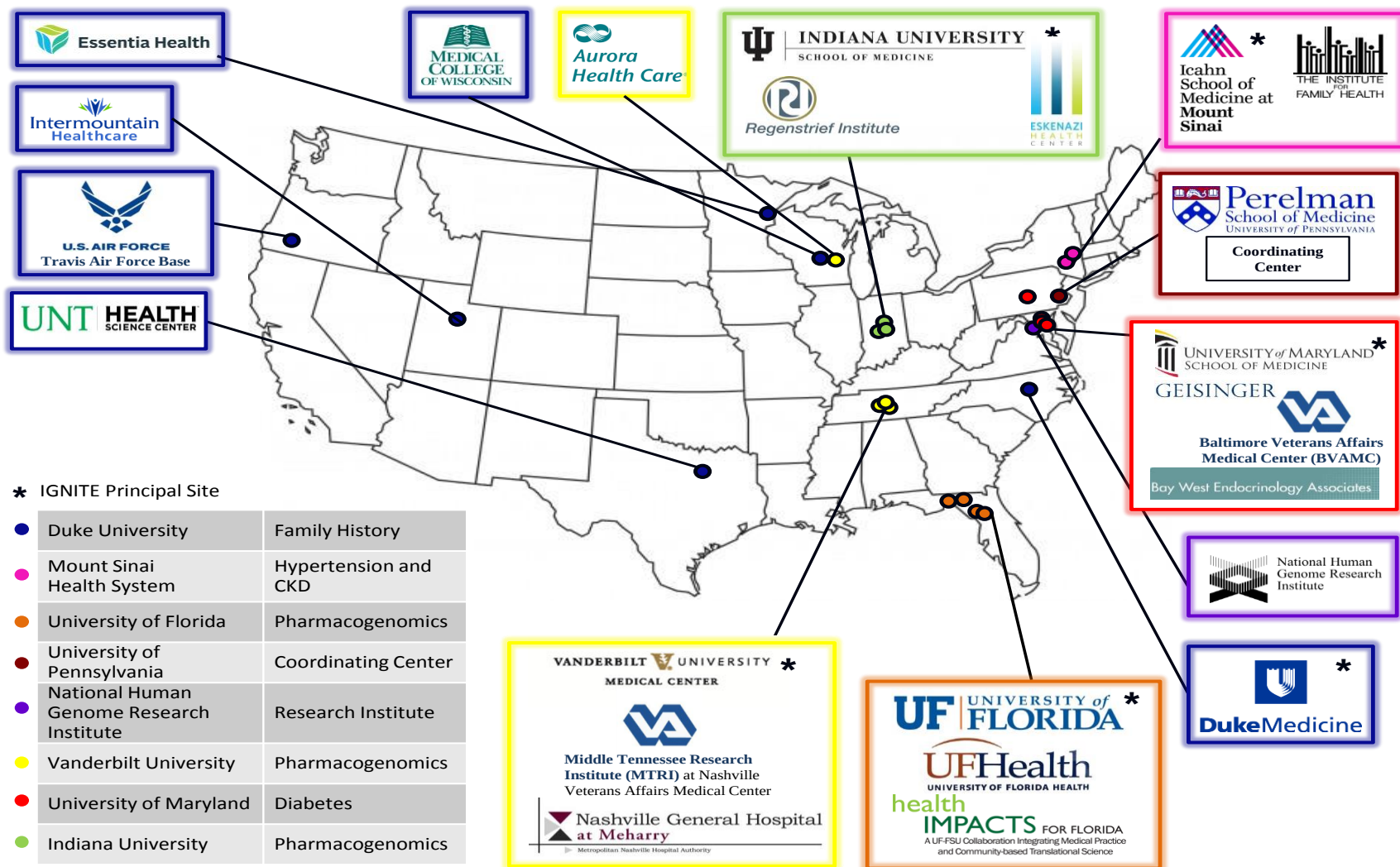
An overarching typology to promote
implementation theory development and
verification about what works where and why
across multiple contexts

Damschroder et al., 2009

CFIR



IGNITE NETWORK



IGNITE as Example

- Goals
 - Use CFIR framework to identify the core implementation components common across projects and determine which contribute to successful implementation of a genomic medicine intervention.
 - To the extent that there are common measures and outcomes across projects, determine clinical benefits and the predictors of those benefits.

Research Plan - Strategy

- *A priori* identification of high-priority CFIR constructs
- Identify important common outcomes: how does each project “define success”?
- Create model for implementation
- Operationalize constructs through generation of Likert-type questionnaire items that can be adapted for each project
- Administer questionnaire(s)

CFIR-based Provider Items

Please respond to the following questions related to the new [genotype testing/genetic testing/the MeTree family history tool] in your institution. Please do not skip any items.

Level of Agreement	1. Strongly Disagree	2. Disagree	3. Neither agree or disagree	4. Agree	5. Strongly Agree
1. Using [genotype testing/genetic testing/the MeTree family history tool] fits within the processes that I already use to care for my patients.	☐	☐	☐	☐	☐
2. Clear goals have been established for integrating [genotype testing/genetic testing/the MeTree family history tool] into clinical practice.	☐	☐	☐	☐	☐
3. Staff have enough time to facilitate the integration of [genotype testing/genetic testing/the MeTree family history tool] into clinical practice.	☐	☐	☐	☐	☐

1. Using [genotype testing/genetic testing/the MeTree family history tool] fits within the processes that I already use to care for my patients.	Workflow/Time
2. Clear goals have been established for integrating [genotype testing/genetic testing/the MeTree family history tool] into clinical practice.	
3. Staff have enough time to facilitate the integration of [genotype testing/genetic testing/the MeTree family history tool] into clinical practice.	
4. I can find/use reliable sources of the information I need to apply [genotype testing/genetic testing/ the MeTree family history tool] while caring for patients.	Knowledge
5. Leaders have openly endorsed and supported [genotype testing/genetic testing/the MeTree family history tool] in visible ways.	Leadership

6. The information generated by [genotype testing/genetic testing/the MeTree family history tool] is important for patient care.

7. I believe that [genotype testing/genetic testing/the MeTree family history tool] is relevant to my current clinical practice.

Beliefs/Attitudes

8. My training has prepared me to treat patients whose family history/genetics place them at high risk for medical conditions.

9. I am confident in my ability to use the results of [genotype testing/genetic testing/the MeTree family history tool].

Training/Self-Efficacy

10. [Genotype testing/genetic testing/the MeTree family history tool] will be an improvement over how I currently assess risk.	Value/Utility
11. [Genotype testing/genetic testing/the MeTree family history tool] will improve my ability to care for patients.	
12. A clearly designated person or team is/will lead the effort to incorporate [genotype testing/genetic testing/the MeTree family history tool] into my clinical practice.	Group-efficacy
13. The implementation leaders/team have the necessary qualities and skills to successfully incorporate [genotype testing/genetic testing/the MeTree family history tool] into my clinical practice.	
14. A variety of strategies are being used to enable staff to use [genotype testing/genetic testing/the MeTree family history tool] to assess patient risk.	Strategies

What Has IGNITE Learned So Far?

- Use of a framework can inform and motivate the right questions to ask
- A lot of implementation is generic
 - but not all

Summary

- Genomic implementation
 - has some unique characteristics
 - but a lot of characteristics common to all implementation
 - must be formally studied to determine
 - what works
 - what doesn't
 - and why