

Welcome to IMPAACT Social Behavioral Scientific Core

SpotLight Series

Adherence in Clinical Trials:

Part 1 - Concepts, Challenges, & Support

Panelists: K Rivet Amico, PhD; Rachel Kidman, PhD

The session will begin shortly

Virtual Attendee Logistics:



Please remain
muted when
not speaking.



Please enter
your questions
into the chat.

Adherence in Clinical Trials: Part 1– Concepts, Challenges, & Support

An SBSC facilitated discussion of Adherence in Clinical Trials

K Rivet Amico & Rachel Kidman

PLEASE PARTICIPATE!

Log in and get ready

- ▶ Adherence
 - ▶ Defined
 - ▶ Why does it matter?
- ▶ Adherence in RCTs
 - ▶ Mutuality Framework
 - ▶ Facilitators
 - ▶ Challenges
- ▶ Adherence in context
 - ▶ Social ecological model of adherence
- ▶ Example of supporting adherence in context
- ▶ Q&A

ONE WORD to describe how you are feeling?

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THANK YOU!

What word (or-connected-words) come to mind for you when you think about adherence?

**Word (or-connected-words) come to mind what you think
about adherence?**

🌐 When poll is active, respond at **pollev.com/rivetamico**

📱 Text **RIVETAMICO** to **37607** once to join

It is estimated, that this percent of people prescribed a medication do not take it as recommended

10%

25%

50%

75%

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Compliance

“the extent to which the patient’s behaviour matches the prescriber’s recommendations”

Non-compliance in this context is readily equated with either the patient’s inability to understand the treatment regimen or its purported benefits, or even as a sign of irrational or maladaptive patient behaviour when he/she refuses to comply.

Adherence

“the extent to which the patient’s behaviour matches agreed recommendations from the prescriber”

Levels of adherence or non-adherence

Elevates shared decision making

Acknowledges “rational” intentional non-adherence

“the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” – WHO 2003

World J Psychiatry, 2014 Jun 22; 4(2): 30–36.
Published online 2014 Jun 22. doi: [10.5498/wjp.v4.i2.30](https://doi.org/10.5498/wjp.v4.i2.30)

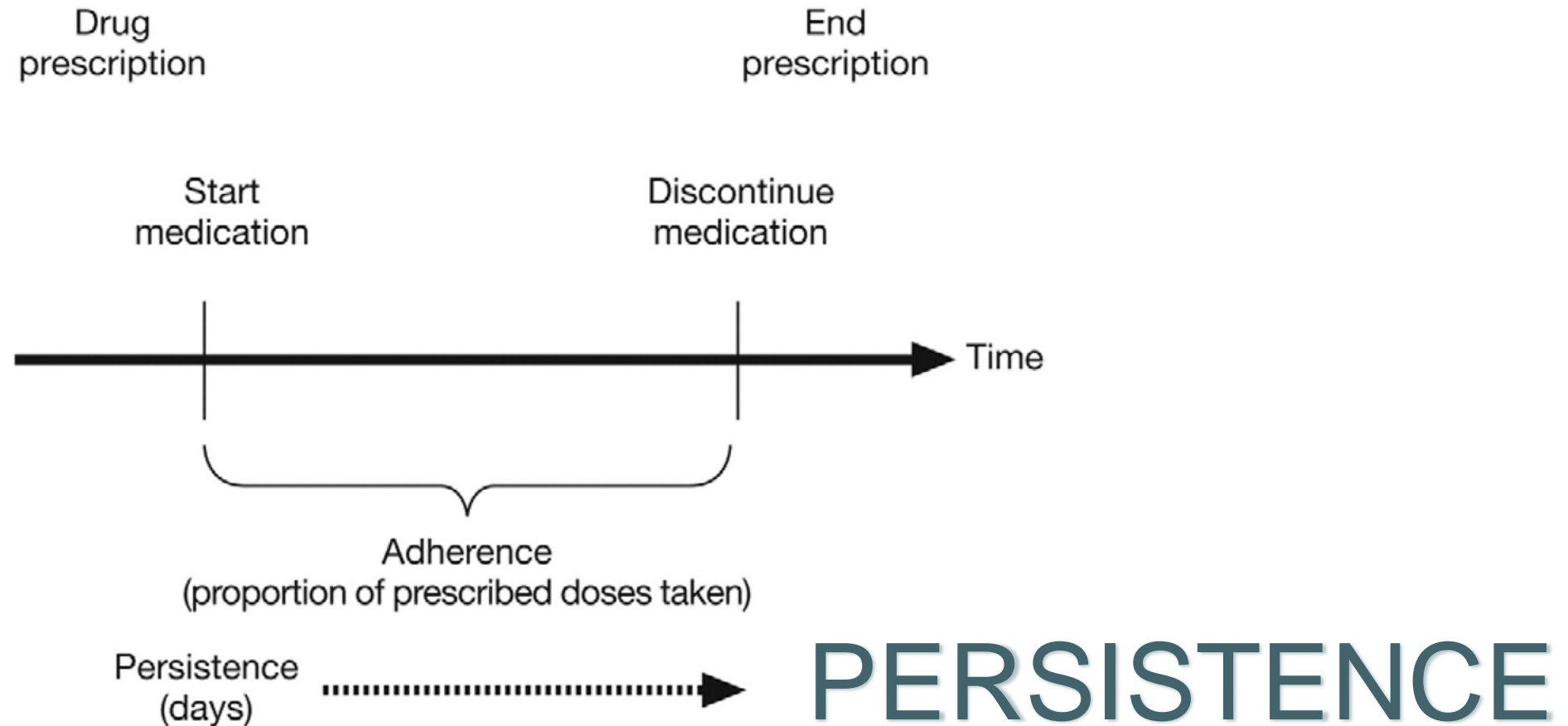
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PMID: [25019054](https://pubmed.ncbi.nlm.nih.gov/25019054/)

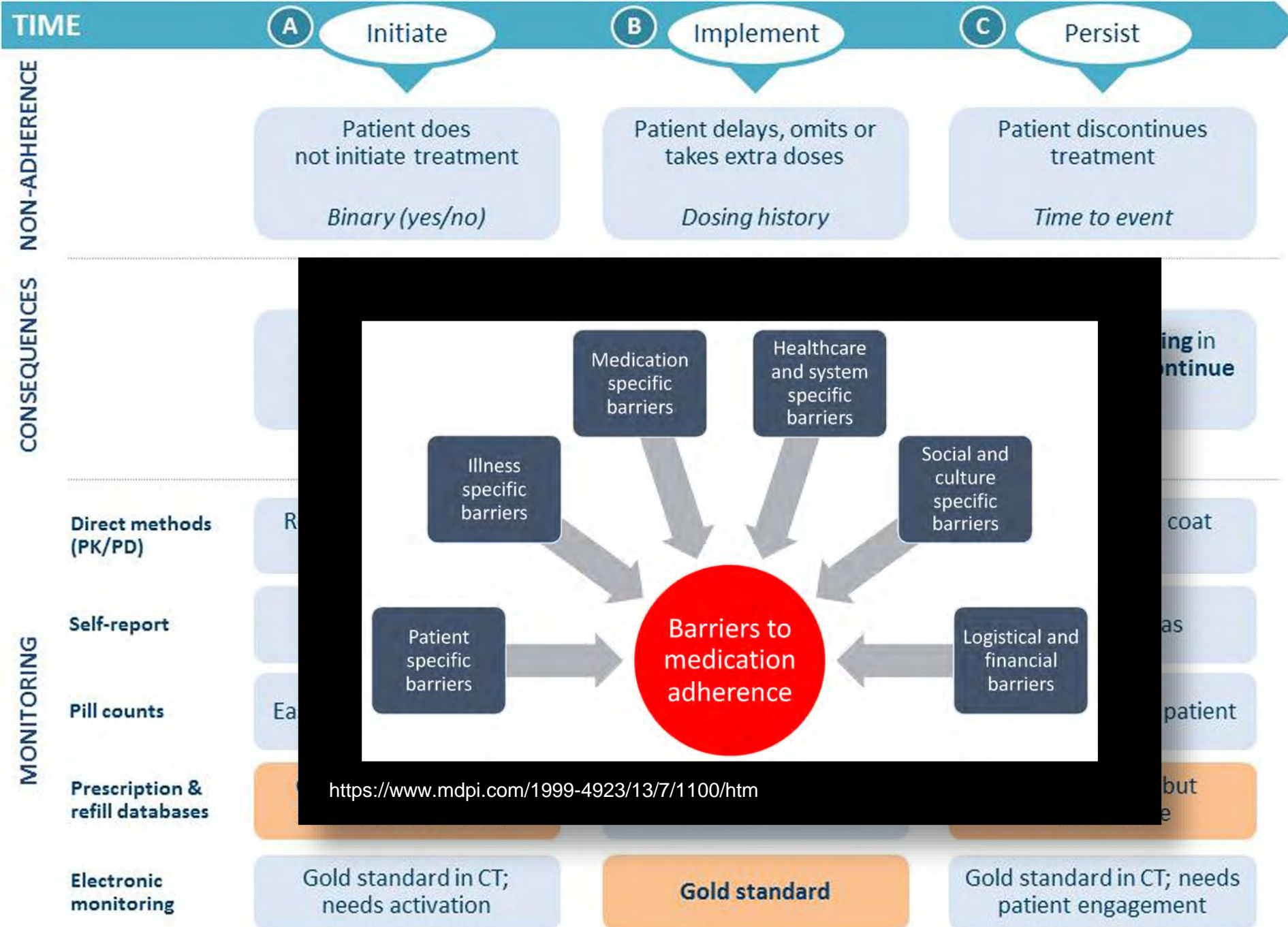
What’s in a name? Compliance, adherence and concordance in chronic psychiatric disorders

[Subho Chakrabarti](#)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4087153/>

Figure 1. Aspects of medication-taking behavior.





- ▶ From Hypertension literature
- ▶ 3 distinct phases
- ▶ NOT static over time

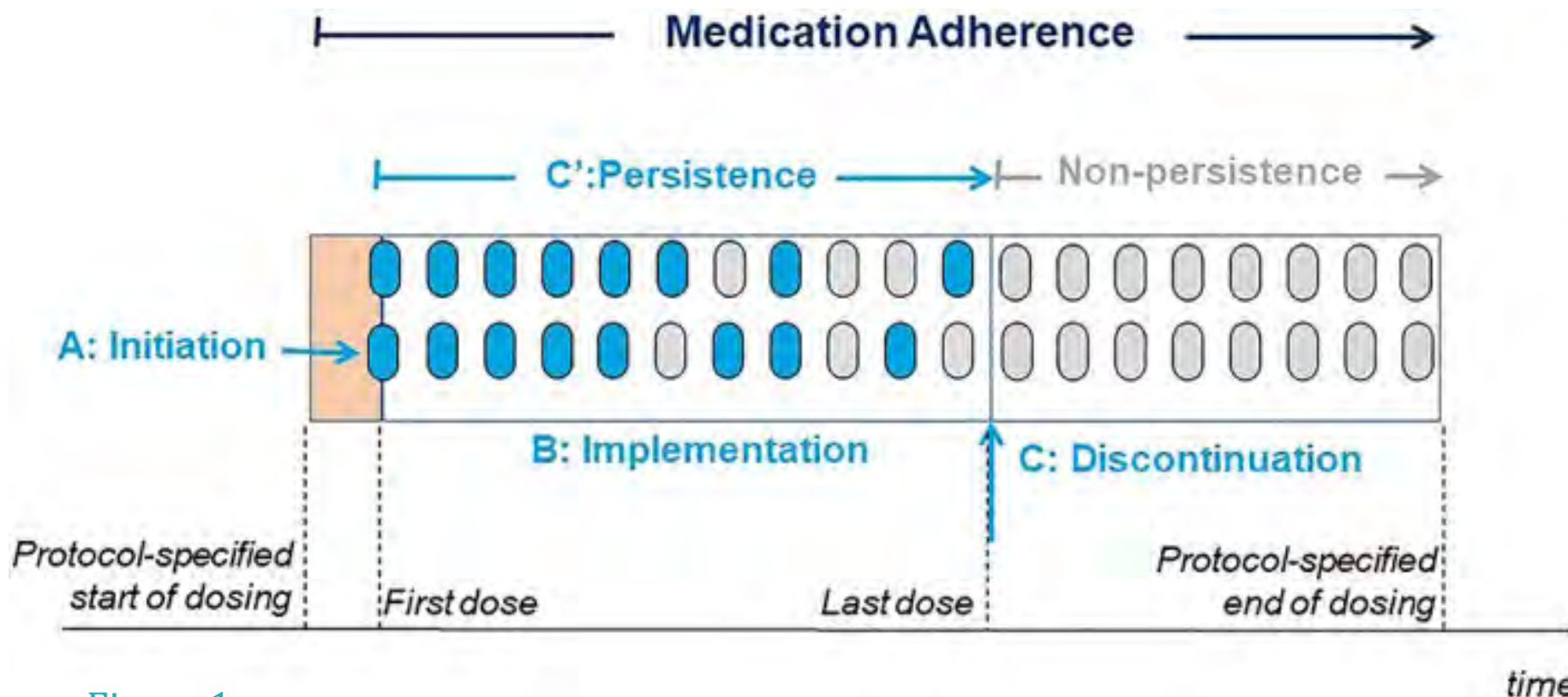


Figure 1

Illustration of the process of medication adherence according to the ABC taxonomy adapted to a clinical trial setting. The example is illustrating a twice-a-day dosing schedule

Adherence and persistence to HIV prevention medications

A. Paradigm for ART and clinical trials: Success is achieved through 100% adherence.

Adherence behavior



Time on drug



B. Prevention-effective adherence paradigm: Success is achieved because PrEP is used during all episodes of HIV exposure. Adherence to PrEP may be periodic and mapped to periods of risk.

Adherence behavior



HIV exposure over time



No risk



No risk

PREVENTION EFFECTIVE ADHERENCE

Haberer JE, Bangsberg DR, Baeten JM, et al. Defining success with HIV pre-exposure prophylaxis: a prevention-effective adherence paradigm.(2015)


Adherence and persistence...

- ▶ Why is it important in clinical trials specifically?

USE CHAT FEATURE PLEASE
OR RAISE HAND

- ▶ Why might people struggle with it in clinical trials specifically?

Mutuality Framework



Amico et al., IAS 2015

PrEP experiences among South African women in the HPTN067 (ADAPT) study: Healthy paranoia (skepticism), Ubuntu, champions and challenges to resolving PrEP dissonance

The ADAPT Study
Alternative Dosing to Augment PrEP Table Taking

NIH

K Rivel Amico, PhD
University of Michigan
Principal Investigator

Gladstone Institute of Virology and Immunology

Desmond Tutu HIV Centre
Mxithamshe

Methods



Average age 26, range 18-52

On self-administered PrEP for 24 weeks

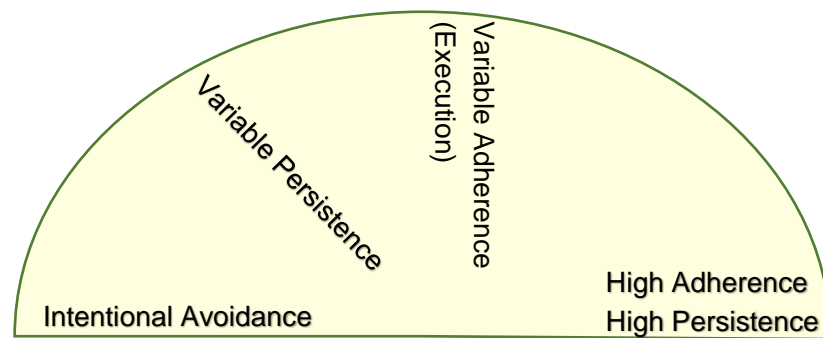
Qualitative data collected within 3-months of final study visit

Invited to participate in FG or IDI in two waves (first and last half of project)

Mixed convenience (FG) and targeted (IDIs) sampling

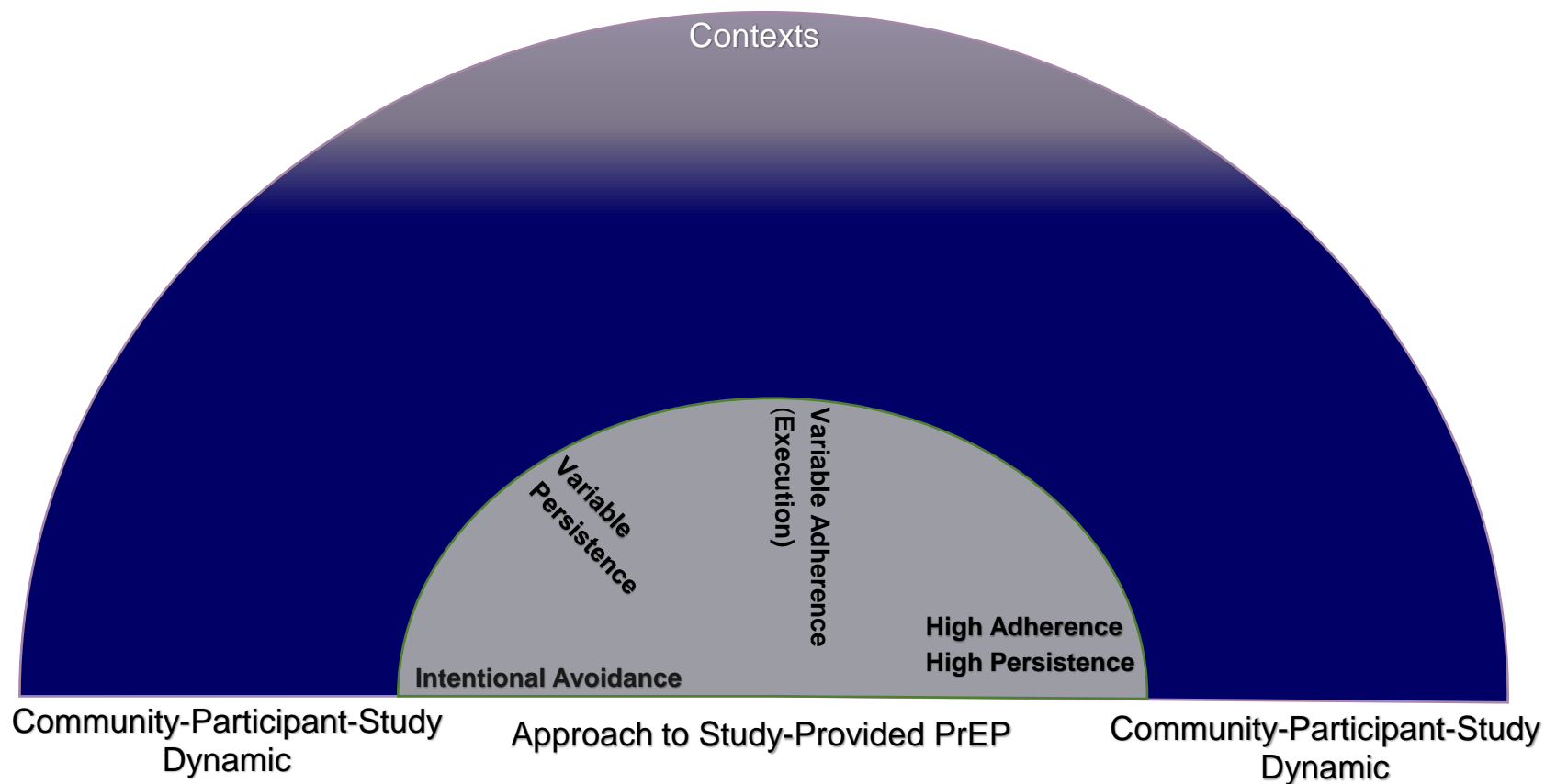
Themes identified with framework analysis

Study Provided PrEP Use



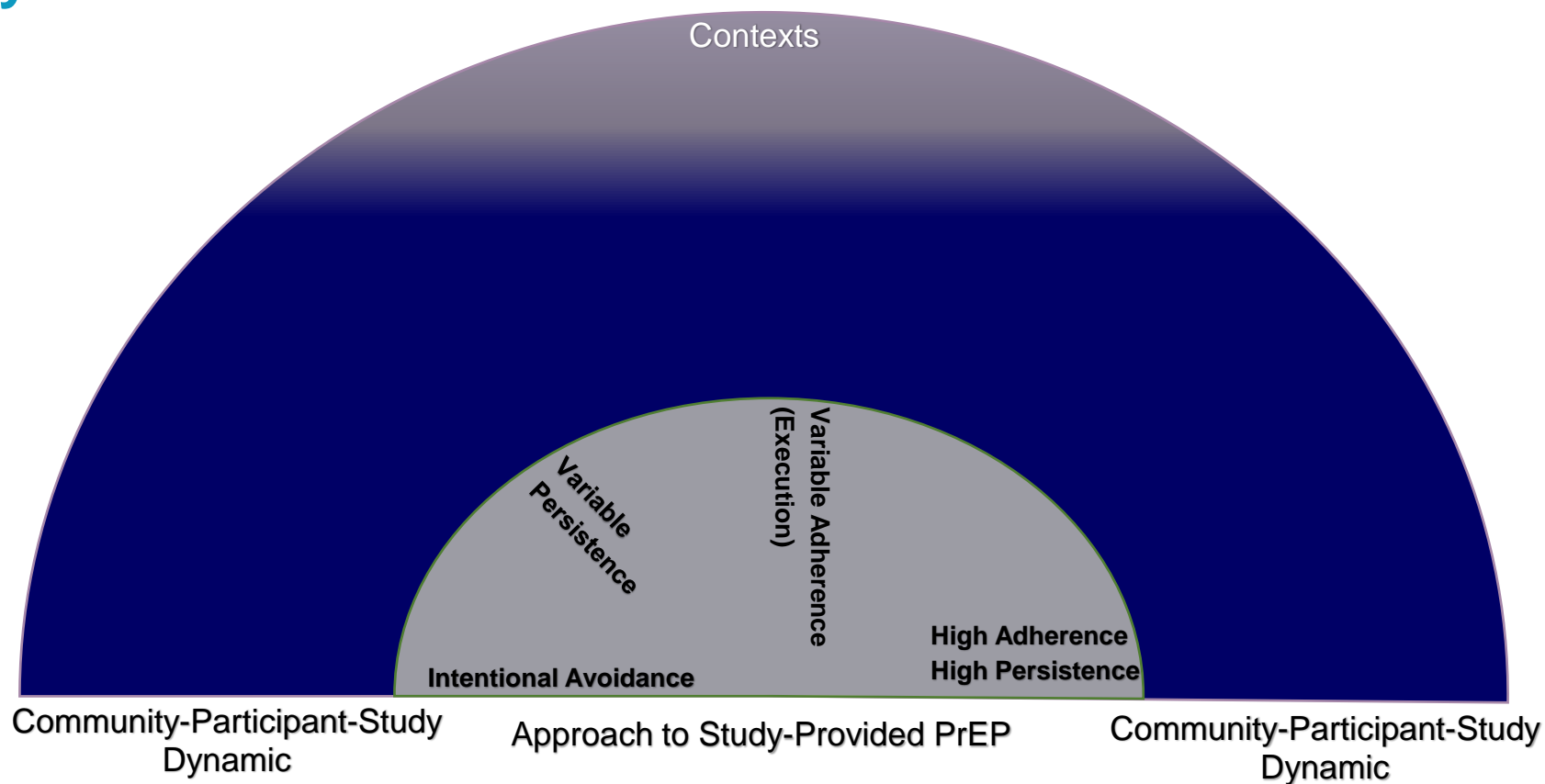
Approach to Study-Provided PrEP

Context



- Value of social and personal resources afforded through participation
- Social-Political History with biomedical research and medical institutions
- Identity attributes as participant or product user (internally, to important others, in the community)
- Cultural world view emphasizing reciprocity
- Product attributes Regimen Burden, Ease of use, Match to context

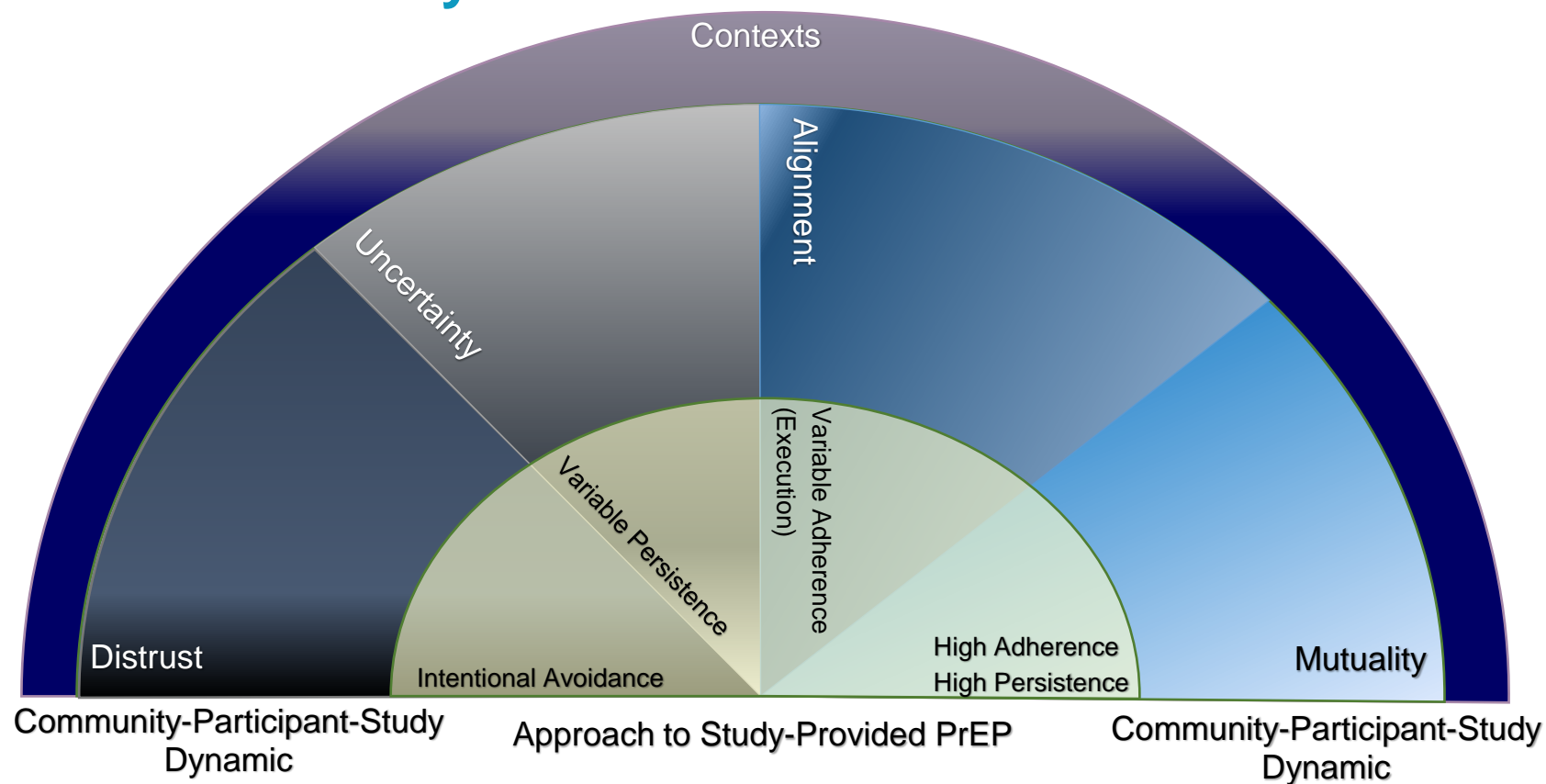
Dynamics



Dynamics – Different ways people negotiate tensions and synergies between community, self, and study/product

- Produce different approaches to study provided PrEP—unique implications for intervention

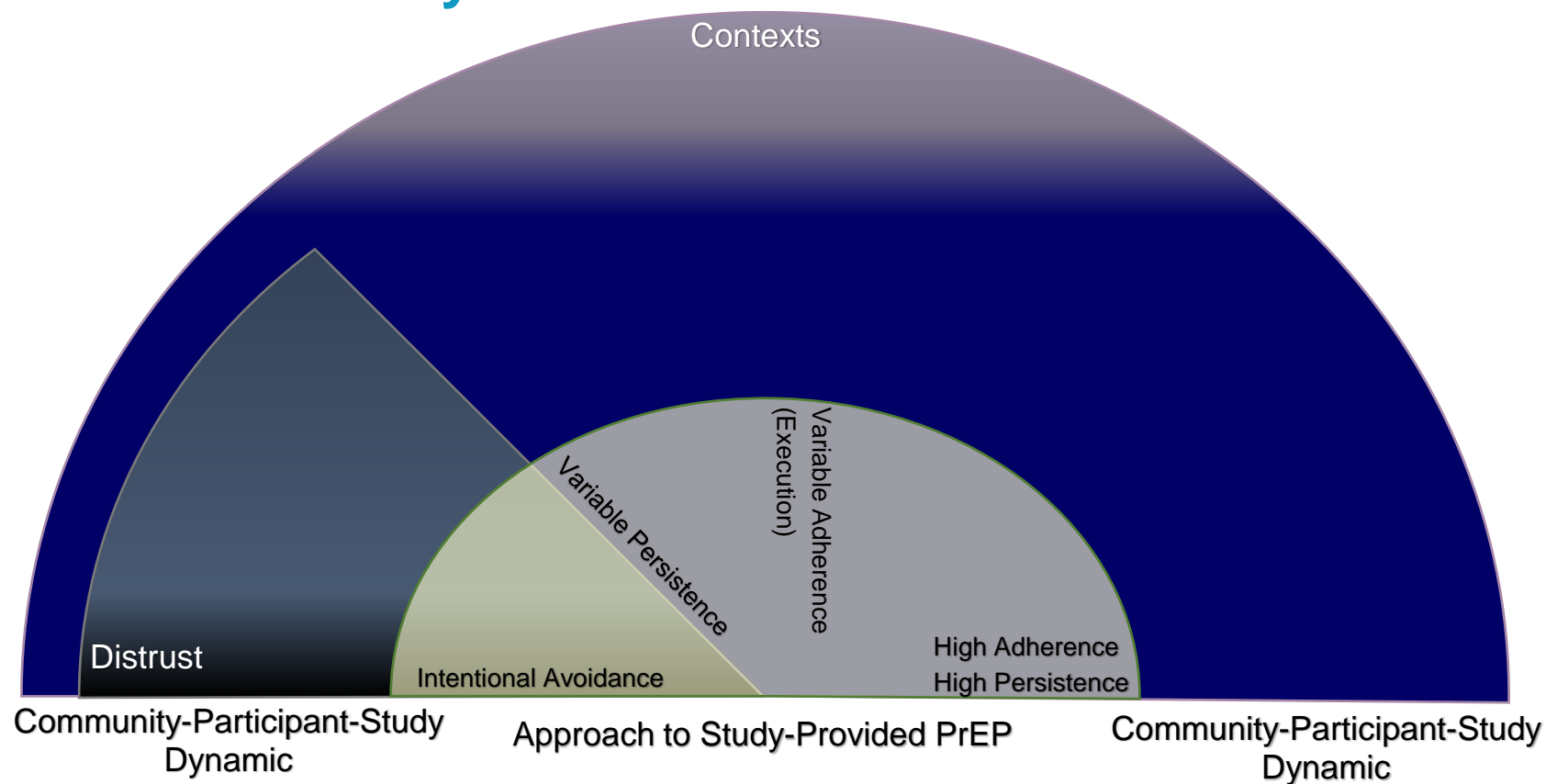
Model of Mutuality



Model identifies 4 unique dynamics ranging from distrust to mutuality

- Explain unique characteristics of each dynamic
- Associated approach to PrEP
- A excerpt highlighting an important aspect of the dynamic

Model of Mutuality-Distrust

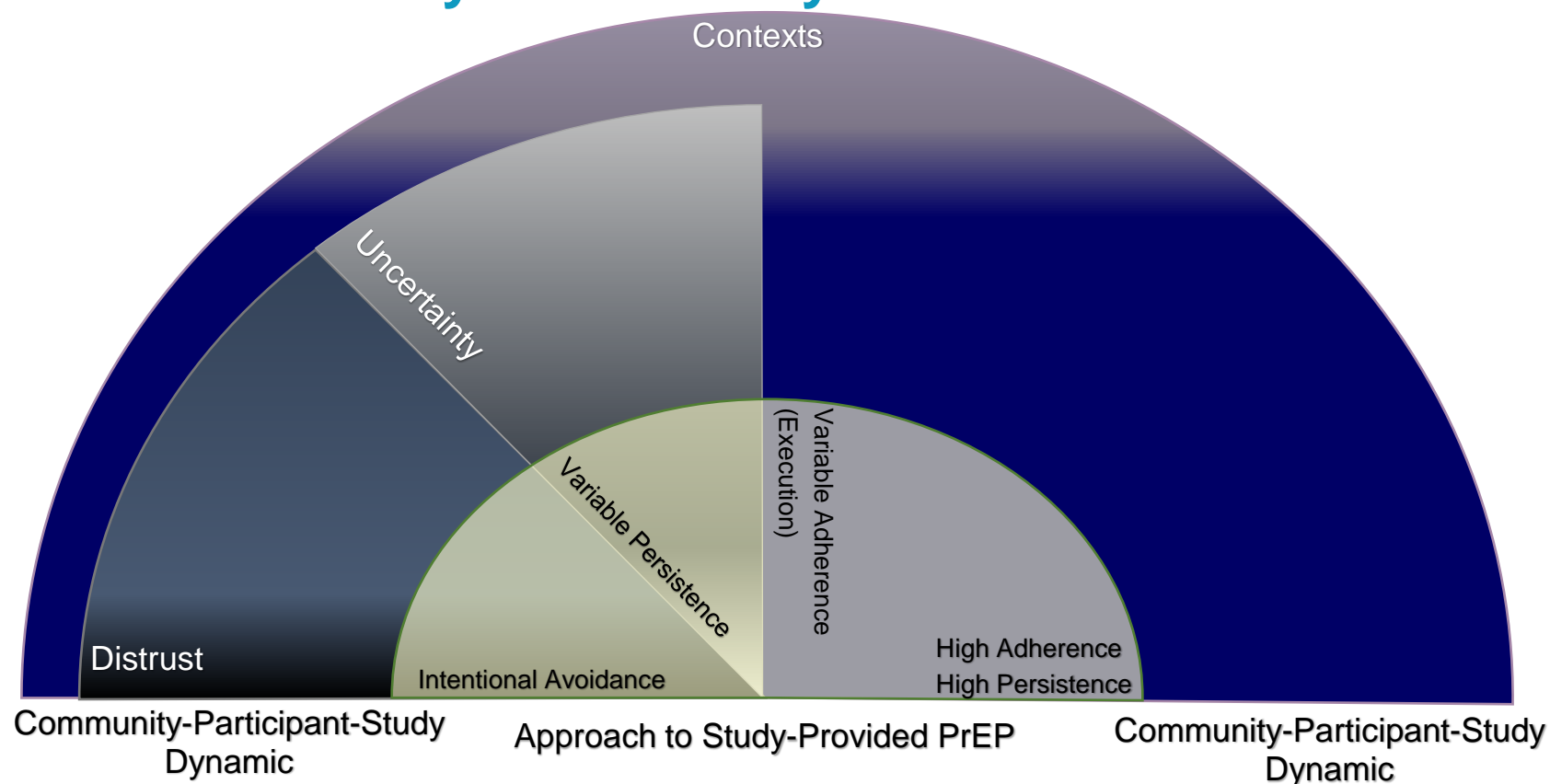


Rejection of product safety, integrity of study, and potential reciprocity to community

Intentional Avoidance of use of PrEP (and disclosure)

“... I will never drink these pills because I don't trust them...” -T IDI

Model of Mutuality- Uncertainty

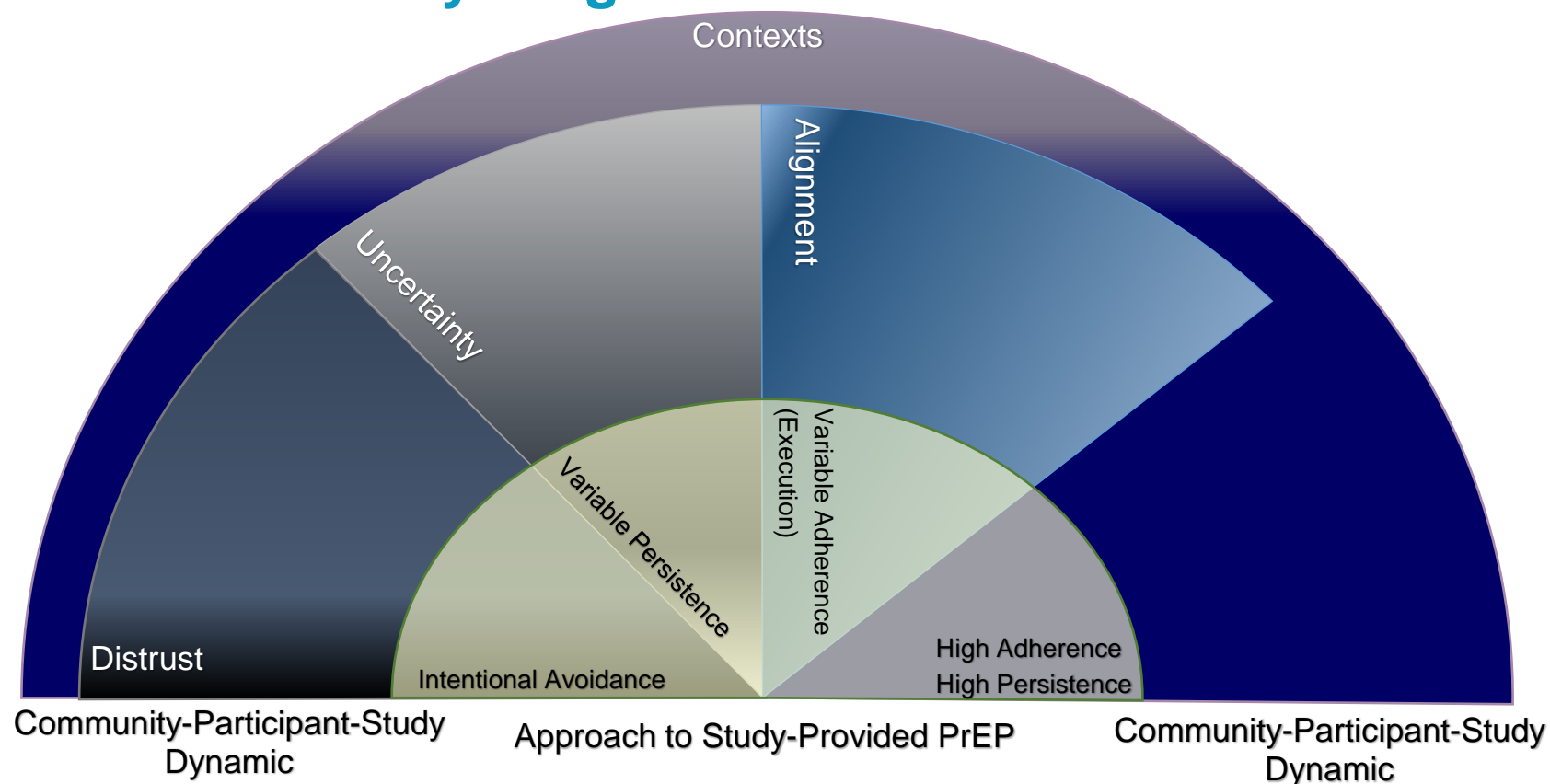


Cautious exploration- not yet sure either way

Variable persistence with PrEP

"...I was getting confused and pressured because I did not know whether to continue take tablets or not."-- D IDI

Model of Mutuality- Alignment

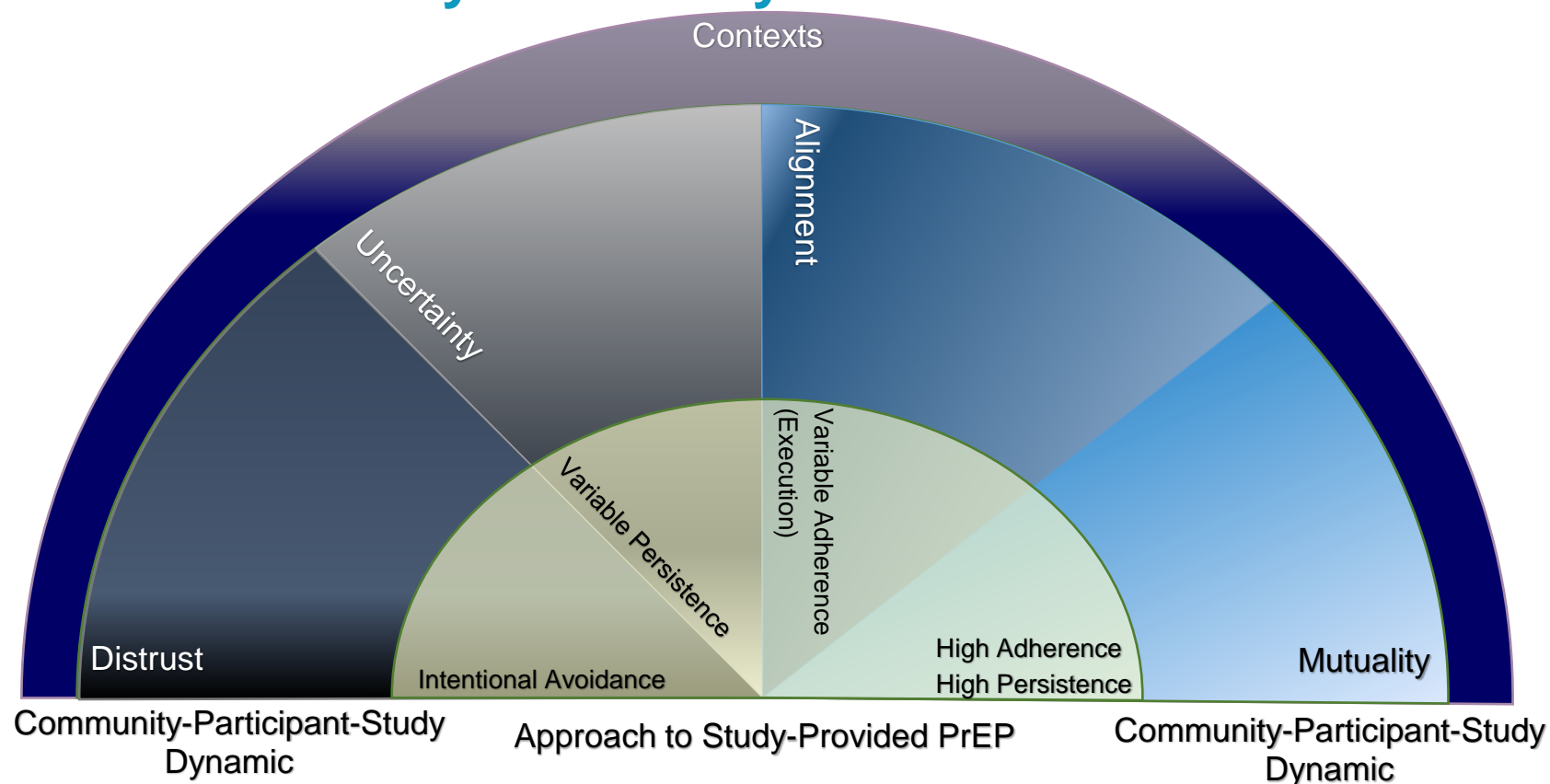


Provisional acceptance- committed to try

Good persistence/Variable adherence to PrEP

"... I wouldn't do any of that [not take the tablets] because I want to see if these pills really, really work" -- T FG

Model of Mutuality - Mutuality

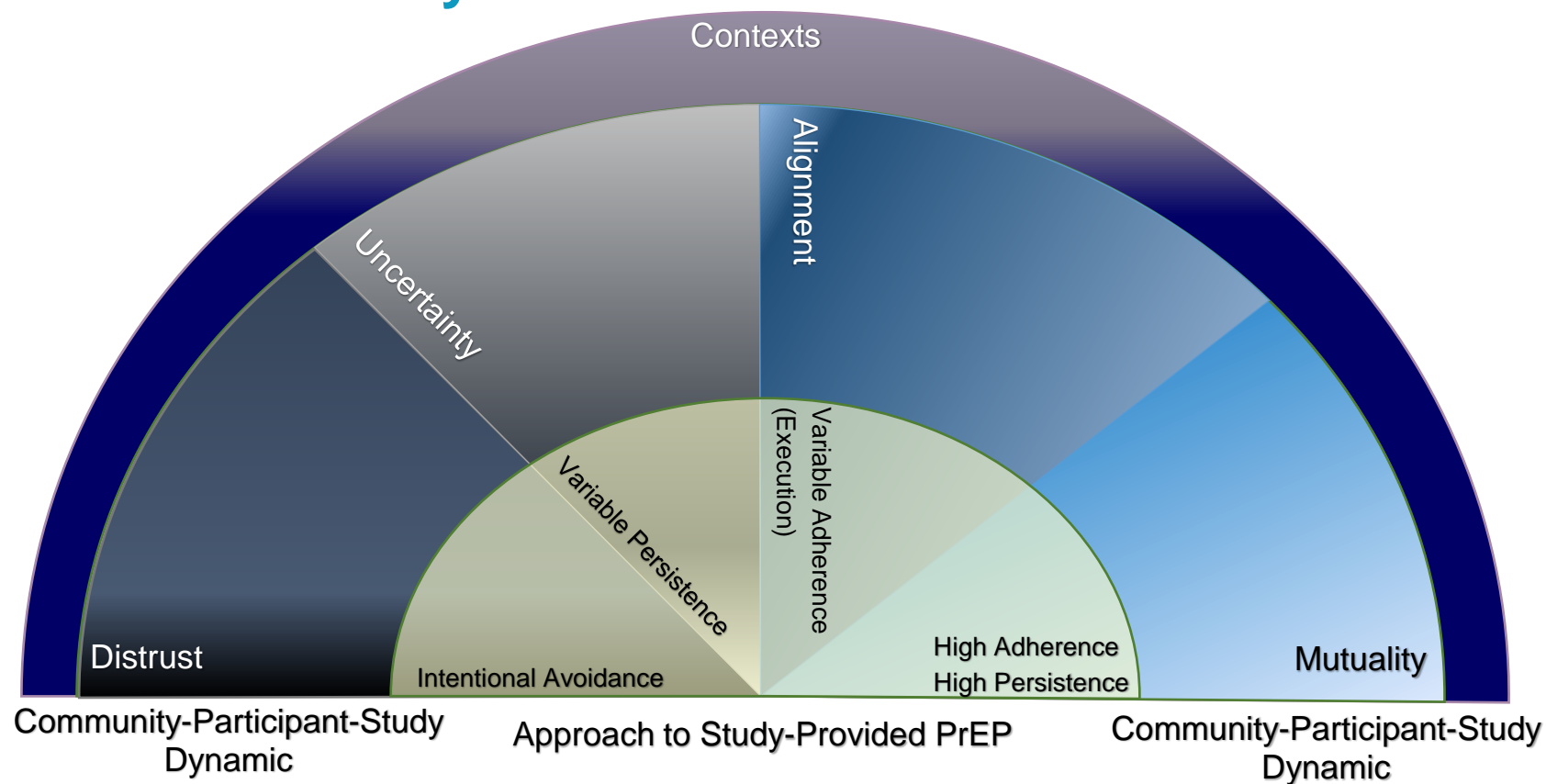


Ownership/Advocacy- Champions

Good persistence/Good adherence to PrEP

"... and I said: "Look here, ask me. And don't you dare say I have HIV, telling everyone in this shop. We are doing research here... to see whether the pills can protect someone from HIV." -- E FG

Model of Mutuality



SUPPORT STRATEGIES MUST REFLECT CURRENT DYNAMIC

EXAMPLES

1:1 targeting of barriers to execution adherence not relevant in DISTRUST and could promote staying in that dynamic

Messaging on importance of adherence may be disempowering in the MUTUALITY dynamic

BELIEFS ABOUT STUDY DRUG AND **RELATIONSHIPS** WITH THE STUDY TEAM AND
THEIR COMMUNITY WERE EMBEDDED IN THE **SOCIAL CONTEXT** OF RESEARCH AND HIV
AND THAT INFLUENCED
UPTAKE
USE/ADHERENCE
NON-ADHERENCE
PERSISTENCE



Distrust



Uncertainty



Alignment



Mutuality

Different Questions About PrEP

Why?
~~Whatever...~~
What's your angle?

What?

How?

Now!

Different Goals for the Care Team

*Build Trust
Earn Trust*

*Support
Exploration
With
Credible
Information*

*Identify
Barriers &
Facilitators &
Build Skills*

*Let
Her
Lead*

*Adapted from Grant from Amico, **Mutuality Framework***



IN YOUR SITES AND COMMUNITIES OR
STUDY GROUPS
WHAT INFLUENCES ADHERENCE?

BRAINSTORM: In your experience, what factors facilitate adherence?



Facilitators of adherence? (one word or connect-words-together)

BRAINSTORM: In your experience, what factors facilitate adherence?

DEBRIEF



BRAINSTORM: In your experience, what factors are barriers to adherence?



Barriers to adherence? (one word or connect-words-together)

BRAINSTORM: In your experience, what factors are barriers to adherence?

DEBRIEF



From the literature

Hendricks et al, 2021; Ammon et al, 2016; Croome et al, 2017; Galea et al, 2018; Yang et al, 2018; Mesic et al, 2019; Hudelson et al, 2015; Heestermans et al, 2016; Kim et al, 2017



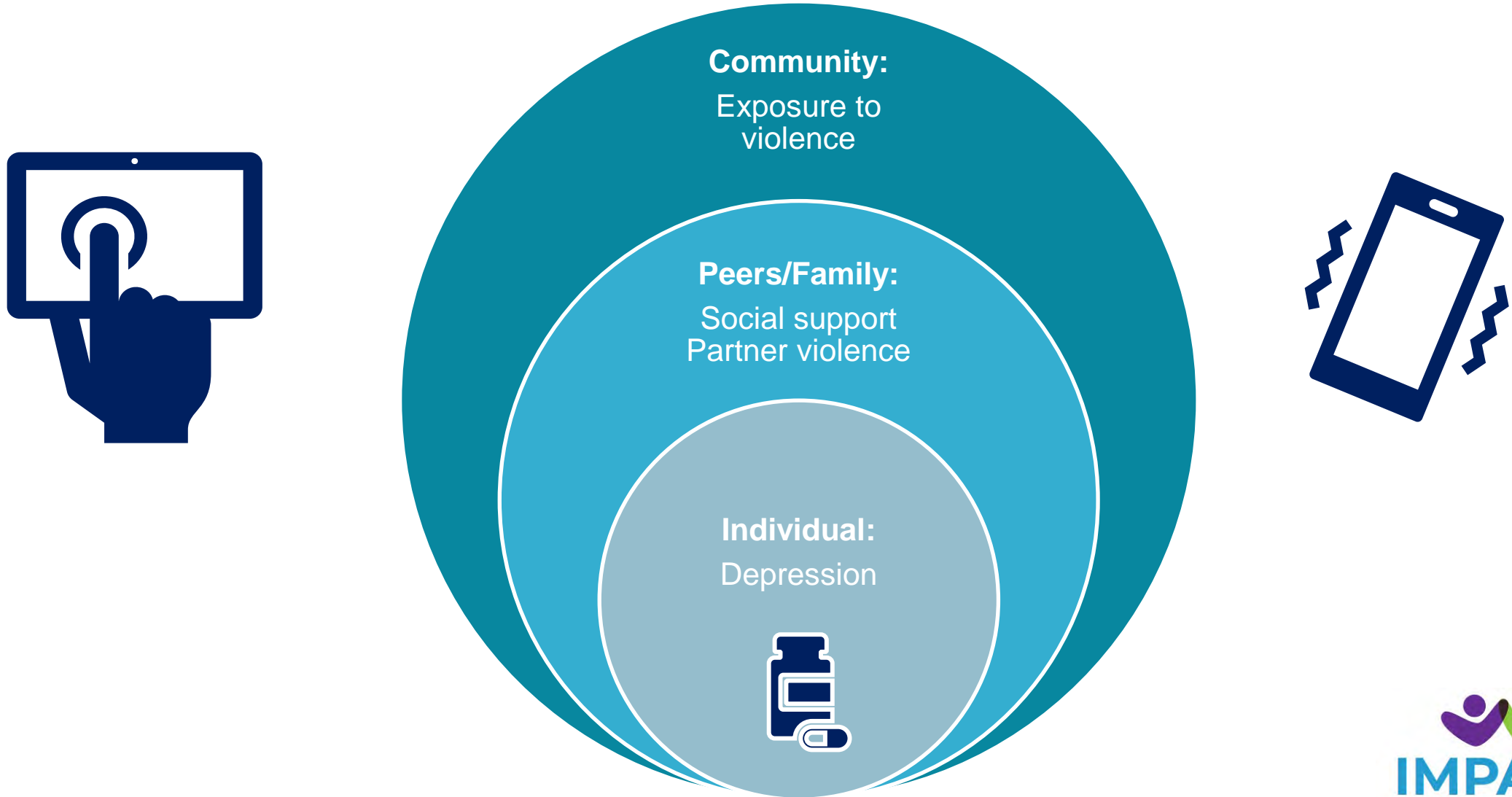
Social ecological model

IF MANY THINGS LEAD TO ADHERENCE, EFFORTS TO IMPROVE ADHERENCE THAT DO NOT ADDRESS THOSE MAY NOT WORK!



SUPPORTING ADHERENCE SHOULD INCLUDE SUPPORT ALL ALONG THE PATHWAY!

Example: adherence among adolescent boys



Discussion and Q&A

How does your site support adherence? Does that include things along the pathway to adherence?

What are the greatest challenges your participants have with adherence?

How open can participants be with study team members about non-adherence?

How is the clinic/counseling team supported in efforts to work with participant adherence?