

Must the evaluation of complex interventions be complex?

Learning from the impact evaluation of DREAMS

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The fascination of what's difficult
Has dried the sap out of my veins, and rent
Spontaneous joy and natural content
Out of my heart.

WB Yeats, 1916

A reflection in 3 parts

1. What is a complex intervention? What makes DREAMS one?
2. How do you evaluate a complex intervention? Without randomisation, can we benefit from emulating a trial?
3. What are the lessons learned from evaluation of DREAMS so far?



The changing programme landscape

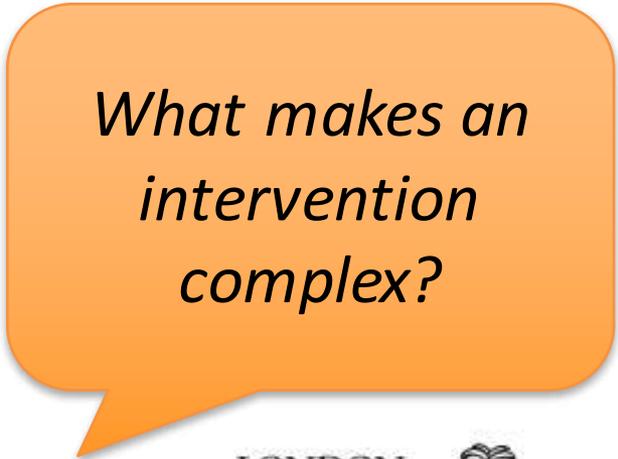
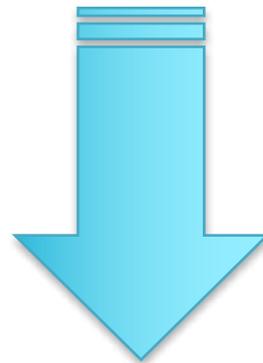


To drive down HIV incidence, increasing consensus that:

- Multiple strategies and multiple sectors are needed (no single intervention is likely to work alone)
- The strategies may differ by context & age
- Similar trend in adolescent health & development...

Increasing advocacy for:

- Combination packages
- Coordinated responses



Complex interventions

“Complexity resides in...

...the number of interacting components, the number and difficulty of behaviours required by those delivering or receiving the intervention, the number of groups or organisational levels targeted by the interventions, the number and variability of outcomes, and the degree of flexibility or tailoring of the intervention permitted.”

Mark Petticrew, “When are complex interventions ‘complex’? When are simple interventions ‘simple’?”
European J of Public Health, 2011

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DREAMS

WORKING TOGETHER FOR AN AIDS-FREE FUTURE FOR GIRLS

The very progress we've made in HIV/AIDS over the last 20 years is at risk right now because of our lack of engagement with adolescent girls and young women.

Ambassador Deborah L. Birx, M.D., U.S. Global AIDS Coordinator & U.S. Representative for Global Health Diplomacy

With girls accounting for over 80 percent of new HIV infections among adolescents in the hardest hit countries, the U.S. government through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), is partnering with the Bill & Melinda Gates Foundation and the Nike Foundation on a \$210 million partnership called DREAMS.

DREAMS seeks to reduce new HIV infections in adolescent girls and young women in 10 sub-Saharan African countries (Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe). The ultimate goal of the partnership is to help girls develop into Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) women.

WHY ADOLESCENT GIRLS AND YOUNG WOMEN?

- Despite considerable progress in the global HIV/AIDS response, gender and age disparities in the high-HIV burden **DREAMS countries** remain almost unchanged



- **380,000** adolescent girls and young women are infected with HIV every year - that is around **1,000 girls every day**



- Keeping adolescent girls and young women HIV free also **positively impacts** their overall **health, education, development, and wellbeing**

Many adolescent girls and young women lack

“Today, we are announcing that PEPFAR is now investing nearly half a billion dollars to support an AIDS-free future for adolescent girls and young women.”

- US National Security Advisor Susan E Rice, 26 Sept 2015

“DREAMS is about **multiple solutions** surrounding **one problem**: new HIV infections among adolescent girls and young women.”

PEPFAR.GOV



Determined

Resilient

Empowered

AIDS-Free

Mentored

Safe

DREAMS targets 4 related groups...



1

Empower Girls and Young Women

Interventions for this population aim to empower girls and to reduce their risk for HIV and violence.

2

Reduce Risk of Sex Partners

This activity aims to characterize "typical" sexual partners of adolescent girls and young women in order to target highly effective HIV interventions.

3

Strengthen Families

Interventions for this population aim to strengthen the family economically, as well as in their ability to parent positively.

4

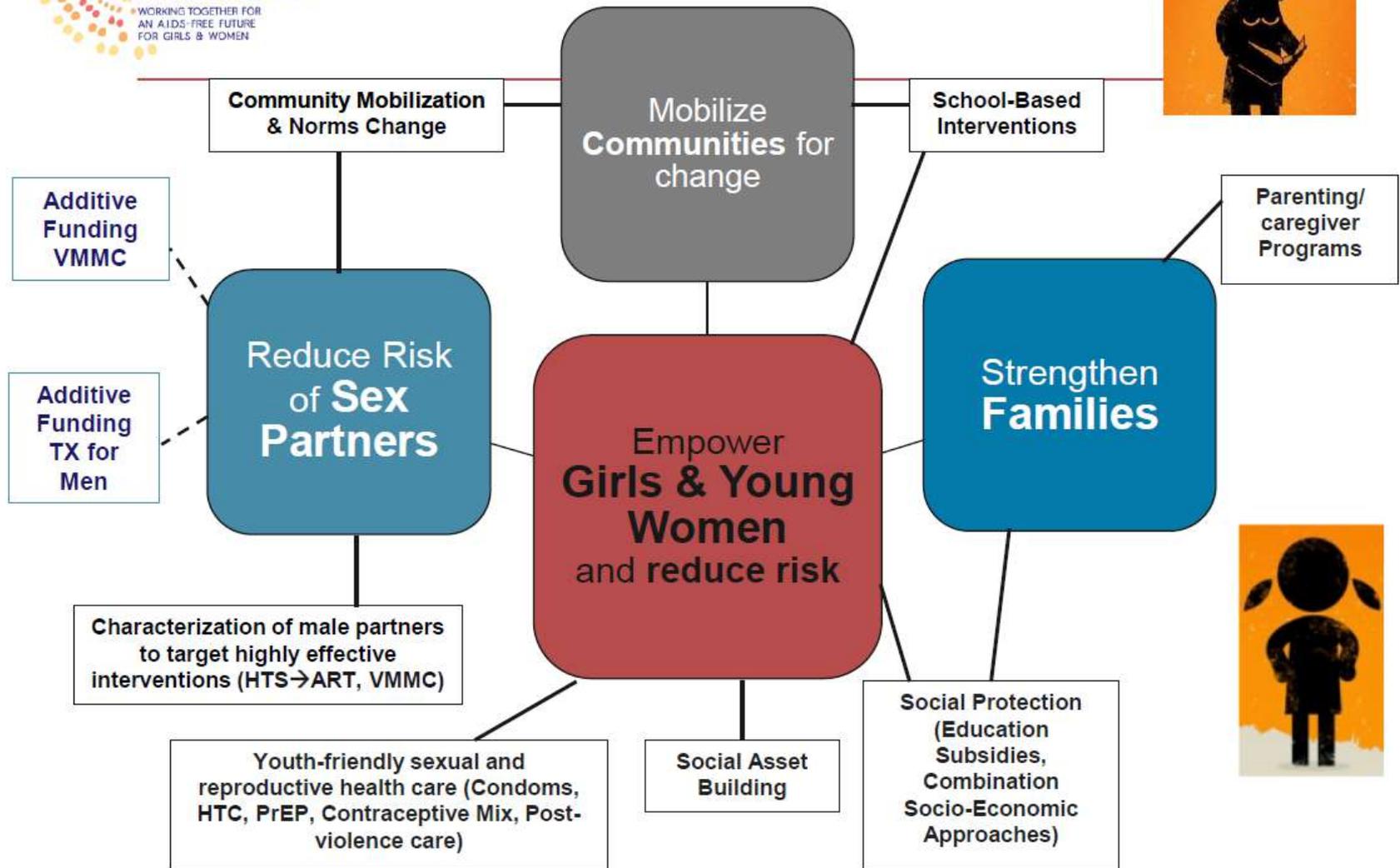
Mobilize Communities for Change

These interventions aim to educate girls, young women, and young men, as well as mobilize communities.

... with many interacting components



The Core Package



Heterogeneity in real-world implementation

- across 65+ districts in 15 countries



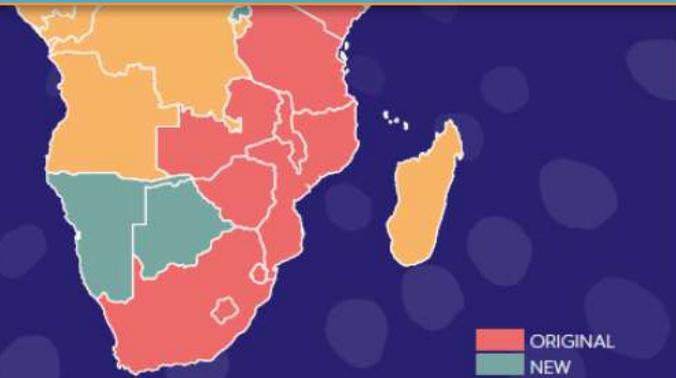
Heterogeneity in real-world implementation

- across 65+ districts in 15 countries

15 DREAMS

COUNTRIES

- Botswana
- Cote d'Ivoire
- Haiti
- Kenya
- Lesotho
- Malawi
- Mozambique
- Namibia
- Rwanda
- South Africa
- Swaziland
- Tanzania
- Uganda
- Zambia
- Zimbabwe



Different interventions in different contexts
Different models of implementation
Different strategies for "layering" (mentors, safe spaces, 'passports', unique IDs...)

Chimbindi & Birdthistle: 'Translating DREAMS into practice: Early lessons from implementation in six settings'
PLOS One 2018

Determined

Resilient

Empowered

AIDS-Free

Mentored

Safe

“Complexity resides in

*...the number of **interactions**,
the number and difficulty of **components** required
by those delivering or receiving the intervention,
the number of **groups or organisational levels**
targeted by the interventions,
the number and **variability of outcomes**, and the
degree of **flexibility or tailoring** of the
intervention permitted.”*

*In all these ways, and more,
DREAMS is a complex
intervention*

Mark Petticrew, “When are complex interventions
‘complex’? When are simple interventions ‘simple’?”
European J of Public Health, 2011

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How do we evaluate such a complex intervention?

(while preserving clarity and utility
and spontaneous joy...?)



It depends on our perspective & question

A complex question

How and whether the components work individually and together? Considering their synergies, phase changes, feedback loops, interactions between outcomes, and the process by which the components bring about change.

A simple question

Is the whole package associated with improved health?

Mark Petticrew, *European J of Public Health*, 2011

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It depends on our perspective & question

A complex question

How and whether the components work individually and synergies, phase interactions between components and by which the components

We started here, because...

Evidence of the individual components is already known

The knowledge gap is whether they have an impact when delivered together as a package.

A simple question

Is the whole package associated with improved health?

Mark Petticrew, *European J of Public Health*, 2011

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How to answer a 'simple question' about impact, given...

No randomisation

Why not?

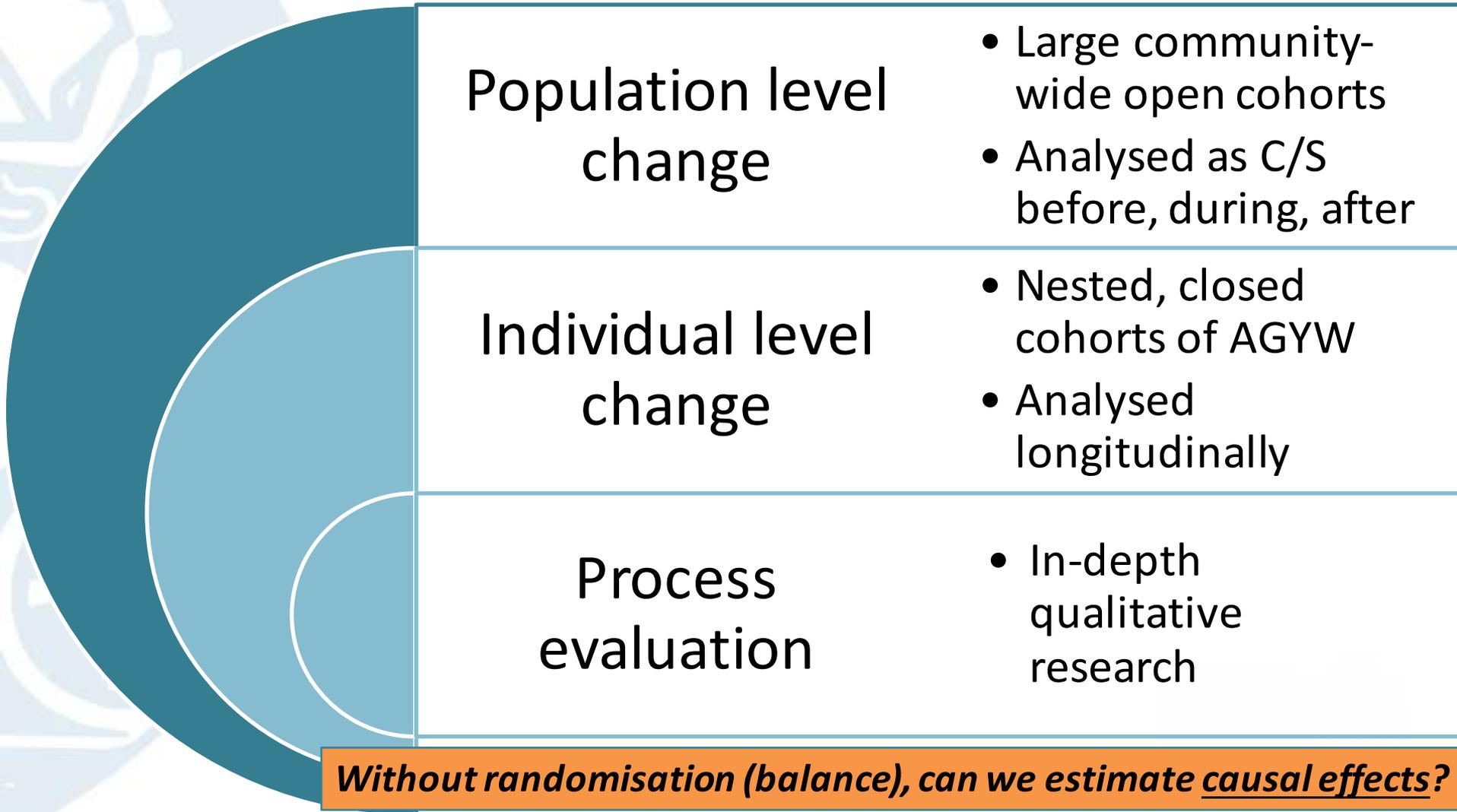
Timing, feasibility, ethics

- An urgency to begin roll-out of DREAMS
- DREAMS would target the most vulnerable adolescent girls and young women in priority districts
- Equipoise: the intervention was expected to be beneficial (hard to justify controls or large expense of a trial)



An observational design

– using population-based longitudinal data within demographic surveillance sites



“The C-Word...”

“... ‘causal’ [must] stop being considered the C-word that investigators and editors avoid. Only by precisely defining the causal effect of interest will we have a chance of estimating it accurately.”

Miguel Hernan, “The C-Word: The more we discuss it, the less dirty it sounds” AJP 2018



Applying causal inference approaches

Answering causal questions using observational data by emulating a target (hypothetical) trial

1. Specifying the target trial
2. Emulating the target trial
3. Triangulating

Though not randomised, the principles & techniques of a randomised trial can help

Miguel Hernan, AJPH 2018

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Applying causal inference approaches



Population level change	<ul style="list-style-type: none">• Large community-wide open cohorts• Analysed as C/S before, during, after
Individual level change	<ul style="list-style-type: none">• Nested, closed cohorts of AGYW• Analysed longitudinally
Process evaluation	<ul style="list-style-type: none">• In-depth qualitative research

Population level change

- Large community-wide open cohorts
- Analysed as C/S before, during, after

Individual level change

- Nested, closed cohorts of AGYW
- Analysed longitudinally

Process evaluation

- In-depth qualitative research

1. Specifying the target trial (the hypothetical experiment)

Classification of 'treatment' groups

Who is a DREAMS beneficiary?

a priori measures

- Invited to participate in DREAMS *versus not* [analogous to ITT]
- Invited and received min 3 core package categories *versus 0-2*

Must be updated over time
(with new beneficiaries)...

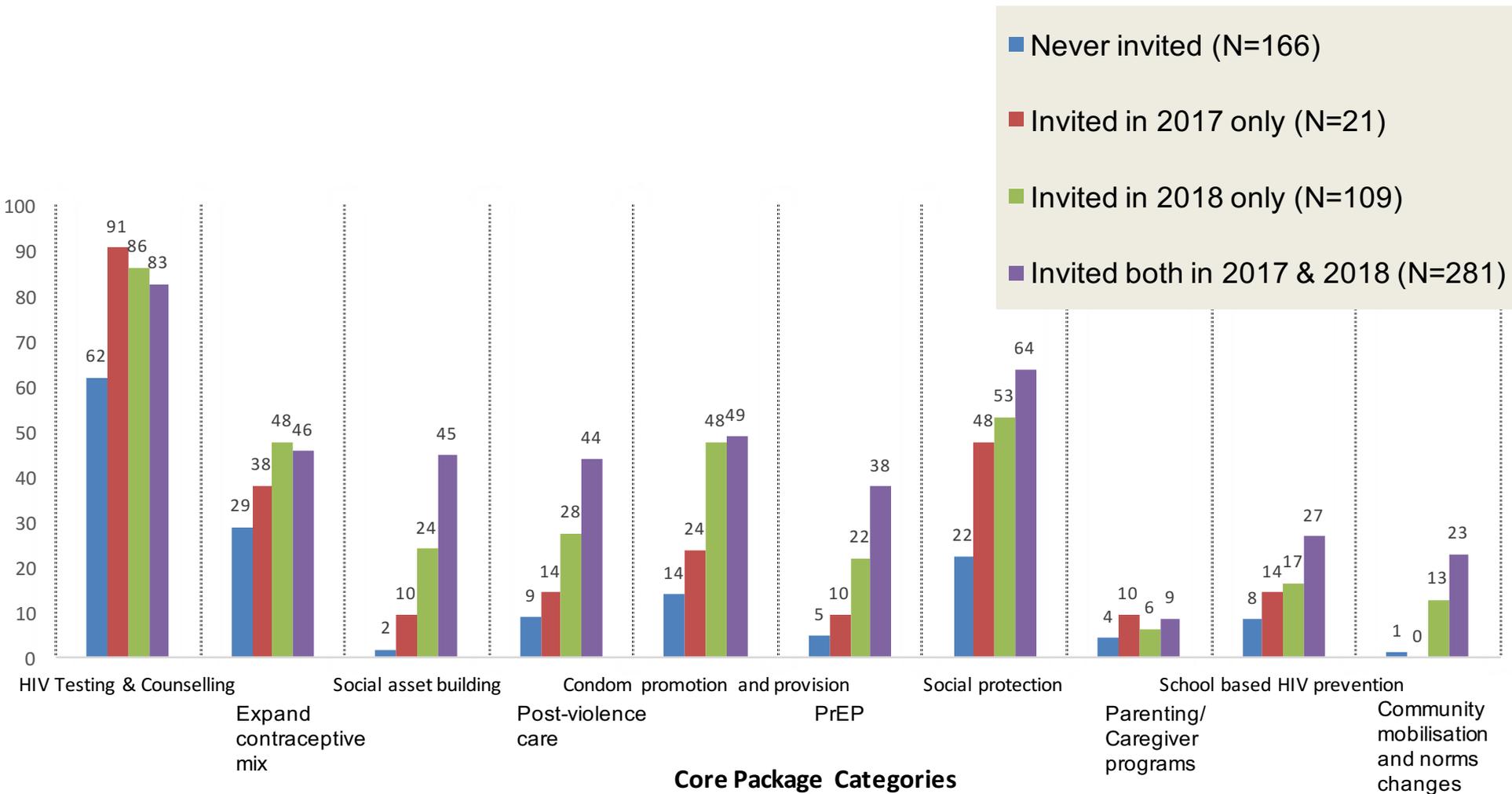
Categorical measure

1. Never / None
2. 2017 only
3. 2018 only
4. 2017 & 2018

Binary measure

- Any DREAMS by 2018:
Yes/No

Participation in DREAMS core package interventions in 2018: 18-22/24 AGYW in Nairobi



2. Emulating the target trial

Applying counterfactual reasoning for causal inference

‘Random assignment’ of treatment groups

Aim to achieve (**near**) balance on baseline covariates

→ Adjust for all (**measured**) confounding factors, e.g., through propensity score* adjustment

Generate overall causal effects

→ Predict outcome for full sample if all *versus* if none got DREAMS

*Propensity score = probability of receiving the intervention based on confounder values (useful if many co-variates, esp/ for rare outcomes; compared with adjustment for each individual confounding variable)



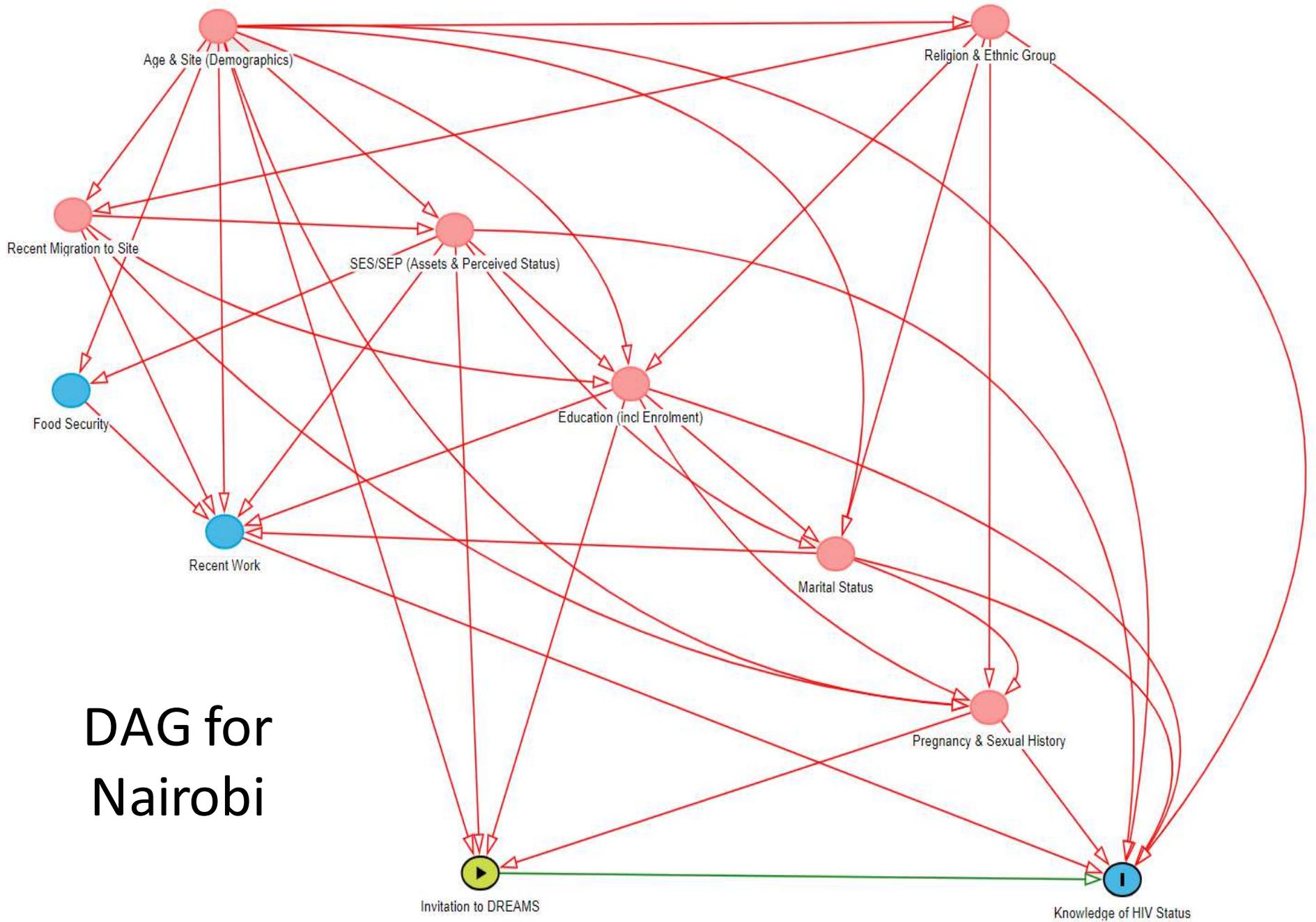
Examples from DREAMS evaluation (before endline data are available)

Early impacts expected on **Knowledge of HIV Status**

What would be the difference in **the proportion of AGYW who know their status** if everybody got DREAMS compared to if nobody got DREAMS?

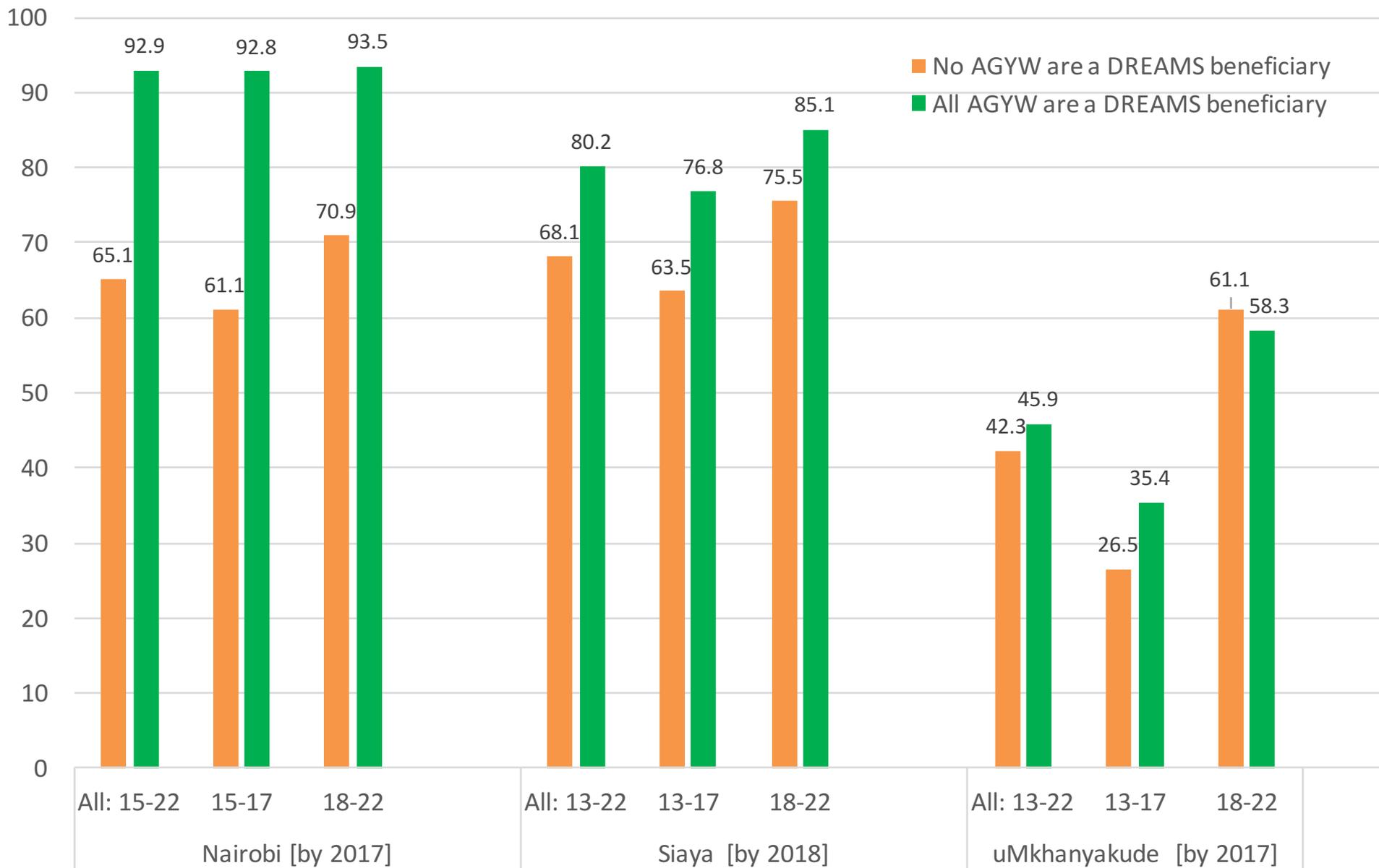
Framing in causal language helps clearly articulate the question and identify a suitable estimand





DAG for Nairobi

Predicted proportions who Know their HIV Status if none versus all benefited from DREAMS (in 3 DREAMS settings)



Back to the causal question...

What would be the difference in **the proportion of AGYW who know their status** if everybody got DREAMS compared to if nobody got DREAMS?

The absolute difference

- Nairobi: **27.7% increase** [95% CI: 22.8%, 32.6%]
- Gem: **12.1% increase** [95% CI 7.7-19.6]
- KwaZulu Natal: effect modification by age
 - 13-17 Year olds: **8.95%** [95% CI 4.8%, 14.4%]
 - 18-22 Year olds: **-2.8%** [95% CI -11.1%, 5.7%]
- Importance of CONTEXT
 - Very different effects across site; age group
- Importance of MECHANISM (how?)
 - different effects depending on targeting and implementation – **need process eval data!**

For complex interventions, 'outcome evaluation' may not be enough



Not enough to know whether an intervention is effective, or even by how much.

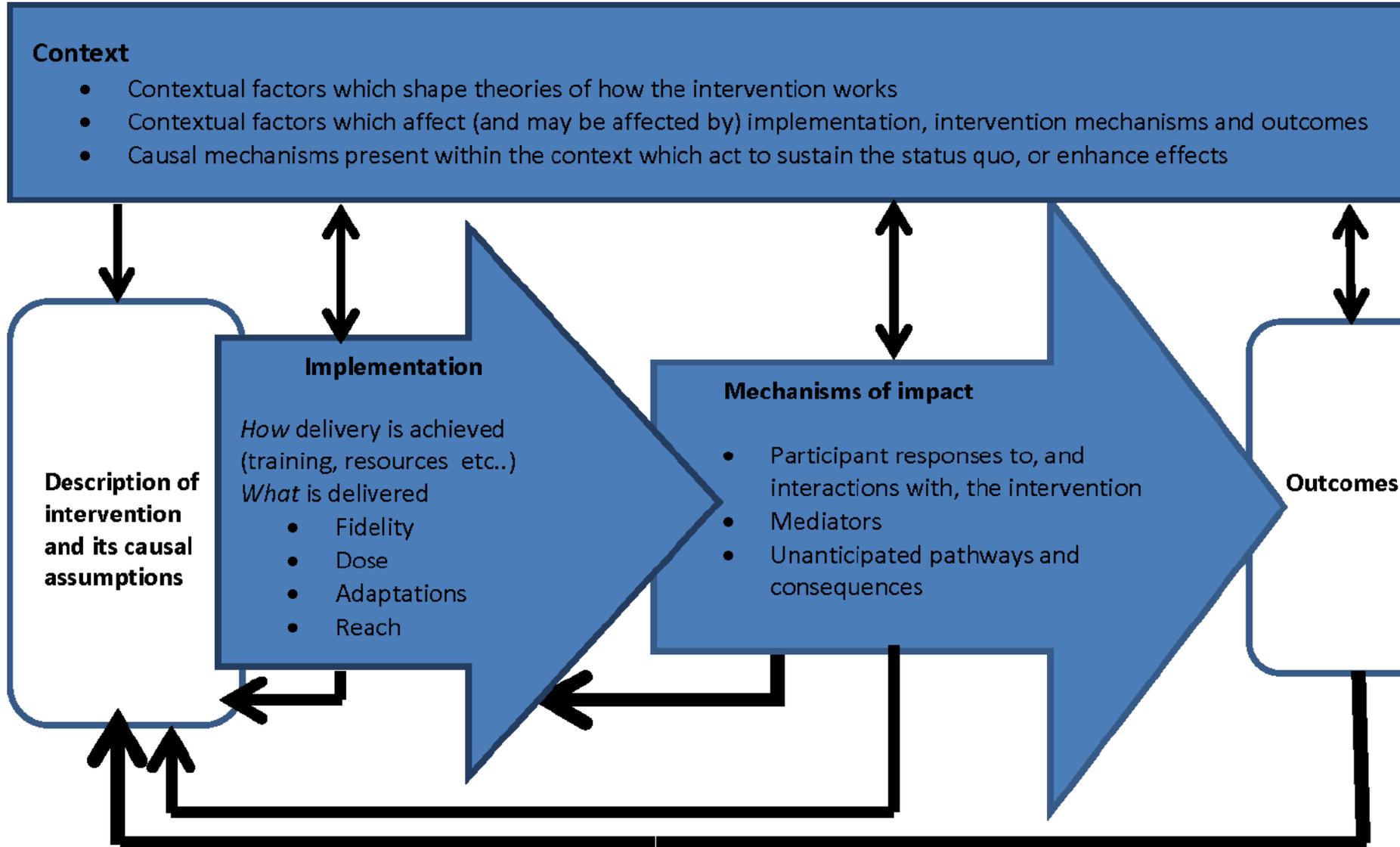
Important to understand how and why, and for whom, especially in the 'real-world', under non-trial conditions, if we want lessons for replication.

“Effect sizes do not provide policy makers with information on how an intervention might be replicated in their specific context, or whether trial outcomes will be reproduced.”



Process evaluation

- An essential part of designing and testing complex interventions
- Guided by 3 key themes...



High Knowledge of HIV Status in Nairobi

A reflection of how the intervention was delivered and received in this context?





Insights from process evaluation

Context

- Contextual factors which shape theories of how the intervention works
- Contextual factors which affect (and may be affected by) implementation, intervention mechanisms and outcomes
- Causal mechanisms present within the context which act to sustain the status quo, or enhance effects

Implementation

How delivery is achieved (training, resources etc..)
What is delivered

- Fidelity
- Dose
- Adaptations
- Reach

Description of intervention and its causal assumptions

Delivery of HIV testing through DREAMS in Kenya...

- HIV testing was offered at time of enrolment into DREAMS, to all AGYW, regardless of age, circumstance, or perceived risk
- All DREAMS interventions are coordinated by one IP, so this approach is consistent and systematic
- IPs were experienced in HIV testing prior to DREAMS
- Testing made available in community-based settings, including DREAMS safe spaces, home-based testing, and referrals to facilities



Insights from process evaluation

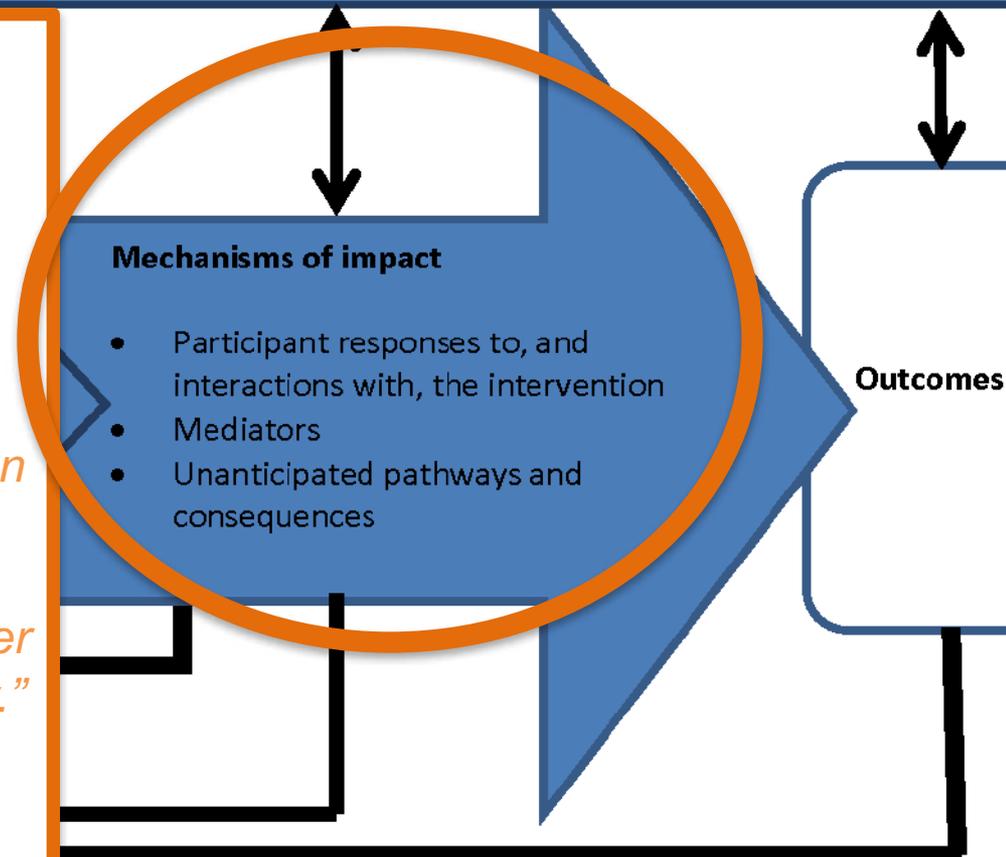
Context

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HIV testing through DREAMS was positively received by AGYW in Kenya, e.g., for the confidentiality...

“Initially there were these people who were afraid of going to the hospital, but right now you find that the HTS person comes to the safe space at least you can have the courage. Because for them they will come and test you and leave, they won’t talk about your results to other people. They will just tell you personally.”

- FGD with out of school AGYW



Must the evaluation of complex interventions be complex?

An answer:

“When it is helpful to see and analyse them as such”

Mark Petticrew, European J of Public Health, 2011

(And it usually is)

Some clarity in the face of complexity...?



If the complex intervention is not randomised, don't necessarily shy away from causality

Aim for causal inference, while wary of the assumptions that can easily be violated unless we:

- Know the intervention, how it is implemented (by/with whom) and how it changes in different contexts and over time
- Consider, measure and account for confounders
- Triangulate: Use multiple, complementary approaches to answer the question (with different advantages and disadvantages)



"Gesamtkunstwerk"

(German: [gə'zamt,kʊnstvɛɪk], translated as "synthesis of the arts", when different forms are combined into a single unified whole)

An elegant aspiration for evaluations of complex interventions



With thanks to colleagues & partners

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Isolde Birdthistle has no conflict of interest and nothing to disclose