Must the evaluation of complex interventions be complex?

Learning from the impact evaluation of DREAMS

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isstdr 2019
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?
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

What makes an intervention complex?
“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
“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.”
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

- Community Mobilization & Norms Change
- Additive Funding VMMC
- Additive Funding TX for Men
- Mobilize Communities for change
- School-Based Interventions
- Parenting/caregiver Programs
- Reduce Risk of Sex Partners
- Empower Girls & Young Women and reduce risk
- Characterization of male partners to target highly effective interventions (HTS→ART, VMMC)
- Social Asset Building
- Social Protection (Education Subsidies, Combination Socio-Economic Approaches)
- Youth-friendly sexual and reproductive health care (Condoms, HTC, PrEP, Contraceptive Mix, Post-violence care)
- Strengthen Families
Heterogeneity in real-world implementation - across 65+ districts in 15 countries
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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
“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
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
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.

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
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

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<tr>
<th>Level of Change</th>
<th>Description</th>
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<tr>
<td>Population level change</td>
<td>• Large community-wide open cohorts</td>
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<td>• Analysed as C/S before, during, after</td>
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<td>Individual level change</td>
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<td>• Analysed longitudinally</td>
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<tr>
<td>Process evaluation</td>
<td>• In-depth qualitative research</td>
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Without randomisation (balance), can we estimate causal effects?
“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” AJPH 2018
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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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

- **HIV Testing & Counselling**
  - Never invited (N=166): 62%
  - Invited in 2017 only (N=21): 91%
  - Invited in 2018 only (N=109): 86%
  - Invited both in 2017 & 2018 (N=281): 83%

- **Social asset building**
  - Never invited (N=166): 29%
  - Invited in 2017 only (N=21): 48%
  - Invited in 2018 only (N=109): 46%
  - Invited both in 2017 & 2018 (N=281): 45%

- **Condom promotion and provision**
  - Never invited (N=166): 22%
  - Invited in 2017 only (N=21): 14%
  - Invited in 2018 only (N=109): 28%
  - Invited both in 2017 & 2018 (N=281): 44%

- **PrEP**
  - Never invited (N=166): 5%
  - Invited in 2017 only (N=21): 10%
  - Invited in 2018 only (N=109): 22%
  - Invited both in 2017 & 2018 (N=281): 24%

- **Social protection**
  - Never invited (N=166): 22%
  - Invited in 2017 only (N=21): 14%
  - Invited in 2018 only (N=109): 48%
  - Invited both in 2017 & 2018 (N=281): 64%

- **School based HIV prevention**
  - Never invited (N=166): 4%
  - Invited in 2017 only (N=21): 10%
  - Invited in 2018 only (N=109): 8%
  - Invited both in 2017 & 2018 (N=281): 17%

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

- **Core Package Categories**
  - Expand contraceptive mix
  - Post-violence care
  - Parenting/Caregiver programs
  - Community mobilisation and norms changes
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)

- **Nairobi** [by 2017]:
  - No AGYW are a DREAMS beneficiary: 92.9%
  - All AGYW are a DREAMS beneficiary: 93.5%

- **Siaya** [by 2018]:
  - No AGYW are a DREAMS beneficiary: 80.2%
  - All AGYW are a DREAMS beneficiary: 85.1%

- **uMkhanyakude** [by 2017]:
  - No AGYW are a DREAMS beneficiary: 65.1%
  - All AGYW are a DREAMS beneficiary: 58.3%
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 of complex interventions: Medical Research Council guidance
BMJ 2015; 350 doi: https://doi.org/10.1136/bmj.h1258
Process evaluation
- An essential part of designing and testing complex interventions
- Guided by 3 key themes...

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

Description of intervention and its causal assumptions

Implementation

\textit{How} delivery is achieved (training, resources etc.)
\textit{What} is delivered
- Fidelity
- Dose
- Adaptations
- Reach

Mechanisms of impact
- Participant responses to, and interactions with, the intervention
- Mediators
- Unanticipated pathways and consequences

Outcomes
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

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
- 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

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”


(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: [ɡəˈzamtˌkʊnstvɛʁk], 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

Isolde Birdthistle has no conflict of interest and nothing to disclose