Community-led randomised controlled trials

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Methods: 1 + 1 = …

Many interventions are out of touch with community needs

Informed participation ensures relevance and cultural safety

(Community-based participatory research)

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Resource allocation often requires counter-factual evidence that is not distorted by confounders: randomised controlled trials

("Higher-level" epidemiological study)

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Community-led cluster randomised controlled trials

1. Dengue prevention (Mexico and Nicaragua)
2. Safe birth in cultural safety (Mexico)
3. Community m-surveillance of maternal mortality (Nigeria)
4. Reducing family violence (Canada, 12 centres)
5. HIV & choice disability (Botswana, Namibia, Swaziland)
6. INSTRUCT: structural causes of HIV (Botswana)

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1. Dengue: the *Camino Verde* trial

1. Prevention centred on temephos (Abate)
2. Dengue still rising (doubled in USA 2012)
3. 150 communities in Mexico and Nicaragua
4. Randomisation after baseline
5. SEPA: socialising evidence for participatory action
   - Community defined interventions
   - Protocol: share evidence, discussion, action plan

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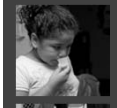
Baseline measurement

Visit and interview households
Nicaragua: 8,402 Mexico: 12,399

Number of residents
Nicaragua: ~42,000 Mexico: 54,728

Container inspections
Nic: 36,298
Mex: 45,013



Paired saliva samples
Nic: 4,870 x 2
Mex: 6,382 x 2

Data about costs of dengue collected

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Community-led interventions

Camino Verde impact assessment 2012-2013

	RR
New cases children aged 5-9y (immunology saliva assay)	
Reported dengue cases per HH	
Ae. aegypti larva count per HH	
Ae. aegypti pupa count per HH	
Households using biological control (larva-eating fish)	

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2. Safe birth in cultural safety (Mexico)

- International maternal mortality reduction mantra: "*take them to the services!*" -- for indigenous people, this is a major rupture
- Xochistlahuaca: Nancue Ñomndaa (Amuzgo)
- Baseline to identify *authentic* midwives (>10) then randomised to intervention/control
- **Intervention midwives present their needs: Respect, safe place, interface with services**

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Safe birth in cultural safety: results

- Non-inferiority (though small trial: 86 vs 320)
- MUCH lower birth complication rate
- Lower neonatal mortality (small numbers)
- Less domestic violence

Main dynamic: Interface increased referrals

Phase III trial: five ethnic groups, same approach

http://cietresearch.org

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4. Rebuilding from resilience (Canada)

- High rates of family violence on-Reserve
- Aboriginal women's shelters overloaded
- Starting belief: Aboriginal communities can do it
- Partnership 12 shelters across Canada; steering committee of shelter directors (CIET as resource)
- **Randomised themselves into two waves**
- Baseline Wave2 = impact assessment Wave1

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Community-led interventions

- Three point protocol:
  1. Develop enabling environment
  2. Concert existing services
  3. Structural changes that alter individual risk
- Look for synergies (eg youth)
- All interventions locally staffed
- Mid-way intervention research
- Examples on www.cietresearch.org

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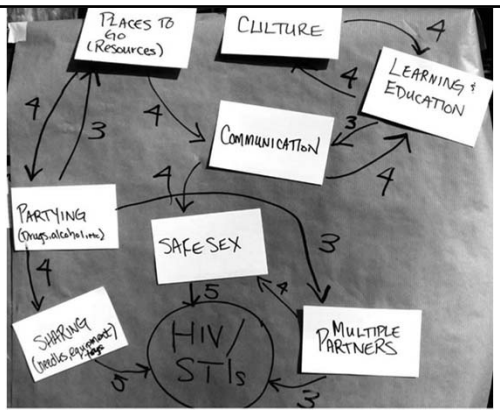

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Use of fuzzy cognitive maps Rebuilding from resilience (Canada)

- Conceptualisation of resilience-related action
- Questionnaire design
- Community development of interventions
- Generating priors for Bayesian analysis
- Understanding why interventions (didn't) work

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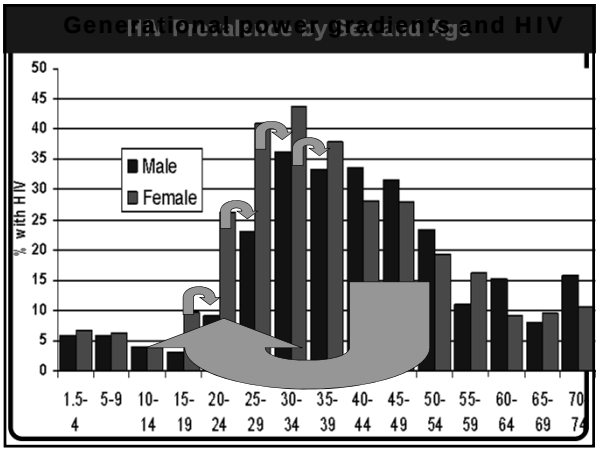

Age-specific female/male diagnosis ratios reflect HIV transmission dynamics

Canada Aboriginal HIV Cases 2006-8		Botswana HIV Cases 2008	
50+y	F/M 0.49	50+y	F/M 0.66
40-9y	F/M 0.73	40-9y	F/M 0.82
30-9y	F/M 0.80	30-9y	F/M 1.19
20-9y	F/M 1.55	20-9y	F/M 2.6
15-19y	F/M 4.0	15-19y	F/M 3.33

International Health 2011;3:193 – 198

NACA Botswana Annual report 2009

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HIV prevention scale-up: what options?

No RCT shows HIV impact	RCT evidence
Abstinence (delay debut)	Male circumcision
Be faithful campaigns	ART (PMTCT, PEP, PrEP)
Condom use (m and f)	Cash transfers
Disclosure campaigns	
Reduce multiple partners	
Testing & counselling (VCT)	
Microcredit schemes	
Reduce gender violence	

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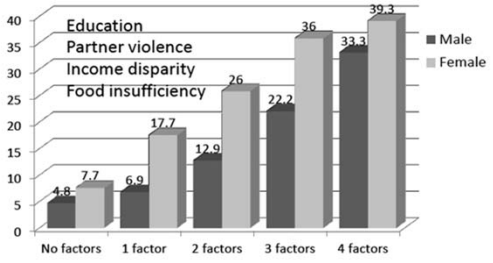
5. Structural Determinants of HIV

What is different about HIV+ 15-29 year-olds?
7464 people in Botswana, Namibia, Swaziland 2008



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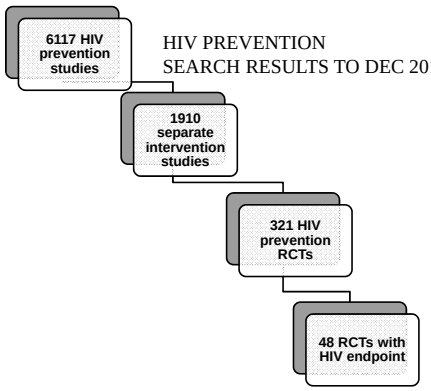
AIDS Behav (2012) 16:189–198



HIV PREVENTION
SEARCH RESULTS TO DEC 2012

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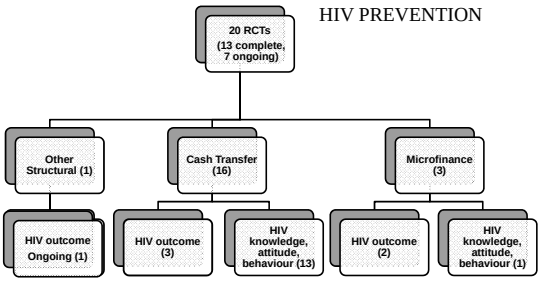

STRUCTURAL
INTERVENTIONS
HIV PREVENTION

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5 published structural interventions with HIV endpoints

Author year	Country	Intervention	Result
Baird 2012	Malawi n=1289	13-22y F: Pay school costs conditional on attendance	OR 0.36 (0.14-0.91) NNT=156
DeWalke 2012	Tanzania n=2399	18-30y MF: cash conditional on HIV-negative test followup	STIs included HIV; no significant effect
Kohler 2011	Malawi n=1076	14-24y MF: Cash conditional on HIV-negative test followup	7 new cases; not powered for HIV
Gregson 2007	Zimbabwe n=9454	15-54y MF: small interest-free loans, training, STI treatment	aIRR 1.27 (0.92-1.75) Not targeted for HIV
Pronyk 2006	S Africa n=2858	34-49y W: microfinancing, HIV and gender training	aOR 1.06 (0.66-1.69) Not targeted for HIV Reduced IPV

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Choice disability trial (Botswana, Namibia and Swaziland)

People cannot implement their prevention choices (related: “constrained choice”)

They do not lack knowledge or means

Forced sex is an obvious example (victims have no choice about protection)

Gendered power differential (transactional sex, abject poverty, age, employment)

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Combination prevention to change infrastructure of HIV transmission

1. Concert existing services in favour of choice disabled
2. Enabling environment for local solutions to choice disability: “Beyond victims & villains”
3. Economic empowerment of young women

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i. Concert prevention services in favour of choice disabled

- Communities are influenced, positively and negatively, by multiple “prevention nodes”
- National poverty alleviation programmes, health centre, church, school, local culture
- Meet each node then convene, discussing who is left out and strategies to include
- Also spiritual dimension/ traditional medicine

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ii. Enabling community environment

- Risk awareness audio-drama: feedback what they said in surveys, develop discussion around their responses
- Started with sexual violence & HIV, ART, choice disablement and transactional sex
- Experience in schools, granny groups, prison groups; new target = sugar daddies

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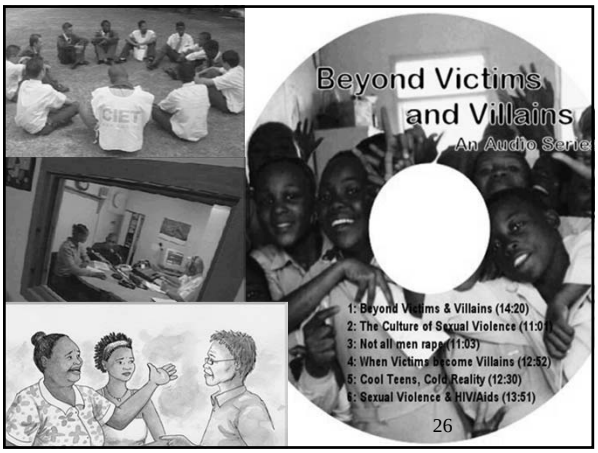

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iii. Empowerment of young women

- Challenge transactional sex for women 15-29y
- Problem 1: high returns from transactional sex
- Problem 2: not good for micro-finance
- Partial solution 1: address also *secondary gains* while trying not to stigmatise
- Partial solution 2: " Self-capitalised" enterprises
- Get out and work…

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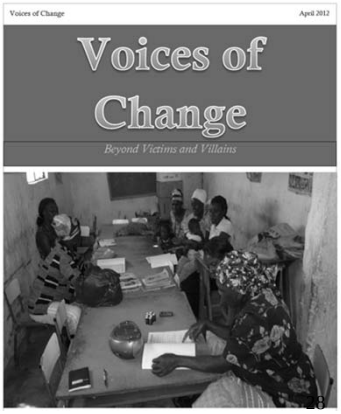

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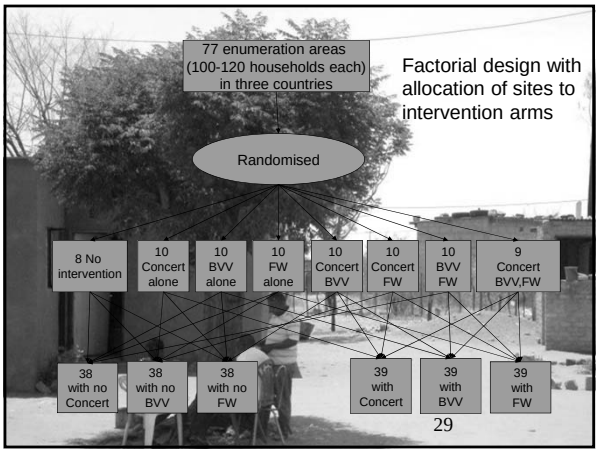

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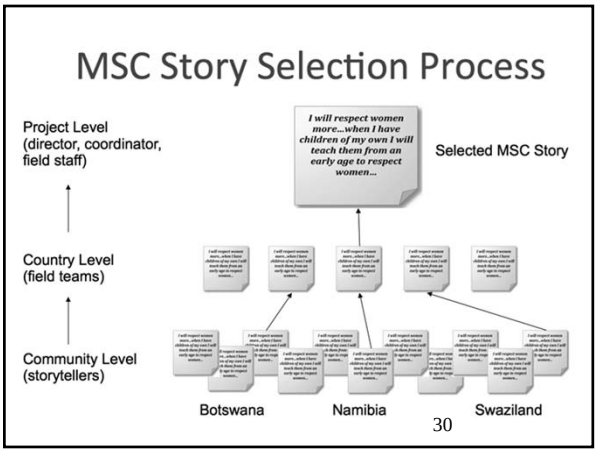

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Generating community priors

- Bayesian analysis requires specification of subjective prior probabilities
- These get applied to the trial results, generating posterior probabilities
- Community priors generated by qualitative process (*how many could this save?*)
- Concerting 5-8/10 BVV 4-6/10 FW 4-8/10
- Lets see…

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5. INSTRUCT – Intersectoral national structural intervention trial (Botswana)

- Structural drivers account for greater part of HIV
- Structural interventions must be local
- Government already doing a lot, but poorly focused on incident cases (women 15-29y)
- Strong commitment by national leadership
- Costs little more than services that don't work

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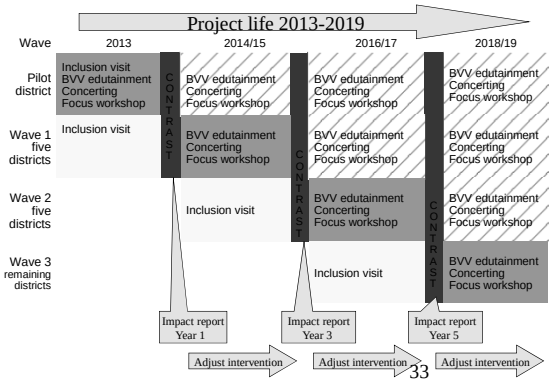
Counterfactual impact assessment



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Core issues in pipeline planning

- Rollout evaluation with advantages of RCT
- Randomisation is pro-equity if resources limited
- Stepped wedge design (off the shelf method)
- Added cost of serious measurement (HIV testing) (larger study size just pays HIV tests n=20,000)
- Doesn't take account of lobby interests and assumes best intentions (what would happen to NAC employees if there was no epidemic)

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Evolving research methods

First generation

- Qualitative studies
- Quantitative (cross-sectional, longitudinal, experimental including RCTs)

Second generation

- Mixed method approaches
- Pragmatic cluster controlled trials

Third generation

- In-service (research as part of delivery)

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Practice-based, pragmatic, real world research

Balance quality science with limited resources.

Advantages: enhanced generalizability and assess effectiveness allowing more rapid translation into daily practice.

Disadvantages: busy staff with limited experience, keeping a practice interested and active for the study, and working from a distance.

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Methods: 1 + 1 = …

Community-based participatory research
- Socialising evidence
- Fuzzy cognitive mapping
- Focus groups
- Talking circles
- Most significant change
- Community meetings
- Generating priors
- Participant-led samples

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"Higher-level" epidemiological study
- Randomisation
- Controls

- Built into service delivery (real world research)

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