The Extended Family of Randomized Roll-Out Designs, Including Stepped Wedge and Dynamic Wait Listed Designs

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Randomized Roll-Out Designs and their Cousins

1. Concept and Appeal of Roll-Out Designs
    - Examples
2. Advantages of a Rollout Design
    - Community
    - Researcher
3. Roll-Out Design and Analysis Choices
4. Summary and References

1. Concept and Appeal of Roll-Out Designs

- **Location/Policy Maker/Community/organization/agency**

  Very committed to wide-scale delivery of a particular intervention

  Ultimately desire scale out or have everyone to get this intervention

  Unwilling to or uncomfortable withholding the intervention by using “controls”

- **Intervention**

  Little or no information available on its benefit or potential harm

  Cannot provide to everyone at once because of logistics/resources

- **Subregions**

  Community can be divided into subregions or areas where intervention can be implemented independently

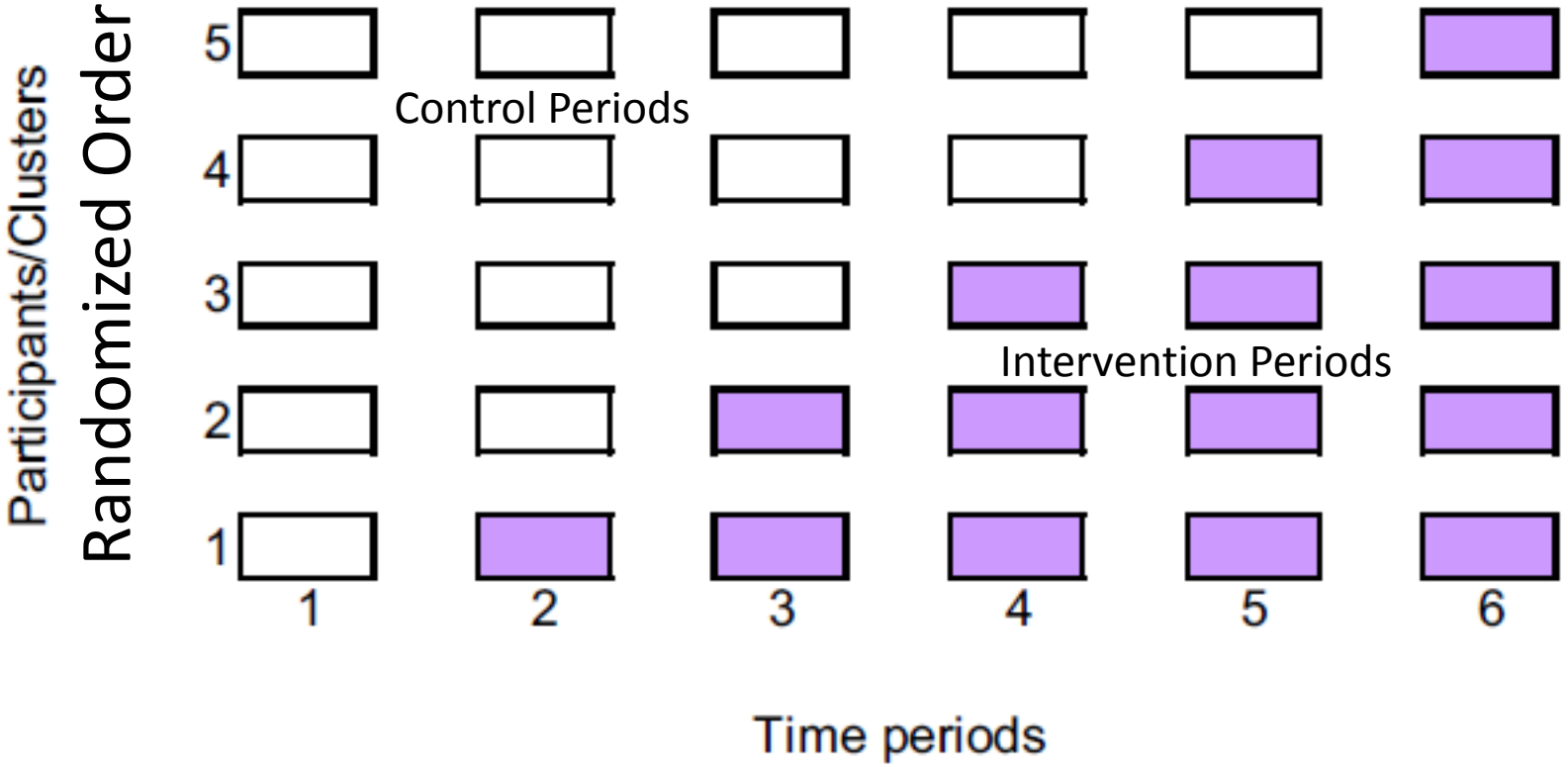
  Outcomes can be assessed in a relatively short period of time

It is possible to construct a rigorous randomized trial to evaluate this intervention by randomizing the timing of when the intervention in introduced.

Randomized Roll-Out Designs Wyman et al., Prev Sci 2015

Units are randomized to when they get the intervention (roll-out)

Randomize by Place and Time -- CH Brown et al., (2009) Ann Rev PH



Stepped Wedge Design – Brown CA & Lilford, BMC Med Research Meth, 2006

Examples

Location	Intervention	Subregions	Name	Year	Ref
Gambia	Hepatitis B Vaccination	17 Vaccination Areas	Stepped Wedge	1987	Gambia Hepatitis Study Group, Cancer Research
Eugene OR & Santa Barbara CA	Mpowerment HIV Prevention for MSM	2 Cities	(Pairwise enrollment) wait-listed design	1996	Kegeles et al., AJPH
Cobb County School District, GA	QPR Youth Suicide Prevention	32 Secondary Schools	Dynamic Wait-Listed Design	2006	Brown et al., Clin Trials
CA and OH Counties	Compare 2 Implementation Strategies for Multidimensional Treatment Foster Care	51 Counties	Head-to-Head Randomized Roll-out Design	2010	Chamberlain et al.

Randomized Roll-Out Designs as a Categorical Name

- More functional and appealing to communities than jargon like Stepped-Wedge and Dynamic Wait-Listed Designs
- Misuse of the term Stepped-Wedge

  Standard Condition → Single Active Intervention

  Standard Condition → Randomize to Intervention A or B
- There are many examples of roll-out designs

2. Advantages of Roll-Out Designs From a Policy Maker or Community Perspective

Ethical Issues

No one should be denied a potentially useful program, as long as it can be delivered with fidelity – Roll-out trials

Traditional research designs like RCTs are unacceptable or foreign in some minority communities and for many policy makers

Allows for programs to improve over time

Decision on which subregion gets the intervention first is fair.

Go First: Immediate access to a potentially beneficial program

Go Later: Program potentially improved through experience

2. Advantages of Roll-Out Designs From a Researcher's Perspective

Ethical Issues

When communities don't hold equipoise about a prevention program

Roll-out designs minimize withholding of a potential beneficial intervention

Statistical Advantages

Improvement over alternative designs

Avoids "readiness bias" of non-randomized community studies

Statistically efficient compared to wait-listed designs – Brown et al. Clinical Trials

This is a True experiment producing strong causal inferences

Even with modest numbers of subregions – Brown et al., Clin Trials 2006

Allows for modeling time and subregion effects – Wyman et al., Prev Sci 2015

Wide range of design choices

Adoption of a New Intervention

Head-to-head Comparisons of two interventions or implementation strategies Brown et al., Ann Rev PH (in press)

3. Roll-Out Design and Analysis Choices

- More Efficient allocation of 32 Schools than a Standard Wait-Listed Design

Year	Time Block	**Wait-Listed Design**		**Dynamic Wait-Listed Design**	
	Time	Intervention	Wait-Listed	Intervention	Wait-Listed
1	1	**16**	**16**	**4**	**28**
	2			**8**	**24**
	3			**12**	**20**
	4			**16**	**16**
2	5	32	0	**20**	**12**
	6			**24**	**8**
	7			**28**	**4**
	8			32	0

Schools Blocked Into 8 Equivalent Groups of 4 who are trained in the same Quarter year

Power increases with even a few subregions

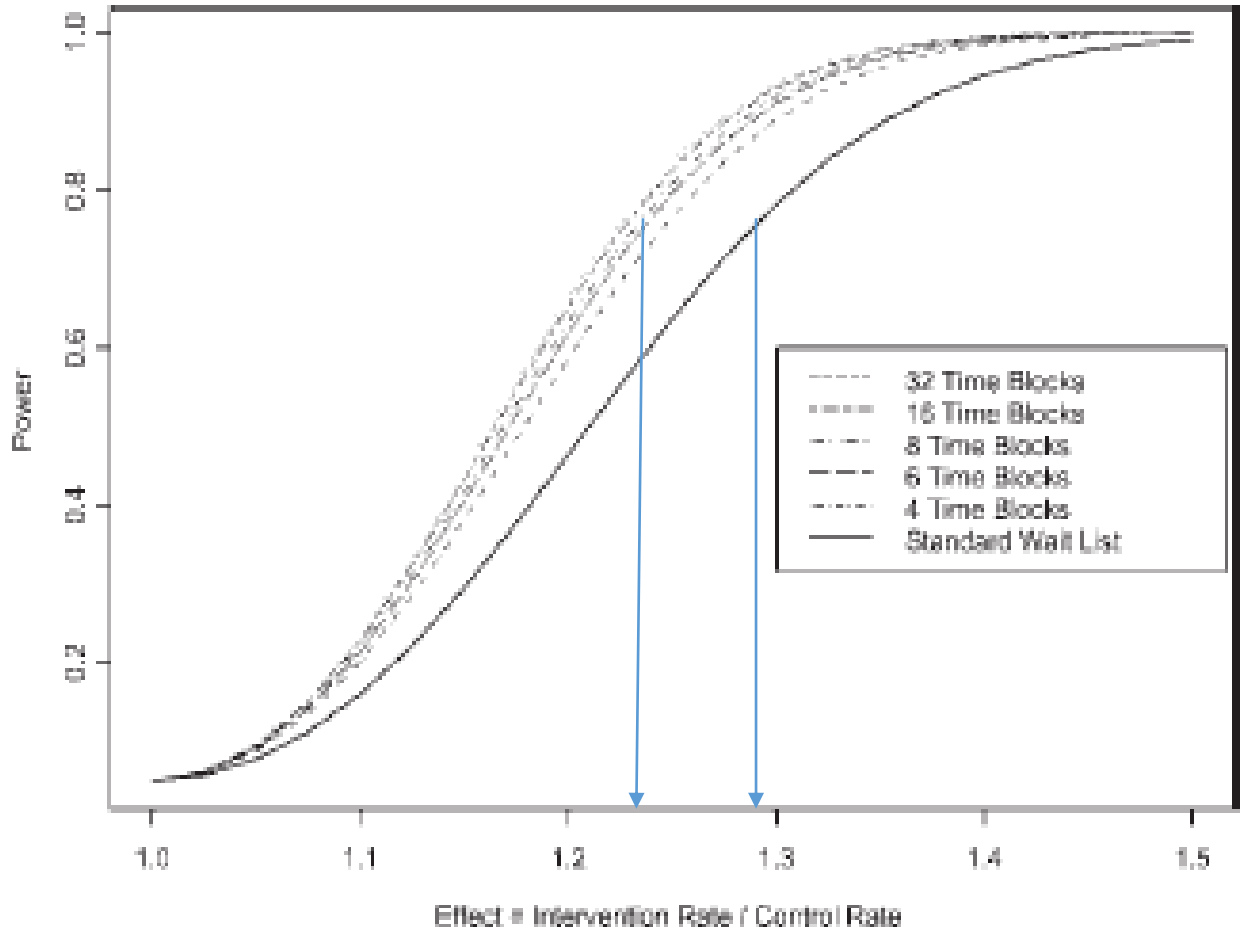


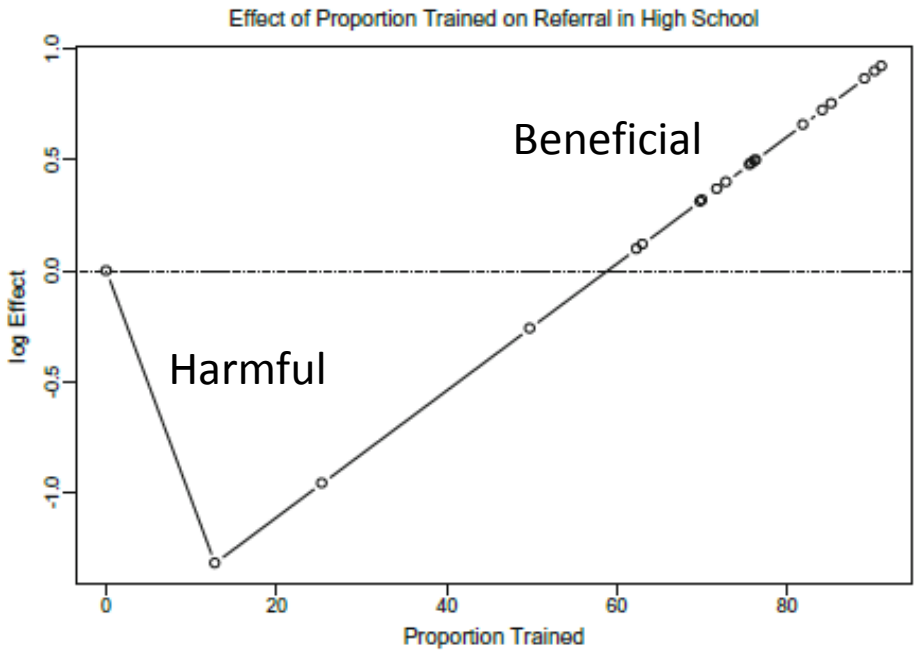
Figure 6 Statistical power for estimating intervention effect on increasing referrals for suicidality with a dynamic wait-listed design begun in the second phase of the Georgia gate-keeper project

Analyses

Model time as a systematic + random effect

Model Sub as a random effect

Model Intervention as fixed, potentially varying in duration

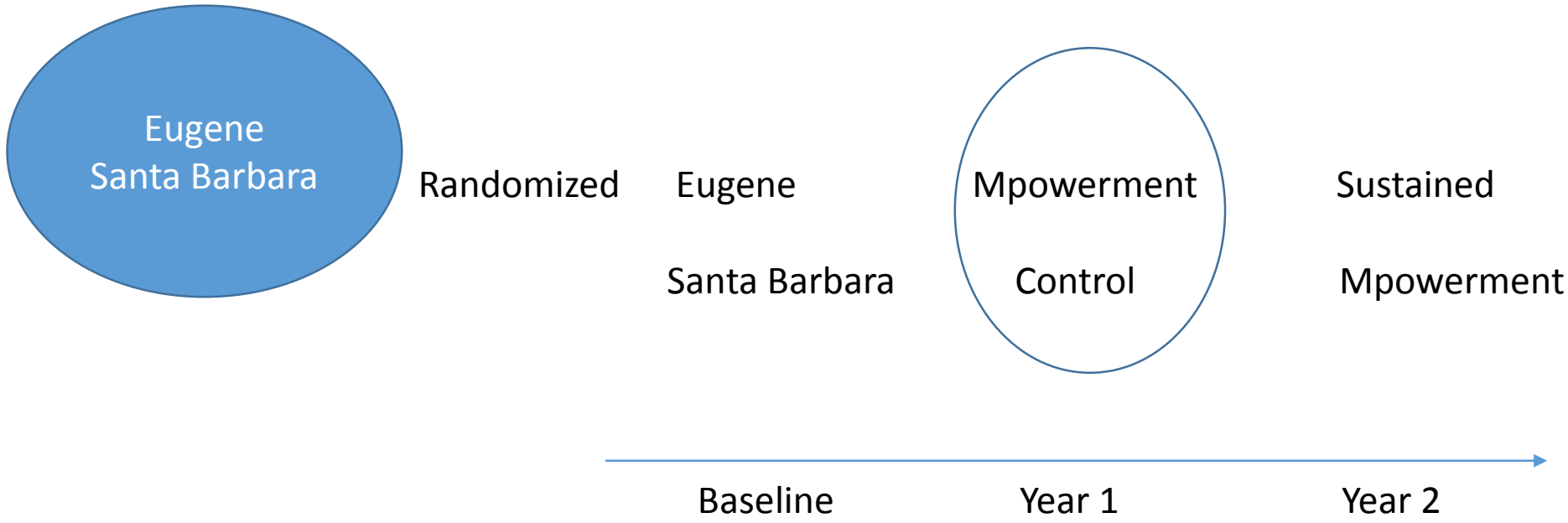


Wyman et al. Prev Sci 2015

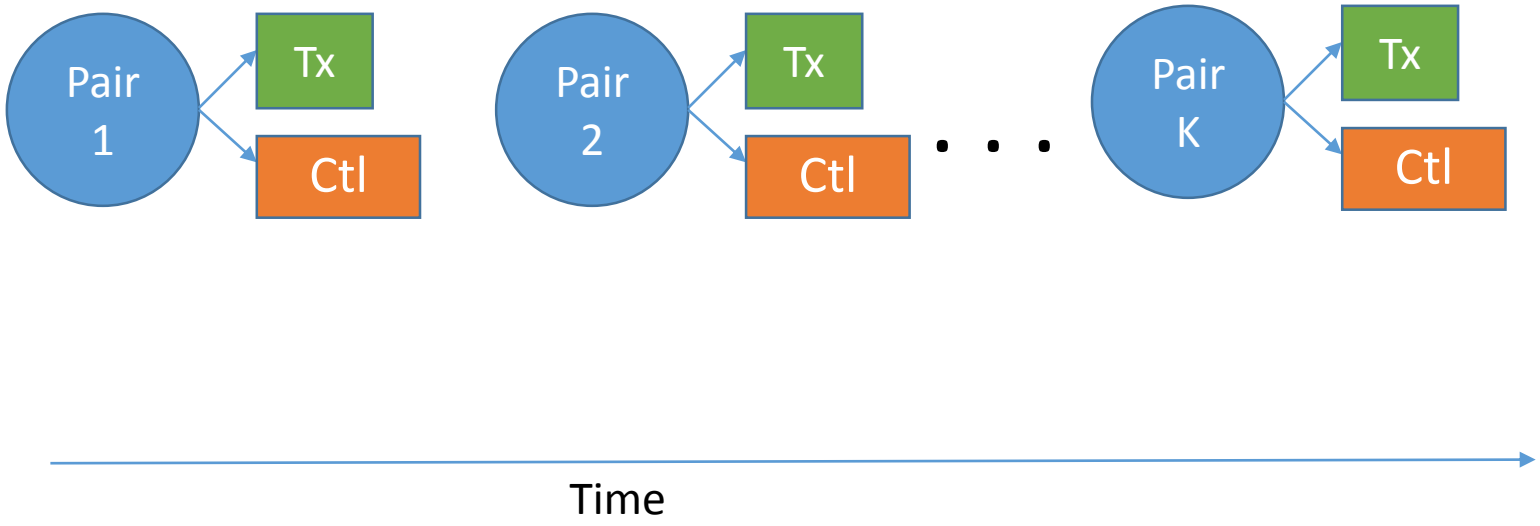
Advantages Even with a Few Units to Randomize

N = 2

Mpowerment Young MSM (Kegeles AJPH 1987)

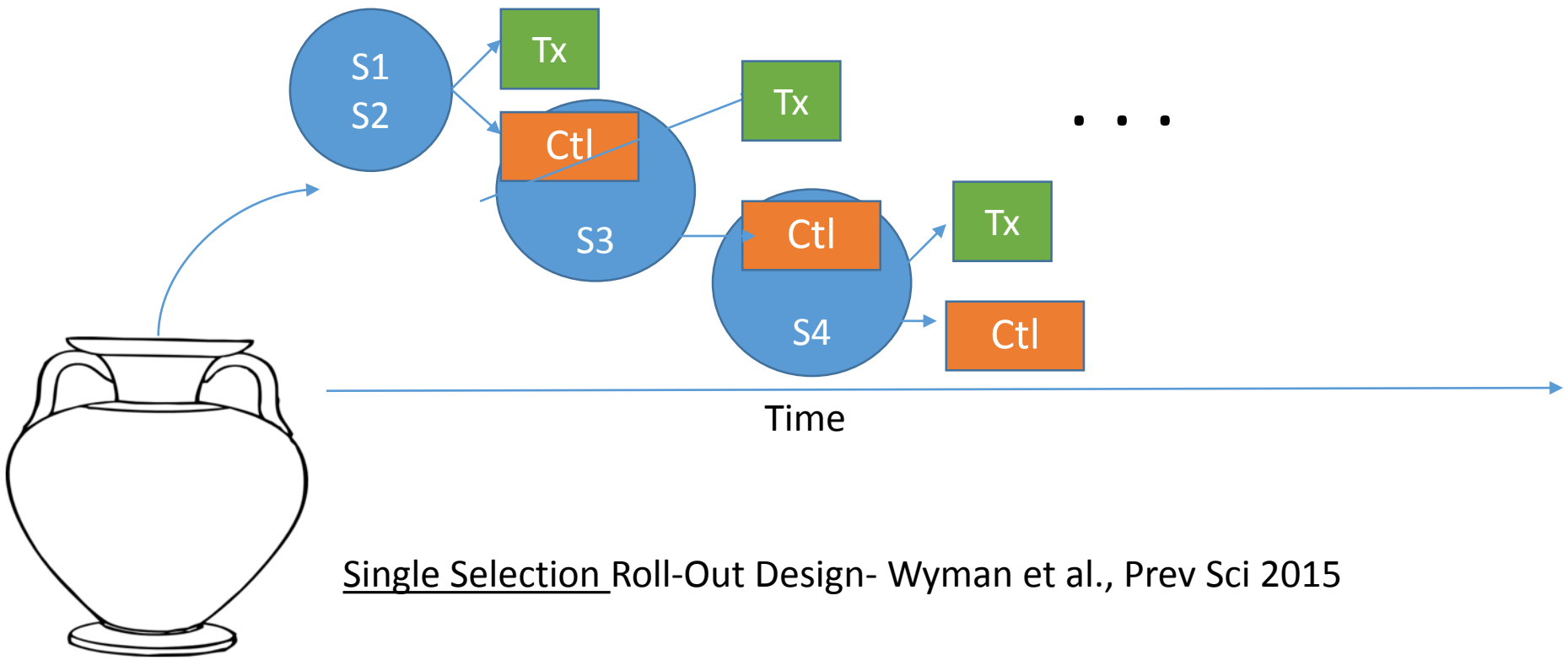


Rollout of Repeated Pairs of Randomized Communities:
Cumulative Trials (Brown et al., Ann Rev PH 2009)



Pairwise Enrollment Roll-Out Design- Wyman et al., Prev Sci 2015

Single Selection Roll-Out of Randomly Selected Communities

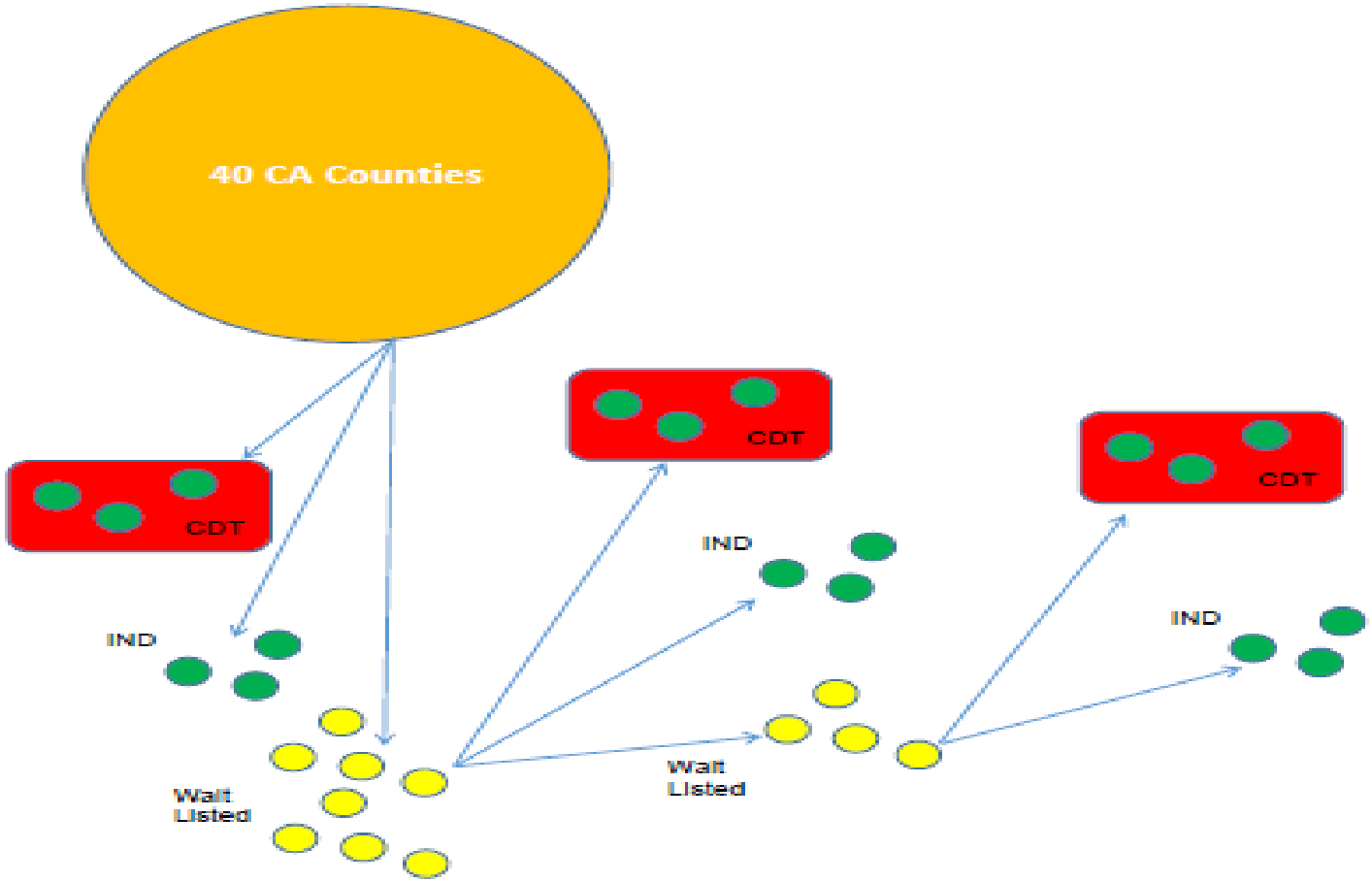


Single Selection Roll-Out Design- Wyman et al., Prev Sci 2015

Head-to-Head Roll-Out Designs (Brown et al., in press Ann Rev PH)

Time	1	2	3	4
Cohort A	0	X*	X	X
	0	Y*	Y	Y
Cohort B	0	0	X*	X
	0	0	Y*	Y
Cohort C	0	0	0	X*
	0	0	0	Y*

Comparison of Community Development Team (CDT) or Independent (Ind) Implementation Strategies (Brown et al., Imp Sci 2014)



4. Summary and References

1. With our limited set of evidence-based community and preventive interventions, especially to address health disparities, **we need to emphasize rigorous evaluation of home-grown programs.**
2. Roll-Out Designs are often appropriate

   Policy Maker or Community Leaders: Ethically get out potentially valuable program

   Researcher: Rigorous and efficient design allowing strong causal inferences
3. A Bestiary of Roll-Out Designs possible

SEA-GOD, SCYLLA

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