LARC training intervention
Results from a cluster randomized trial

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Objectives

- Describe our study intervention to increase LARC access for women at high risk for unintended pregnancy
- Report impact of intervention on LARC access
- Identify strategies to integrate LARC into routine clinical care in the U.S.

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Building on successful models

- **Planned Parenthood** in N. California trained in new IUD indications and simplified screening
  - Post-abortion insertions increased
  - Repeat abortion reduced
- **Kaiser Permanente** in N. California removed cost barriers & conducted evidence-based education
  - Provider attitudes and practices improved
  - IUD use increased
- **CHOICE project** in St. Louis eliminated cost & used standardized LARC counseling
  - High LARC use & continuation, including teens
  - Low pregnancies in LARC users

Goodman *et al*. *Contraception* 2008
Postlethwaite *et al*. *Contraception* 2007
Winner *et al*. *NEJM* 2012

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Leap of faith

- **Very few RCTs with contraceptive education & counseling have succeeded**
  - Post-abortion contraception no results
  - Some repeated intensive counseling results
  - Some evidence for tiered counseling approach

Arrowsmith *et al*. *Cochrane Database Syst Rev* 2012
Lopez *et al*. *Cochrane Database Syst Rev* 2013
Halpern *et al*. *Cochrane Database Syst Rev* 2011
Ferreira *et al*. *Cochrane Database Syst Rev* 2009

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How to increase LARC access?

- **Formative research to design intervention**
  - LARC training important for Family Medicine, Nursing, & Counselors
  - All providers, even Ob\Gyn, have overly restrictive views of eligible patients
  - Trained providers have low risk perceptions, few clinic flow problems, and higher provision
  - Contraceptive funding policies key for access

Thompson *et al*. *Contraception* 2011
Morse *et al*. *Perspect Sex Reprod Health* 2012
Harper *et al. Fam Med* 2012

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Findings informed intervention

CME-accredited on-site training module

- Grand Rounds: updated evidence and method indications
  - *CDC Medical Eligibility Criteria for Contraception*
  - Provider video of successful LARC integration
  - Counseling on methods by tiers of effectiveness
  - Cultural competency, ethics
- Hands-on training
  - Clinicians – pelvic models
  - Health educators – role play, counseling tools
- Patient education LARC video for clinic waiting room
- Billing and reimbursement assistance for cost issues

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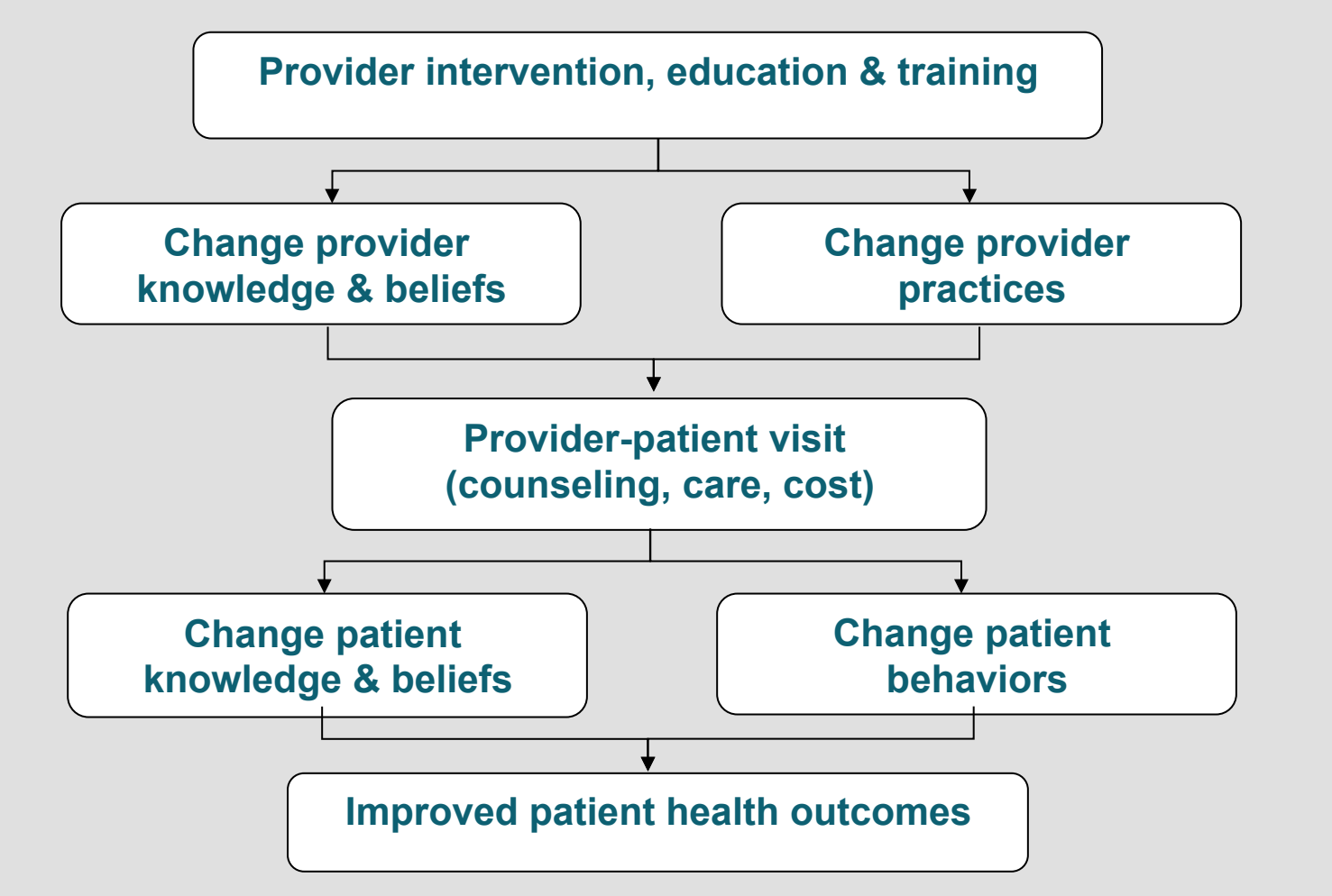
Clinic intervention to patient outcomes



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Study design

- **Design**
  Cluster Randomized Trial (2011-13)
- **Research question**
  Can we improve LARC access with an in-service training on skills & counseling?
- **Intervention**
  CME-accredited in-service training on LARC

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Clinic sites

- **40 eligible Planned Parenthood clinics**
  - ≥ 400 clients per year
  - No shared staff with other study sites
  - No LARC interventions; <20% LARC use

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Sample size

Two group continuity corrected c^2 test of equal proportions, with varying LARC assumptions

	1	**2**	3
Test significance level, a	0.05	**0.05**	0.05
Group 1 proportion	0.04	**0.04**	0.04
Group 2 proportion	0.10	**0.09**	0.08
Odds ratio, $y = p_2 (1 - p_1) / [p_1 (1 - p_2)]$	2.67	**2.37**	2.09
n per group	255	**339**	484
N per group with 20% loss to f-u	340	**424**	605

Multiply sample size by design effect (Variance Inflation Factor)
1+(m-1)o

1,170 or 585 per arm → Recruit 30 per clinic (1,200), or up to 40 in case of greater attrition

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Patient cohort (N=1,500)

- **Women eligible**
  - 18-25 years
  - Received contraceptive counseling
  - Not pregnant
  - Speak English or Spanish

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Methods

- **Computerized randomization**
- **Allocation stratified by clinic size, concealed until study initiation**
- **20 intervention clinics trained** (2011-12)
- **Patient cohort (n=1500) recruited from clinics, followed 12 months**
- **Analyses blinded by study arm**
- **Registered with ClinicalTrials.gov** (NCT01360216)
- **CONSORT guidelines, extension CRT**

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Providers trained

- **Over 250 staff trained at intervention sites by clinician-counselor training team**
- **Average rating "Excellent" for all measures on CME evaluation**
  - Quality of faculty, Educational content, Topic selection, Relevance to practice
  - Cultural and linguistic competency

- **Planned practice change**
  - Counsel by order of effectiveness
  - Use improved IUD insertion techniques

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Sources for study measures

- **Primary outcome analysis**
  - Patient questionnaires (n=1,500)
  - Clinic service statistics (n=300,000)

  - Biological testing (n=1,500)
  - Medical record review (n=1,500)
  - Provider surveys (n=500)

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Patient measures & analysis

- **Primary outcome measure**
  - Choice of LARC method (yes/no)
- **Intent to treat analysis**
- **GEE (generalized estimating equations) for clustered data with robust standard errors**

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Baseline characteristics

Characteristic	Arm 1 (n=801)	Arm 2 (n=697)
Age, mean years	21.5	21.4
Race/ethnicity, %		
White	49.8	49.2
Latina	24.8	30.3
African-American	14.5	14.9
Asian/other	10.9	5.6
Nulliparous, %	73.4	67.5
LARC use (past), %	4.0	4.6
Medicaid expansion, %	59.9	59.8

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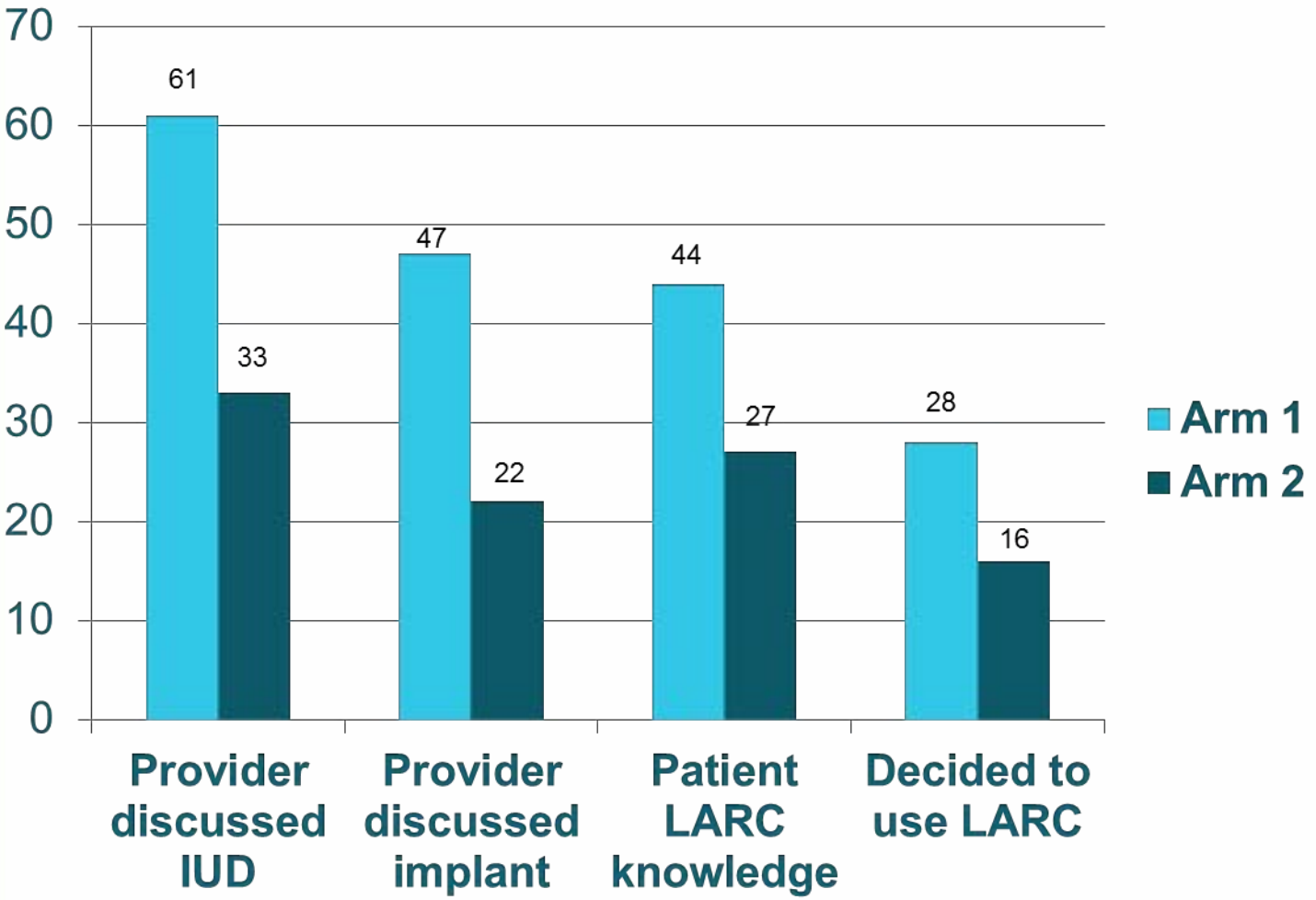
Results: LARC access, by arm



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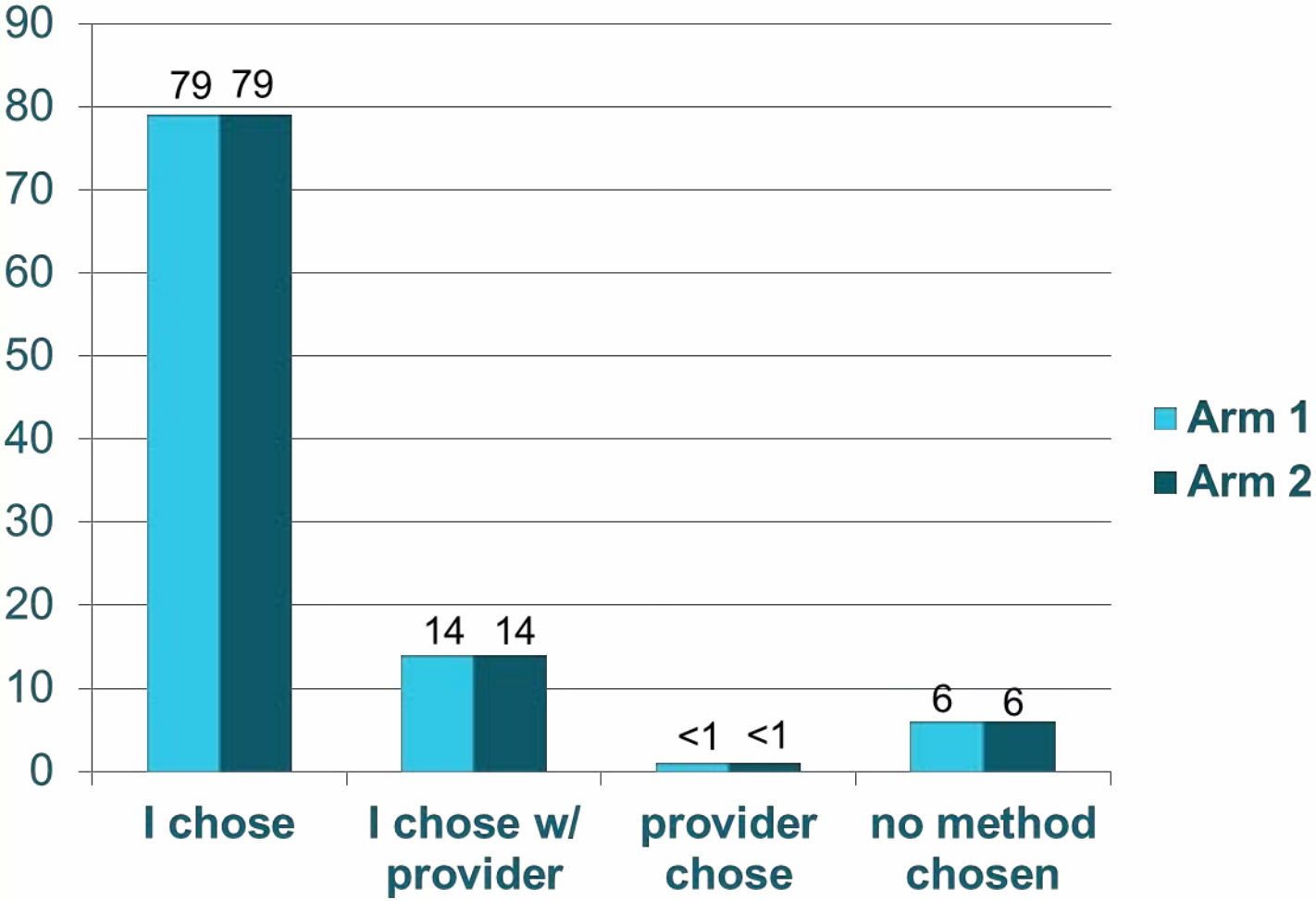
Results: Women's method choice, by arm



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Results: GEE models of chose LARC

- **Study arm measuring intervention effect**
  - Odds ratio **1.97** [95% CI 1.3 2.9]
  - Intraclass correlation 0.05 [95% CI 0.02 0.08]

- **Sub-analyses by arm, including socio-demographic, reproductive & policy factors**
  - Odds ratio **2.2**

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Results: Clinic service statistics of LARC use, by arm

- **GEE model of change in proportion of contraceptive clients using LARC** (n=297,670)
  - 12-months pre-intervention to 12-months post
  - Significantly higher in arm 1 versus arm 2 ($p<0.001$)

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Significance of findings

- **Contraceptive RCTs rarely successful**
- **Replicable intervention: half-day training**
- **Real world setting in community clinics**
- **As part of research:**
  - extensive training & education occurred
  - improved clinical care for at-risk women
- **Collaboration with PPFA, serving 3 million at-risk women**

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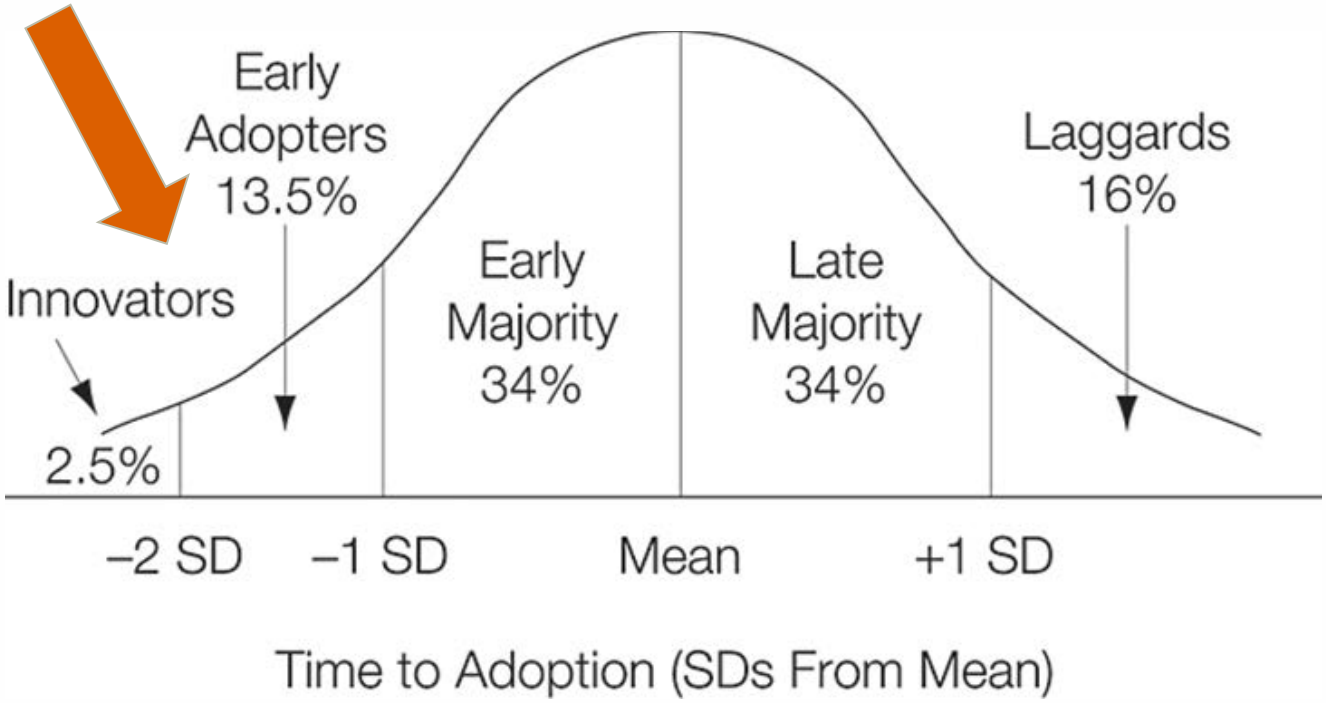

Conceptual framework: Diffusion of Innovation

Berwick. *JAMA* 2003

Rogers, *Diffusion of Innovation* 1995

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Thank you

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