



Reductions in pregnancy rates in the USA with long-acting reversible contraception: a cluster randomised trial

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Summary

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See [Editorial](#) page 504

See [Comment](#) page 514

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Background Unintended pregnancy remains a serious public health challenge in the USA. We assessed the effects of an intervention to increase patients' access to long-acting reversible contraceptives (LARCs) on pregnancy rates.

Methods We did a cluster randomised trial in 40 reproductive health clinics across the USA in 2011–13. 20 clinics were randomly assigned to receive evidence-based training on providing counselling and insertion of intrauterine devices (IUDs) or progestin implants and 20 to provide standard care. Usual costs for contraception were maintained at all sites. We recruited women aged 18–25 years attending family planning or abortion care visits and not desiring pregnancy in the next 12 months. The primary outcome was selection of an IUD or implant at the clinic visit and secondary outcome was pregnancy within 12 months. We used generalised estimating equations for clustered data to measure the intervention effect on contraceptive selection, and used survival analysis to assess pregnancy rates.

Findings Of 1500 women enrolled, more at intervention than control sites reported receiving counselling on IUDs or implants (565 [71%] of 797 vs 271 [39%] of 693, odds ratio 3·8, 95% CI 2·8–5·2) and more selected LARCs during the clinic visit (224 [28%] vs 117 [17%], 1·9, 1·3–2·8). The pregnancy rate was lower in intervention group than in the control group after family planning visits (7·9 vs 15·4 per 100 person-years), but not after abortion visits (26·5 vs 22·3 per 100 person-years). We found a significant intervention effect on pregnancy rates in women attending family planning visits (hazard ratio 0·54, 95% CI 0·34–0·85).

Interpretation The pregnancy rate can be reduced by provision of counselling on long-term reversible contraception and access to devices during family planning counselling visits.

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Introduction

Healthy People 2020 recognises unintended pregnancy as an important public health challenge in the USA.¹ National estimates reveal persistently high unintended pregnancies (51% of pregnancies) and they disproportionately occur in women aged 18–24 years with low incomes and from racial or ethnic minority groups.² The Centers for Disease Control and Prevention (CDC) recommends increasing access to long-acting reversible contraceptives (LARCs) to reduce unintended pregnancy.³ Intrauterine devices (IUDs) and contraceptive implants are seldom used in the USA, compared with in other developed countries (eg, 9% in the USA vs 23% in France).^{4,5} Almost all clinicians provide oral contraceptives and condoms, which have failure rates of 9% and 18%, respectively,^{6,7} but fewer offer IUDs or implants, which both have failure rates lower than 1%.⁶ Thus US women have little knowledge of LARCs.⁸ IUDs are generally offered to a highly restricted subgroup of patients, such as parous, married women, rather than to young women at highest risk of unintended pregnancy.^{9,10} National data show that, contrary to the evidence-based CDC recommendations on medical eligibility criteria for contraceptive use,¹¹ only 38% of physicians providing contraception in the USA offer IUDs to adolescents, 53% to nulliparous women, and 25% immediately after abortion.^{9,10}

We designed a clinic intervention to educate providers to integrate IUDs and implants into routine contraceptive care. The intervention was designed to be cost effective and replicable, and, ultimately, to reach a large number of at-risk women. Clinic-based interventions are particularly important for increasing use of contraception and reducing unintended pregnancy because highly effective methods are only available from health-care providers. Nevertheless, no clinic-based intervention has yet effectively reduced pregnancy in randomised trials.^{12,13} Our training intervention was based on formative research that identified priorities in translating evidence on LARCs into clinical practice.⁹ These priorities included increasing providers' knowledge of eligibility, indications for different methods, insertion skills, and introducing the WHO tiers-of-effectiveness evidence-based approach to contraceptive counselling to increase women's knowledge of method effectiveness.¹⁴

Small non-randomised studies of interventions for provider education and counselling have shown improved outcomes of family planning and abortion patients.^{15,16} The CHOICE Project observational cohort study in St Louis, MO, USA, showed reductions in pregnancy rates when trained providers offered no-cost LARCs and counselling on method effectiveness to at-risk women.¹⁷ In this study we investigated whether

a clinic-level intervention in a randomised trial could improve access to LARCs and reduce pregnancy rates.

Methods

Study design

We did a cluster randomised trial in 40 clinics across the USA. A cluster design was necessary to avoid contamination among providers (unintentional over-spill of the effects of educational intervention to control patients) that might occur with randomisation within individual clinics. All study sites were Planned Parenthood Federation of America (PPFA) health centres, whose patients include young and low-income women from diverse racial or ethnic groups. Eligible clinics saw at least 400 women annually, of whom less than 20% received IUDs or implants, but had no specific LARC intervention programme and did not share staff with another study clinic.

We recruited women who were scheduled to attend visits for family planning or care after abortion, as they are at high risk of unintended pregnancy. Recruitment started in May, 2011, and lasted for an average of 2 months at each site. Eligible women were aged 18–25 years, at risk of pregnancy (sexually active within the previous 3 months and not pregnant), and did not want to be pregnant within the next 12 months. Patients who were identified at presentation to the clinic as being potentially eligible were given a study flyer before being invited to participate and screened by research staff. Women who agreed to participate gave written informed consent. The study was approved by the University of California, San Francisco Committee on Human Research and the Allendale Investigational Review Board, Old Lyme, CT, USA.

Randomisation and masking

Randomisation of clinics was done by an independent statistician at the University of California, San Francisco Clinical and Translational Science Institute, according to a computer-generated schedule. Randomisation was stratified by clinic size (up to 4000 vs more than 4000 patients seen annually). Enough allocations were generated for 48 sites to enable replacement of sites if clinics withdrew between allocation and study initiation. Clinics were unaware of allocation until the study started, after which masking was not possible because the intervention clinics received training.

Intervention

Clinics in the intervention group were provided with training for 0–5 days. Training was multifaceted and designed to improve providers' method-specific knowledge and counselling and placement skills. Attendees could attain continuing medical education credits for didactic activities related to updated evidence on use of copper and levonorgestrel-releasing IUDs and progestin subdermal contraceptive implants,¹¹ and for

interactive activities related to insertion of IUDs. Training in insertion of implants was scheduled separately with the manufacturer. The counselling training presented the WHO tiered contraceptive effectiveness chart,¹⁴ and explained the CDC recommended use of open-ended questions on pregnancy intentions.¹⁸ Patient-centred counselling with shared decision making was emphasised.¹⁹ LARC-specific ethics issues, including the importance of removal upon the patient's request, were also discussed. Attendees were shown a video illustrating successful integration of LARC methods into clinical practice, including same-day insertions. Clinics were given an educational video for patients to show in waiting rooms. Technical assistance for LARC billing was provided, although usual costs for contraception were maintained at study sites to test the intervention under real-life conditions. Control clinics received no training and maintained standard contraceptive care.

Assessments

After contraceptive counselling, participants completed a self-administered baseline questionnaire that was based on previous contraceptive research and was pretested.^{20,21} At the end of the participant's visit, the provider completed a visit summary form in which they documented the counselling provided and the method of contraception selected. Participants were not informed of intervention sites having received training.

We collected data from participants 12 months after the initial visit with questionnaires, home urine pregnancy tests (AccuHome, Germaine Laboratories, San Antonio, TX, USA, sensitive to 20 mIU/mL human chorionic gonadotropin), and review of medical records. Additionally, we used questionnaires at 3, 6, and 9 months to collect data on contraception, including choice and use, continuation, satisfaction, failures, and pregnancies, and each respondent did a home urine pregnancy test at 6 months. Participants received \$20 for each questionnaire and \$30 for each pregnancy test completed. After the end of the study in May, 2013, clinic service statistics on provision of contraceptives to all patients were compiled for the 12-month periods before and after the intervention.

Study outcomes

The primary study outcome was selection of an IUD or implant. This outcome was selected a priori to measure the effect of the intervention on women's desire for LARCs independent of intervening factors, such as cost or device availability, which can affect actual insertion. The secondary outcome was pregnancy incidence during follow-up (dated from the last menstrual period), and was selected to capture the effect of the intervention on biological outcome, under the full range of real-world circumstances. We also assessed women's experience of counselling, including knowledge of contraceptive effectiveness (ranked from most effective as IUD or implant, injections, pills, and condoms) and autonomy

in contraceptive decision making to assess whether counselling was patient-centred and decision making was shared with the provider.

Statistical analysis

We based our calculation of sample size on a two-group comparison of the proportion of women choosing LARCs. The mean LARC uptake at clinic enrolment was 4%²² and we expected that the intervention would lead to 10% of women choosing LARCs.¹⁵ To achieve $\alpha=0.05$ and 80% power, therefore, we required at least 316 women in each study group. To account for an expected 20% loss to follow-up, 395 women would be needed in each group. To account for non-independence in observations, we multiplied the sample size by the design effect, or variance inflation factor.²³ With an average cluster size of 30 and an estimated intracluster correlation coefficient of 0.02, we inflated the sample by 1.58, bringing the total number of participants to 1248, or 624 per group. We estimated that this number would also provide sufficient power to measure differences in pregnancy rates between groups with survival analysis, including covariate analysis.^{15,20} The final recruitment goal, therefore, was set at 1600 participants in case of lower recruitment than anticipated at any site in view of the large number of sites in the study.

Analyses were done by intention to treat. To estimate the intervention effect on women's choice of LARC, we used logistic regression with generalised estimated equations to account for clustering, with robust SE. We repeated analyses with multivariable models, including covariates known to affect choice of contraceptive method, selected a priori, including age, racial or ethnic origin, parity, previous methods used (past 3 months), desired timing of next pregnancy, and visit type at the clinic level (family planning or abortion care).²⁰ Interactions with visit type and intervention were assessed to measure differences in the intervention effect by visit type. We used the clinic service statistics for contraception use in the 12 months before and after the intervention to do supplementary analysis by generalised estimated equations with robust SE of whether the change in proportion of patients receiving LARCs differed between study groups.

For pregnancy rates we used life-table analysis and Kaplan-Meier survival estimates. Our regression models used survival analysis with shared frailty (to account for clustering) to estimate time to first pregnancy.²⁴ Each woman with follow-up data contributed observation time to the analysis and was censored if she became pregnant, was lost to follow-up, or exited the study. Cox's proportional hazards models with shared frailty were estimated to measure the intervention effect, including covariates and the interaction terms intervention and visit type. We repeated pregnancy analyses with medical record data for all women to check for consistency, and we did sensitivity analyses on unintended pregnancies. We also did attrition analyses. To check the proportional hazards assumptions, we estimated Schoenfeld residuals. Multiple imputations were applied to account for missing data (less than 1% for any variable). The researcher who assessed outcomes (CHR) was unaware of group assignment. All analyses were done with Stata (version 13) and reported differences were significant at $p<0.05$. The study is registered at ClinicalTrials.gov (NCT01360216).

Role of the funding source

The funder of the study had no role in study design data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

Results

55 clinics were assessed for participation, of which 45 were randomised (five of which were replacement clinics) and 40 participated (figure 1). Clinics were located in 15 US states, covering all regions (California, Colorado, Connecticut, Florida, Hawaii, Idaho, Michigan, Minnesota, New Jersey, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, and Washington). 23 clinics recruited women attending family planning visits (12 in

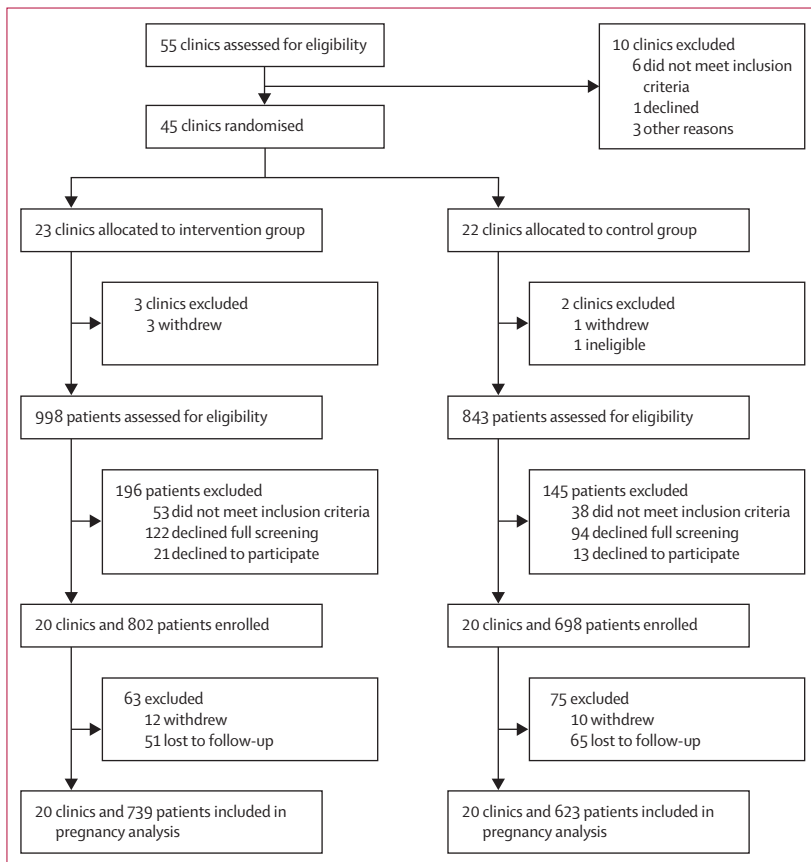


Figure 1: Trial profile

the intervention group, 11 in the control group) and 17 recruited women attending abortion care visits (eight and nine, respectively). Cluster sizes varied: 37 clinics recruited 30 or more participants, one recruited 20, and two recruited six participants. Of 1841 eligible women, 1500 were enrolled (figure 1). All 1500 women were included in the analysis of contraceptive choice and 1362 (91%) were included in the pregnancy analyses.

Baseline characteristics did not differ between groups for the clinics or participants (tables 1, 2). At the baseline clinic visit, 617 (41%) of women were seen by physicians, and the rest by advanced practice clinicians. In the intervention group, 565 (71%) of 797 women reported that their provider discussed LARCs, compared with 271 (39%) of 693 in the control (odds ratio [OR] 3.8, 95% CI 2.8–5.2). By contrast, the combined rates of discussion did not differ between groups for oral contraceptive pills and injections (645 [81%] of 797 intervention vs 576 [83%] of 693 control). Knowledge of method effectiveness was significantly higher among women in the intervention group than in the control group (349 [44%] of 793 vs 187 [27%] of 689; OR 2.1, 95% CI 1.6–2.8). Among intervention providers who reported that they discussed LARCs and method effectiveness with most participants, protocol fidelity was 87% for IUDs and 81% for implants.

The selection of LARCs differed between groups. In the intervention arm, women were more likely to choose LARCs than in the control group (table 3). The intraclass correlation was 0.05 (95% CI, 0.02 to 0.08). Multivariable analysis showed a significant intervention effect on selection of LARCs (table 3) that was not affected by visit type. Clinic service statistics analyses from 177 871 contraceptive patients in the 12 months before the intervention and 145 399 in the 12 months afterwards were consistent with analyses from participant data showing an increase in the proportion of women using LARCs in the intervention group compared with in the control group (2.3% vs 2.0%, coefficient for difference 0.004, 95% CI 0.003–0.004). The intervention did not alter women's autonomy in contraceptive decision making, being the same in the two groups: in each group 78% of women reported that they chose the method alone, 14% that they chose the method with the provider, 7% that they chose no method, and less than 1% that the provider chose the method.

During follow-up there were 211 pregnancies (16.6 per 100 person-years). In the intervention group the pregnancy rate was 15.0 per 100 person-years and in the control group was 18.5 per 100 person-years (hazard ratio [HR] 0.89, 95% CI 0.64–1.24). In an analysis stratified by visit type, the pregnancy rate was significantly lower in the intervention group among women attending family planning visits than in the control group (7.9 vs 15.4 per 100 person-years; HR 0.54, 95% CI 0.34–0.85; figure 2). Overall, the likelihood of pregnancy was higher

among women attending abortion visits than among those attending family planning visits, with no significant difference in the rates between the intervention and control groups after abortion (26.5 vs 22.3 per 100 person-years; HR 1.35, 95% CI 0.91–2.02). We found a significant intervention effect associated with a decrease in pregnancy rate by nearly half in women who attended family planning visits (table 4). Results

	Intervention (n=20)	Control (n=20)	Total (n=40)
Clinic type			
Family planning	12 (60%)	11 (55%)	23 (58%)
Abortion	8 (40%)	9 (45%)	17 (43%)
Clinic size			
≤4000 clients per year	13 (65%)	14 (70%)	27 (68%)
>4000 clients per year	7 (35%)	6 (30%)	13 (33%)

Table 1: Baseline characteristics of clinics

	Intervention (n=802)	Control (n=698)	Total (n=1500)
Sociodemographic characteristics			
Mean (SD) age (years)	21.5 (2.2)	21.5 (2.1)	21.5 (2.2)
Racial or ethnic origin			
White	399 (49.8%)	345 (49.4%)	744 (49.6%)
Latina	200 (24.9%)	208 (29.8%)	408 (27.2%)
Black	117 (14.6%)	105 (15.0%)	222 (14.8%)
Other	86 (10.7%)	40 (5.7%)	126 (8.4%)
Currently married (n=1486)	39 (4.9%)	51 (7.4%)	90 (6.1%)
Highest education (n=1489)			
High school or less	575 (72.2%)	517 (74.6%)	1092 (73.3%)
Some college	111 (13.9%)	91 (13.1%)	202 (13.6%)
College degree	110 (13.8%)	85 (12.3%)	195 (13.1%)
Health insurance type (n=1490)			
Private	244 (30.6%)	203 (29.3%)	447 (30.0%)
Medicaid or State	217 (27.2%)	192 (27.7%)	409 (27.5%)
None	305 (38.3%)	265 (38.2%)	570 (38.3%)
Don't know	31 (3.9%)	33 (4.8%)	64 (4.3%)
Reproductive and contraceptive history			
Nulliparous (n=1489)	585 (73.4%)	467 (67.5%)	1052 (70.7%)
Desired timing of next pregnancy (n=1489)			
<2 years	70 (8.8%)	85 (12.3%)	155 (10.4%)
≥2 years	591 (74.3%)	493 (71.1%)	1084 (72.8%)
None	135 (17.0%)	115 (16.6%)	250 (16.8%)
Contraception use past 3 months (n=1491)			
LARC*	31 (3.9%)	32 (4.6%)	63 (4.2%)
Depot medroxyprogesterone injection	59 (7.4%)	46 (6.6%)	105 (7.0%)
Pill, vaginal ring, or transdermal patch	325 (40.9%)	252 (36.2%)	577 (38.7%)
Condom or barrier method	203 (25.5%)	211 (30.3%)	414 (27.8%)
None	177 (22.3%)	155 (22.3%)	332 (22.3%)
Unprotected intercourse past 3 months (n=1486)	513 (64.7%)	468 (67.5%)	981 (66.0%)

LARC=long-acting reversible contraception. *Intrauterine device or progestin implant.

Table 2: Baseline characteristics of participants

	Chose LARC		Intervention effect	
	Intervention (n=802)	Control (n=698)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Chose LARC	224 (27.9%)	117 (16.8%)	1.91 (1.31–2.79)*	2.20 (1.58–3.08)†
Chose IUD	152 (19.0%)	94 (13.5%)	1.49 (0.96–2.31)	1.70 (1.18–2.44)*
Chose implant	79 (9.9%)	25 (3.6%)	2.93 (1.57–5.48)*	3.05 (1.73–5.39)†

Models were adjusted for age, ethnic origin, parity, LARC use within 3 months before enrolment, desired timing of next pregnancy, and clinic type. LARC=long-acting reversible contraception. OR=odds ratio. IUD=intrauterine device. *p<0.01. †p<0.001.

Table 3: Study outcomes by selected LARC method

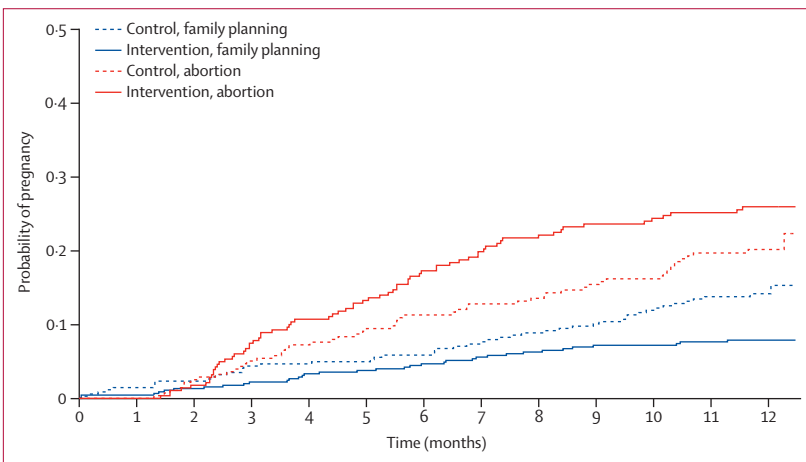


Figure 2: Kaplan-Meier estimates of time to first pregnancy

	Main effects		Main effects plus interaction	
	Unadjusted HR (95% CI)	Adjusted HR (95% CI)	Unadjusted HR (95% CI)	Adjusted HR (95% CI)
Intervention vs control	0.89 (0.64–1.24)	0.99 (0.74–1.34)	0.54 (0.34–0.85) †	0.61 (0.39–0.97) ‡
Abortion care vs family planning	2.34 (1.68–3.26) §	2.11 (1.53–2.90) §	1.47 (0.96–2.26)	1.49 (0.98–2.26)
Interaction term	2.52 (1.36–4.67) †	2.29 (1.27–4.12) †

HR=hazard ratio. *Assessed in 1362 women, including two pregnant at baseline. †p<0.01. ‡p<0.05. §p<0.001.

Table 4: Pregnancy outcomes*

remained consistent in analyses of models adjusted for covariates and involving all 1500 participants, and in sensitivity analysis of unintended pregnancies. To investigate the difference in pregnancy findings between women attending family planning and abortion visits, we assessed whether women in the intervention group choosing LARCs could obtain them, and found that the number was much higher in family planning visits than in abortion visits (74 [73%] of 101 vs 51 [44%] of 115).

In a check of proportional hazards assumptions with Schoenfeld residuals, intervention met the assumptions for proportionality in models with only main effects, but visit type did not. Both features, however, met the assumptions in models that included interaction terms.

Attrition was similar by study group, age, previous contraceptive use, and pregnancy intention. Women attending abortion care visits and parous women were slightly more likely to be lost to follow-up and black women slightly less likely than others.

Discussion

The study intervention increased women’s choice of highly effective methods without impinging on decision-making autonomy. The rate of unintended pregnancy was substantially reduced among women who attended family planning visits, although not among those who attended abortion care visits. Many young women in the USA want to delay childbearing, but report having unprotected intercourse, as in our study population.²⁵ Clinic visits are important opportunities for education of patients, especially in the use of unfamiliar methods, although many providers do not give advice on LARCs.¹⁰ The American College of Obstetricians and Gynecologists and the American Academy of Pediatrics recommend that LARCs be offered as first-line methods, including to adolescents.^{26,27} At the control clinics in this study, however, fewer than half of women reported receiving LARC counselling, whereas most received counselling about oral contraceptives. By contrast, the intervention led to increased discussion of LARCs with young at-risk women and improved knowledge of method effectiveness. Following the theory of planned behaviour, perceived behavioural control can help to strengthen intentions and increase adoption of preventive behaviours.²⁸ In this study, counselling on method effectiveness might have strengthened women’s perceived control over pregnancy risks (ie, the ability to prevent pregnancy with effective contraception) and led to the increased selection of highly effective methods.

We found a significant reduction of nearly half in pregnancy incidence among participants attending family planning visits, which is in contrast to findings in previous randomised trials (panel).¹² One small study with an intensive home-visit intervention (regular visits for 2 years) in Baltimore, MD, USA, showed a lower pregnancy rate among black teen mothers than in the control group.³⁰ Effective clinic interventions are critical for improving contraceptive care. Strengths of the intervention used in this study are that it is highly replicable, is appropriate for assessment by implementation science, and was targeted at the clinic level, meaning that a large and diverse population of patients was reached efficiently: the annual volume of patients receiving contraception in the intervention group clinics was more than 100000. Furthermore, we included 40 sites spanning all geographic regions of the USA. The intervention was associated with improvement in a health outcome long-resistant to change.

Results differed among women attending abortion care visits, where subsidised contraception is less available than in family planning in the USA. As in previous randomised studies,¹³ pregnancy rates remained high

Panel: Research in context**Systematic review**

Three systematic reviews of contraceptive counselling and education formed the basis of our literature review. Lopez and colleagues¹² assessed seven trials involving 4536 women, with five being done at multiple sites. Four of the studies were done in the USA and three in developing countries. Two studies provided multiple educational sessions: in one measuring contraceptive choices, more effective methods (ie, sterilisation) were selected, but neither showed improved use of effective contraceptives at 6 months. Five trials provided one educational session and found that contraceptive effectiveness was best communicated with a tiered chart rather than tabulated pregnancy numbers, and with audiovisual aids. The review concluded that strategies to present pregnancy risk data should be tested in clinics to measure the effects on choice of contraceptives. The authors concluded that the overall quality of evidence was low.¹² Arrowsmith and colleagues²⁹ did a review of nine studies of provider training (including community distribution), education, and counselling strategies to improve acceptance of copper intrauterine devices, involving 7960 women. Six studies showed increased uptake, but the authors judged the quality of evidence to be moderate to low. A systematic review of three studies involving 694 women showed no evidence of increased contraceptive acceptance after abortion.¹³

Interpretation

We designed a highly replicable clinic-level intervention aimed at increasing women's access to highly effective contraception, including same-day insertion, in a trial based on real-world care. Our findings support that use of contraception after abortion remains an area in need of future research. By contrast, we found that our educational intervention was associated with reduced pregnancy rates among young at-risk women attending family planning clinics.

among women attending abortion care visits, irrespective of study group, with almost 25% of women becoming pregnant within 12 months. Additionally, although women chose LARCs after abortion, fewer were able to obtain them than women attending family planning visits (44% vs 73%). Cost barriers to uptake of contraception are high in the abortion care setting in the USA,^{22,31} which is highlighted by the real-world cost conditions we maintained in this study. In some states, women must return to a family planning clinic to qualify for contraceptive coverage. Increased pregnancy risks are associated with an increased number of visits, and an estimated 30% of women do not return after abortion for IUD insertions.³² Same-day insertion is associated with increased uptake of IUDs, but funding coverage for contraceptives with high up-front costs²² is necessary to allow this approach in low-income populations.^{32,33} 38% of participants in this study reported they had no insurance.

The CHOICE Project showed the positive effect of eliminating charges for expensive but highly cost-effective methods; provision of LARCs plus a range of short-acting methods at no cost was associated with substantial reductions in pregnancy and abortion rates.^{17,34} Future research should investigate the effects of no cost contraception after abortion on the rate of unintended pregnancies and explore the reasons why women who want to use LARCs are not able to obtain them.

This study has limitations. It was accomplished within a large network of specialised reproductive-health clinics and, therefore, results might not be generalisable to all clinics with different providers or populations of patients. The cluster design was intended to address the challenges of contamination, but it could have occurred. At the same time as the study period, other LARC training initiatives and medical guidelines encouraged providers to offer highly-effective methods.^{16,26} although we have no reason to think that these changes would have affected study groups differently. Strengths of this study include a cluster randomised design, use of biological pregnancy testing, and a high rate of follow-up.

Cost-effective, replicable interventions to reduce the risk of unintended pregnancy are much needed in the USA, where the health of women and infants is poor compared with that in similar countries. Contraceptives are, therefore, essential preventive care, and our results show that clinicians can successfully integrate the use of highly effective methods into clinical practice and reduce pregnancy rates among women attending family planning clinics.^{35,36}

Contributors

CCH, PDD, and JJS were involved in the study concept and design. CCH and KMT acquired the data. CHR did the statistical analysis. All authors contributed to interpretation of the data. CCH and CHR drafted the report and all authors participated in review for important intellectual content. CCH, KMT, and JJS obtained funding for and CCH and KMT supervised the study.

Declaration of interests

CCH and JJS serve as consultants to Medicines360, a non-profit organisation. CLW has served as a consultant for Agile, Bayer, and Merck. JJS is also a consultant to WomanCare Global. The other authors declare no competing interests.

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