Zika Virus Infection Among U.S. Pregnant Travelers — August 2015–February 2016

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After reports of microcephaly and other adverse pregnancy outcomes in infants of mothers infected with Zika virus during pregnancy, CDC issued a travel alert on January 15, 2016, advising pregnant women to consider postponing travel to areas with active transmission of Zika virus. On January 19, CDC released interim guidelines for U.S. health care providers caring for pregnant women with travel to an affected area (*1*), and an update was released on February 5 (*2*). As of February 17, CDC had received reports of nine pregnant travelers with laboratory-confirmed Zika virus disease; 10 additional reports of Zika virus disease among pregnant women are currently under investigation. No Zika virus–related hospitalizations or deaths among pregnant women were reported. Pregnancy outcomes among the nine confirmed cases included two early pregnancy losses, two elective terminations, and three live births (two apparently healthy infants and one infant with severe microcephaly); two pregnancies (approximately 18 weeks' and 34 weeks' gestation) are continuing without known complications. Confirmed cases of Zika virus infection were reported among women who had traveled to one or more of the following nine areas with ongoing local transmission of Zika virus: American Samoa, Brazil, El Salvador, Guatemala, Haiti, Honduras, Mexico, Puerto Rico, and Samoa. This report summarizes findings from the nine women with confirmed Zika virus infection during pregnancy, including case reports for four women with various clinical outcomes. U.S. health care providers caring for pregnant women with possible Zika virus exposure during pregnancy should follow CDC guidelines for patient evaluation and management (*1,2*). Zika virus disease is a nationally notifiable condition. CDC has developed a voluntary registry to collect information about U.S. pregnant women with confirmed Zika virus infection and their infants. Information about the registry is in preparation and will be available on the CDC website.

Zika virus is a mosquito-borne flavivirus that was first isolated from a rhesus monkey in Uganda in 1947 (*3*). For several decades, only sporadic human disease cases were reported from Africa and Southeast Asia. In 2007, an outbreak was reported on Yap Island, Federated States of Micronesia (*3*),

and outbreaks subsequently were reported from several Pacific Island countries (*4*). Local transmission of Zika virus was first identified in the Region of the Americas (Americas) in Brazil in May 2015 (*5*). Since that time, transmission of Zika virus has occurred throughout much of the Americas; as of February 18, a total of 32 countries and territories worldwide have active transmission of Zika virus (http://www.cdc.gov/zika/geo/active-countries.html). Interim guidelines for evaluation and management of pregnant women who have traveled to areas with ongoing local transmission of Zika virus include offering laboratory testing after return from travel (*2*).

During August 1, 2015–February 10, 2016, CDC received 257 requests for Zika virus testing for pregnant women. Among these requests, 151 (59%) included information indicating that the woman had a clinical illness consistent with Zika virus disease (i.e., two or more of the following signs or symptoms: acute onset of fever, rash, conjunctivitis, or arthralgia). The remaining requests did not document an illness compatible with Zika virus disease, but reporting of symptom information might have been incomplete.

Laboratory confirmation of recent Zika virus infection includes detection of 1) Zika virus, viral RNA, or viral antigen, or 2) Zika virus immunoglobulin M (IgM) antibodies with Zika virus neutralizing antibody titers ≥4-fold higher than neutralizing antibody titers against dengue or other flaviviruses endemic to the region where exposure occurred. Among the 257 pregnant women whose specimens were tested at CDC, 249 (97%) tested negative for recent Zika virus infection and eight (3%) had confirmed Zika virus infection. In addition to the eight patients with laboratory testing performed at CDC, one confirmed case was reported to CDC from a state health department with capacity to test for Zika virus infection.

Among nine pregnant women with confirmed Zika virus disease, no hospitalizations or deaths were reported. All nine women reported at least one of the four most commonly observed symptoms (fever, rash, conjunctivitis, or arthralgia), all women reported rash, and all but one woman had at least two symptoms. Among the six pregnant women with Zika virus disease who reported symptoms during the first trimester, outcomes included two early pregnancy losses, two elective pregnancy terminations, and delivery of a live

born infant with microcephaly; one pregnancy is continuing. Among two women with Zika virus infection who had symptoms during the second trimester of pregnancy, one apparently healthy infant has been born and one pregnancy is continuing. One pregnant woman reported symptoms of Zika virus infection in the third trimester of pregnancy, and she delivered a healthy infant.

Selected Case Reports

Patient A. In January 2016, a pregnant woman in her 30s reported symptoms of fever, rash, arthralgia, myalgia, and malaise at 6–7 weeks' gestation. She had traveled to a Zika-affected area at approximately 5 weeks' gestation. Serologic testing confirmed recent Zika virus infection. She experienced a spontaneous early pregnancy loss and underwent a dilation and curettage at approximately 8 weeks' gestation. Products of conception were sent to CDC for testing, and Zika virus RNA was detected by reverse transcription-polymerase chain reaction (RT-PCR) and immunohistochemical (IHC) staining (6).

Patient B. In January 2016, a pregnant woman in her 30s underwent laboratory testing for Zika virus infection. She reported a history of travel to a Zika-affected area at approximately 11–12 weeks' gestation. One day after returning from travel, she developed fever, eye pain, and myalgia. The next day, she developed a rash. Serologic testing confirmed recent Zika virus infection. At approximately 20 weeks' gestation, she underwent a fetal ultrasound that suggested absence of the corpus callosum, ventriculomegaly, and brain atrophy; subsequent fetal magnetic resonance imaging demonstrated severe brain atrophy. Amniocentesis was performed, and Zika virus RNA was detected by RT-PCR testing. After discussion with her health care providers, the patient elected to terminate her pregnancy.

Patient C. In late 2015, a woman in her 30s gave birth to an infant at 39 weeks' gestation. The infant's head circumference at birth was 27 cm (<3rd percentile), indicating severe microcephaly (http://www.cdc.gov/growthcharts/who_charts. htm). After delivery, an epidemiologic investigation revealed that the woman had resided in Brazil until 12 weeks' gestation. She reported that she had experienced fever, rash, arthralgia, and headache at 7–8 weeks' gestation. Evidence of Zika virus infection in the mother was confirmed by serologic testing. Molecular and pathologic evaluation of the placenta demonstrated Zika virus RNA by RT-PCR and IHC, respectively. The infant exhibited hypertonia, difficulty swallowing, and seizures, and computerized tomography scan demonstrated multiple scattered and periventricular brain calcifications. Funduscopic examination revealed a pale optic nerve and mild macular chorioretinitis. Newborn hearing screening was

normal. The infant was discharged from the hospital with a gastrostomy feeding tube.

Patient D. A pregnant woman in her 30s traveled to a Zika-affected area at approximately 15 weeks' gestation. She reported symptoms of fever, rash, arthralgia, and headache beginning at the end of her travel (at approximately 17–18 weeks' gestation). Serologic testing confirmed evidence of Zika virus infection. At approximately 40 weeks' gestation, she delivered a full-term, apparently healthy infant with no reported abnormalities and a head circumference of 34.5 cm. Cranial ultrasound, newborn hearing screen, and ophthalmologic examination of the infant were all normal.

Discussion

On January 19, 2016, CDC released interim guidelines recommending that pregnant women who had traveled to areas with ongoing local transmission of Zika virus and who had symptoms consistent with Zika virus disease be tested for Zika virus infection (1). These guidelines were updated and expanded on February 5 to offer Zika virus testing to all pregnant women with Zika virus exposure, regardless of the presence of symptoms (2). Although Zika virus testing can be performed in some state, territorial, and local health departments, most testing before mid-February 2016 was performed at CDC. Based on tests performed at CDC as of February 17, 2016, only a small number of pregnant women who reported clinical illness consistent with Zika virus disease had laboratory evidence of a recent Zika virus infection. The combination of clinical signs and symptoms consistent with suspected Zika virus disease, including fever, rash, conjunctivitis, and arthralgia, is not specific to Zika virus disease; there are other causes of this clinical presentation (7). Among the nine pregnant women with Zika virus infection, all reported a clinical illness, including eight women with ≥2 signs and/or symptoms, and one with a generalized rash. The finding of reported clinical illness among all women who tested positive for Zika virus might be related to the initial testing criteria for pregnant women recommended by CDC, which required the presence of clinical illness consistent with Zika virus disease. Additional testing performed as of February 24, 2016 identified no confirmed cases among 162 pregnant women without reported symptoms.

Two women with confirmed Zika virus infection experienced spontaneous pregnancy losses in the first trimester of pregnancy. Although Zika virus RNA was detected in the specimens from both of these cases, it is not known whether Zika virus infection caused the pregnancy losses. First trimester pregnancy loss is common, occurring in approximately 9%–20% of all clinically recognized pregnancies (8), with higher rates in older women. Pregnancy loss has been observed in association

Summary

What is already known about this topic?

Because of the risk for Zika virus infection and its possible association with adverse pregnancy outcomes, CDC issued a travel alert on January 15, 2016, advising pregnant women to consider postponing travel to areas with ongoing local transmission of Zika virus. CDC also released guidelines for Zika virus testing for pregnant women with a history of travel while pregnant to areas with ongoing Zika virus transmission.

What is added by this report?

This report provides preliminary information on testing for Zika virus infection of U.S. pregnant women who had traveled to areas with Zika virus transmission. As of February 17, 2016, nine U.S. pregnant travelers with Zika virus infection had been identified. No Zika virus–related hospitalizations or deaths were reported among pregnant women. Pregnancy outcomes included two early pregnancy losses, two elective terminations, and three live births (two apparently healthy infants and one infant with severe microcephaly); two pregnancies (18 weeks' and 34 weeks' gestation) are continuing without known complications.

What are the implications for public health practice?

In this small case series, Zika virus infection during pregnancy was associated with a range of outcomes, including early pregnancy losses, congenital microcephaly, and apparently healthy infants. Additional information will be available in the future from a newly established CDC registry for U.S. pregnant women with confirmed Zika virus infection and their infants.

with Zika virus infection (6) and after infections with other flaviviruses (e.g., dengue, West Nile, Japanese encephalitis) (9–11); however, a causal relationship has not been established. Additional histopathologic evaluation and RT-PCR testing of tissues from pregnancy losses might provide additional insight into maternal-fetal transmission of Zika virus and the link between maternal-fetal transmission and pregnancy losses.

Seven pregnant women with confirmed Zika virus infection reported fever during pregnancy. Fever has been determined to increase the risk for adverse pregnancy outcomes, including neural tube defects (12). It is not known whether fever might have affected pregnancy outcomes among these pregnant women with Zika virus infection. Because of the potential risks for poor outcomes associated with fever during pregnancy, acetaminophen should be used to treat fever during pregnancy (12).

Approximately half a million pregnant women are estimated to travel to the United States annually from the 32 (as of February 18, 2016) Zika-affected countries and U.S. territories with active transmission of Zika virus (personal communication, Bradley Nelson, February 23, 2016). These numbers might decrease if pregnant women follow CDC recommendations (1) and postpone travel to areas with ongoing local

Zika virus transmission. Pregnant women and their partners should also be aware of the risk for Zika virus infection through unprotected sex with an infected male partner, and carefully follow CDC interim guidelines for preventing sexual transmission of Zika virus infection (13). Health care providers should notify their state, local, or territorial health department about women with possible exposure to Zika virus during pregnancy for assistance in arranging testing and interpreting results. CDC has developed a registry to collect information on U.S. pregnant women with confirmed Zika virus infection and their infants. Information gathered from public health officials or health care providers will include clinical information about the pregnancy and the infant at birth and through the first year of life. This voluntary registry has been determined to be a nonresearch public health surveillance activity, and as such, it is not subject to institutional review board requirements. Health care providers are encouraged to discuss participation in the U.S. registry* with pregnant women with Zika virus infection.

*For inquiries about the U.S. Pregnancy Registry, please contact the corresponding author.

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Zika Virus and Birth Defects — Reviewing the Evidence for Causality

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SUMMARY

The Zika virus has spread rapidly in the Americas since its first identification in Brazil in early 2015. Prenatal Zika virus infection has been linked to adverse pregnancy and birth outcomes, most notably microcephaly and other serious brain anomalies. To determine whether Zika virus infection during pregnancy causes these adverse outcomes, we evaluated available data using criteria that have been proposed for the assessment of potential teratogens. On the basis of this review, we conclude that a causal relationship exists between prenatal Zika virus infection and microcephaly and other serious brain anomalies. Evidence that was used to support this causal relationship included Zika virus infection at times during prenatal development that were consistent with the defects observed; a specific, rare phenotype involving microcephaly and associated brain anomalies in fetuses or infants with presumed or confirmed congenital Zika virus infection; and data that strongly support biologic plausibility, including the identification of Zika virus in the brain tissue of affected fetuses and infants. Given the recognition of this causal relationship, we need to intensify our efforts toward the prevention of adverse outcomes caused by congenital Zika virus infection. However, many questions that are critical to our prevention efforts remain, including the spectrum of defects caused by prenatal Zika virus infection, the degree of relative and absolute risks of adverse outcomes among fetuses whose mothers were infected at different times during pregnancy, and factors that might affect a woman's risk of adverse pregnancy or birth outcomes. Addressing these questions will improve our ability to reduce the burden of the effects of Zika virus infection during pregnancy.

POTENTIAL RELATIONSHIP BETWEEN ZIKA VIRUS INFECTION AND BIRTH DEFECTS

Since the identification of the Zika virus in Brazil in early 2015, the virus has spread rapidly throughout the Americas (www.cdc.gov/zika/geo/active-countries.html). An increase in the number of infants with microcephaly in Brazil was first noted in September 2015, after the recognition of Zika virus transmission in the country earlier in the year[1]; this was followed by the recognition of a similar increase in French Polynesia after an outbreak there in 2013 and 2014.[2] Despite accumulating evidence that supports the link between Zika virus infection and microcephaly, most experts have taken care not to state that Zika virus infection is causally related to these adverse outcomes.[3] This cautious approach toward ascribing Zika virus as a cause of birth defects is not surprising, given that the last time an infectious pathogen (rubella virus) caused an epidemic of congenital defects was more than 50 years ago, no flavivirus has ever been shown definitively to cause birth defects in humans,[4] and no reports of adverse pregnancy or birth outcomes were noted during previous outbreaks of Zika virus disease in the Pacific Islands.[5,6]

On the basis of the available evidence, the public health response to the outbreak of Zika virus disease has moved forward, with the distribution of health messages about the importance of mosquito-bite prevention, recommendations by public health authorities in some of the most severely affected countries to delay pregnancy, and advisories that pregnant women avoid travel to areas with active Zika virus transmission.[7] However, communications regarding Zika virus have been challenging: a recent survey showed

low levels of knowledge and concern about Zika virus in the United States.[8] The recognition of Zika virus as a cause of microcephaly and other serious brain anomalies would allow for more direct communication, which might lead to improved understanding of and adherence to public health recommendations. Therefore, a review of the evidence linking Zika virus infection and adverse pregnancy and birth outcomes is needed.

As is typically the case in epidemiology and medicine, no "smoking gun" (a single definitive piece of evidence that confirms Zika virus as a cause of congenital defects) should have been anticipated. Instead, the determination of a causal relationship would be expected to emerge from various lines of evidence, each of which suggests, but does not on its own prove, that prenatal Zika virus infection can cause adverse outcomes. Two approaches have been used to identify potential teratogens (exposures to a mother during pregnancy that have a harmful effect on her embryo or fetus)[9]: first, the identification of a combination of a rare exposure and a rare defect (sometimes referred to as the astute clinician approach),[10] and second, the use of epidemiologic data to confirm an association. Many teratogens were first identified by means of the rare exposure–rare defect approach, including rubella virus, which was identified after an ophthalmologist noted a characteristic form of cataracts in infants whose mothers had rubella during pregnancy,[11] and heavy alcohol use, which was identified as a teratogen after the recognition of a characteristic pattern of malformations that became known as the fetal alcohol syndrome.[12] In contrast, some teratogens have been identified on the basis of epidemiologic studies (e.g., valproic acid was identified as a teratogen after a case–control study showed an odds ratio of 20 for the association of spina bifida with use of this drug during the first trimester of pregnancy).[13]

SHEPARD'S CRITERIA

In 1994, Thomas Shepard, a pioneer in the field of teratology, proposed a set of seven criteria for "proof" of human teratogenicity (Table 1) that incorporated both approaches.[9] These criteria were an amalgamation of criteria developed by other teratologists and guided by methods that were used to identify previous teratogens. These criteria have been used to guide discussions

about causation in teratology-related litigation[30] and to assess other potential teratogens.[10] We used Shepard's criteria[9] as a framework to evaluate whether the currently available evidence supports the hypothesis that prenatal Zika virus infection is a cause of microcephaly and other brain anomalies (Table 1).

According to these criteria, causality is established when either criteria 1, 3, and 4 (rare exposure–rare defect approach) or criteria 1, 2, and 3 (epidemiologic approach) are fulfilled. The first criterion states that a proven exposure to an agent must occur at a critical time during prenatal development. The severe microcephaly and other brain anomalies that have been observed in many infants are consistent with an infection occurring in the first or early second trimester of pregnancy. Several case reports and studies have shown that women who had fetuses or infants with congenital brain anomalies that were believed, on the basis of the mother's symptoms or laboratory confirmation, to be due to Zika virus infection were infected in the first or early second trimester of pregnancy, as determined either according to the timing of the symptoms or according to the timing of travel to an area where Zika virus is endemic.[14-20] An analysis of the timing of laboratory-confirmed Zika virus transmission in certain states in Brazil and of the increase in the cases of microcephaly identified the first trimester as the critical time period for infection.[1] Zika virus infections that occur later in pregnancy have been associated with poor intrauterine growth, fetal death, or in some pregnancies, defects on prenatal imaging that have not yet been confirmed postnatally because the pregnancies are ongoing.[14] We conclude that Shepard's first criterion has been met.

Shepard's second criterion requires that two epidemiologic studies of high quality support the association. Although ecologic data do not necessarily qualify as an epidemiologic study, data from Brazil regarding the temporal and geographic association between Zika virus infection and the later appearance of infants with congenital microcephaly are compelling.[1,31,32] Two epidemiologic studies also provide support.[2,14] In a study conducted during the outbreak in Brazil, 88 pregnant women who had had an onset of rash in the previous 5 days were tested for Zika virus RNA. Among the 72 women who had positive tests, 42 underwent prenatal ultrasonography, and fe-

Table 1. Shepard's Criteria for Proof of Teratogenicity in Humans as Applied to the Relationship between Zika Virus Infection and Microcephaly and Other Brain Anomalies.*

Criterion No.	Criterion	Evidence	Criterion Met?
1	Proven exposure to the agent at one or more critical times during prenatal development	On the basis of case reports, case series, and epidemiologic studies of microcephaly that are associated with laboratory-confirmed or presumed Zika virus infection, the timing of Zika virus infection associated with severe microcephaly and intracranial calcifications appears to be in the late first or early second trimester.[14-20]	Yes
2	Consistent findings by ≥2 high-quality epidemiologic studies, with control of confounding factors, sufficient numbers, exclusion of positive and negative bias factors, prospective studies if possible, and relative risk ≥6	On the basis of data from Brazil, the temporal and geographic association between Zika virus illness and cases of microcephaly is strong.[1] Two epidemiologic studies have been published. In a study in Brazil[14] that used a prospective cohort design, 29% of women with Zika virus infection at any time during pregnancy had abnormalities on prenatal ultrasonography, some of which have not been confirmed postnatally, In a study in French Polynesia,[2] retrospective identification of eight cases of microcephaly and the use of serologic and statistical data and mathematical modeling suggested that 1% of fetuses and infants born to women with Zika virus infection during the first trimester had microcephaly; the risk ratio in this analysis was approximately 50, as compared with the baseline prevalence of microcephaly. No other epidemiologic studies have examined this association to date.	Partially
3	Careful delineation of clinical cases; a specific defect or syndrome, if present, is very helpful	The phenotype has been well characterized in fetuses and infants with presumed congenital Zika virus infection, including microcephaly and other serious brain anomalies, redundant scalp skin, eye findings, arthrogryposis, and clubfoot.[15,20-23] The phenotype in some infants appears to be consistent with the fetal brain disruption sequence,[20,22] which has been observed after infection with other viral teratogens.[24]	Yes
4	Rare environmental exposure that is associated with rare defect	Reports of fetuses and infants with microcephaly who are born to women with brief periods of travel to countries with active Zika virus transmission are consistent with Zika virus being a rare exposure.[16,18,19] The defect, congenital microcephaly, is rare, with a birth prevalence of approximately 6 cases per 10,000 liveborn infants, according to data from birth-defects surveillance systems in the United States.[25]	Yes
5	Teratogenicity in experimental animals important but not essential	No results of an animal model with Zika virus infection during pregnancy and fetal effects have yet been published.	No
6	Association should make biologic sense	Findings are similar to those seen after prenatal infection with some other viral teratogens (e.g., cytomegalovirus, rubella virus).[26] Animal models have shown that Zika virus is neurotropic,[27,28] which supports biologic plausibility. Evidence that Zika virus infects neural progenitor cells and produces cell death and abnormal growth,[29] along with evidence of Zika virus in brains of fetuses and infants with microcephaly, on the basis of immunohistochemical staining and identification of Zika virus RNA and live virus,[16,17,19] provides strong biologic plausibility.	Yes
7	Proof in an experimental system that the agent acts in an unaltered state	This criterion applies to a medication or chemical exposure, not to infectious agents.	NA

* The criteria listed here were proposed by Shepard.[9] Criteria 1, 2, and 3 or criteria 1, 3, and 4 are considered to be essential, whereas criteria 5, 6, and 7 are helpful but not essential. Partial evidence is insufficient to meet a criterion. NA denotes not applicable.

tal abnormalities were observed in 12 (29%); none of the 16 women with negative tests had fetal abnormalities. The abnormalities that were observed on ultrasonography varied widely, and some findings lacked postnatal confirmation because the pregnancies were ongoing.[14]

A retrospective analysis after the 2013–2014 outbreak of Zika virus disease in French Polynesia identified eight cases of microcephaly; the authors used serologic and statistical data and mathematical modeling to estimate that 1% of the fetuses and neonates who were born to mothers who had been infected with Zika virus in the first trimester had microcephaly[2] — a prevalence

that was approximately 50 times as high as the estimated baseline prevalence. However, this estimate was based on small numbers, confidence intervals were wide, and the risk of other adverse outcomes (e.g., other brain anomalies) was not assessed.[2] Although these studies provide important evidence in support of a causal relationship between Zika virus and microcephaly and other brain anomalies, both have limitations as noted by their authors, such as a lack of control for confounding factors and relatively small numbers of cases, and therefore they do not meet the stringent criteria set by Shepard. Thus, we conclude that Shepard's second criterion has not yet been satisfied.

The third criterion, careful delineation of clinical cases with the finding of a specific defect or syndrome, appears to be met. Previous teratogens have caused specific birth defects or syndromes rather than a broad range of birth defects.[33] Many fetuses and infants with presumed congenital Zika virus infection have had a typical pattern, including severe microcephaly, intracranial calcifications, and other brain anomalies, sometimes accompanied by eye findings, redundant scalp skin, arthrogryposis, and clubfoot[15,20-23]; such findings have led authors to use the term "congenital Zika syndrome."[22,34,35] On the basis of clinical details from a limited number of cases, some infants with presumed congenital Zika virus infection have had features that were consistent with fetal brain disruption sequence,[24] a phenotype involving the brain that is characterized by severe microcephaly, overlapping cranial sutures, prominent occipital bone, redundant scalp skin, and considerable neurologic impairment.[20,22] For example, 11 of 35 infants (31%) with microcephaly whose cases were reported to a Brazil Ministry of Health registry had excessive and redundant scalp skin,[20] a finding that is not typically seen in other forms of microcephaly.[36] These findings suggest an interruption of cerebral growth, but not in that of the scalp skin, after an injury (e.g., viral infection, hyperthermia, or vascular disruption) that occurred after the initial formation of brain structures, followed by partial collapse of the skull. The fetal brain disruption sequence is rare; only 20 cases were identified in a literature review in 2001.[24]

Shepard's fourth criterion refers to the association between a rare exposure and a rare defect; we conclude that this criterion also has

been met. The concept behind this criterion is that a rare defect occurring after a rare exposure during pregnancy implies causation because of the unlikelihood of the two rare events occurring together.[10] Microcephaly is a rare defect that is estimated to occur in 6 infants per 10,000 live-born infants in the United States.[25] Zika virus would not be a rare exposure among women living in Brazil during the Zika virus outbreak. However, reports of adverse birth outcomes among travelers who spent only a limited time period in an area where there is active Zika virus transmission are consistent with Zika virus being a rare exposure.[16,18,19]

A recent report is illustrative: a pregnant woman traveled for 7 days to Mexico, Guatemala, and Belize during her 11th week of gestation and had a positive test for Zika virus immunoglobulin M (IgM) antibodies 4 weeks later. On fetal ultrasonography and magnetic resonance imaging performed at 19 to 20 weeks of gestation, severe brain anomalies were diagnosed in the fetus, and the pregnancy was terminated at 21 weeks of gestation. Microcephaly was not present at the time of pregnancy termination, but the head circumference had decreased from the 47th percentile at 16 weeks of gestation to the 24th percentile at 20 weeks of gestation (a finding that is consistent with the timing of diminishing head sizes in previous cases),[14] which suggests that microcephaly would have developed in the fetus had the pregnancy continued.[16] In this woman, Zika virus would be considered a rare exposure, and her fetus had a rare outcome.

The last three criteria are helpful if they are present, but they are not considered to be essential. The fifth criterion, the need for an animal model that shows teratogenicity, has not been met. Although animal models have shown that Zika virus is neurotropic,[27,28] no studies that tested for teratogenicity in an animal model have been published, although studies are under way. The sixth criterion, that the association should make biologic sense, is clearly met here. Other viral infections have had similar effects (microcephaly and eye problems).[24,26] In addition, pathologic evidence supports this association: Zika virus RNA has been seen in damaged mononuclear cells (presumably glial cells and neurons) in the brains of newborns with microcephaly,[17] and the virus appears to be neurotropic.[17,19] Live Zika virus has been cultured from the brain of a fetus

Table 2. Bradford Hill Criteria for Evidence of Causation as Applied to the Relationship between Zika Virus Infection and Microcephaly and Other Brain Anomalies*

Criterion	Evidence	Criterion Met?
Strength of association	A recent epidemiologic study from French Polynesia suggests a strong association between prenatal Zika virus infection and microcephaly (estimated risk ratio, approximately 50).[2] The substantial increase in the number of cases of microcephaly and other brain anomalies that have been associated with the Zika virus outbreak in Brazil suggests a strong association.[1,2]	Yes
Consistency	Two epidemiologic studies, one from Brazil and one from French Polynesia,[2,14] support the association between prenatal Zika virus infection and microcephaly and other serious brain anomalies. The observed increase in the number of cases of microcephaly after outbreaks of Zika virus infection in Brazil and French Polynesia, as well as preliminary reports of cases in Colombia, support consistency.[1,2,42] Case reports of Zika virus infection in fetuses or infants with microcephaly or other brain anomalies who were born to mothers who traveled to areas of active Zika virus transmission support consistency.[16,18,19]	Yes
Specificity	Other causes of microcephaly exist; however, on the basis of clinical descriptions that are available for a small number of infants with presumed congenital Zika virus infection,[20] the clinical phenotype linked to the Zika virus appears to be an unusual form of microcephaly that is consistent with the fetal brain disruption sequence.	Yes
Temporality	Zika virus infection in mothers during pregnancy precedes the finding of microcephaly or other brain anomalies in fetuses or infants.[14-20] Zika virus outbreaks in Brazil and French Polynesia preceded the increase in the number of cases of microcephaly.[1,2]	Yes
Biologic gradient	Infection is a phenomenon that is either present or absent; there is no dose–response relationship. No data are available regarding whether women with an increased viral load have a higher risk of adverse pregnancy or birth outcomes.	NA
Plausibility	Findings are similar to those seen after prenatal infection with some other viral teratogens (e.g., cytomegalovirus and rubella virus).[26] Evidence that Zika virus infects neural progenitor cells and produces cell death and abnormal growth,[29] along with evidence of Zika virus in brains of fetuses and infants with microcephaly, on the basis of on immunohistochemical staining and identification of Zika virus RNA and live virus,[16,17,19] provides strong biologic plausibility.	Yes
Coherence	No results in an animal model of effects of Zika virus on pregnancy have yet been published, but animal models have shown that Zika virus is neurotropic,[27,28] a finding that is consistent with prenatal Zika virus infection causing microcephaly and other brain anomalies. Zika virus infects neural progenitor cells and produces cell death and abnormal growth,[29] a finding that is consistent with a causal relationship between Zika virus infection and microcephaly.	Yes
Experiment	No experimental animal model of Zika virus teratogenicity is available.	No
Analogy	No other flavivirus has been shown to definitively cause birth defects in humans,[4] but flaviviruses, Wesselsbron and Japanese encephalitis viruses, have been shown to cause stillbirth and brain anomalies in animals.[43] Findings are similar to those seen after prenatal infection with other viral teratogens (e.g., cytomegalovirus, rubella virus).[26]	Yes

* The criteria listed here were proposed by Hill.[40] We have updated a recent analysis by Frank et al.[41]

with severe brain anomalies after maternal infection at 11 weeks of gestation.[16] Furthermore, Zika virus efficiently infects neural progenitor cells and produces cell death and abnormal growth, thus providing a possible mechanism for microcephaly.[29] The seventh criterion, proof in an experimental system that the agent acts in an unaltered state, is aimed at medications or chemical exposures and does not apply to infectious agents. Thus, given Shepard's criteria as a framework,

criteria 1, 3, and 4 have been satisfied — evidence that is considered sufficient to identify an agent as a teratogen.

OTHER CRITERIA

Other criteria can also be used to assess this relationship. Koch's postulates, developed in the late 19th century, are often cited as necessary to show causation in infectious disease; however, many authors have noted the need for Koch's postulates to be updated to accommodate modern technologies.[37-39] The Bradford Hill criteria[40] provide another framework to assess causation; Frank et al. recently used these criteria to assess the relationship between prenatal Zika virus infection and microcephaly and concluded that additional information was needed to assume that the relationship was causal.[41] However, several key pieces of evidence have become available since they performed their analysis, including two epidemiologic studies,[2,14] a study of the effects of Zika virus on neural progenitor cells,[29] and a case report of a fetus with brain anomalies and decreasing head size from whose brain live Zika virus was isolated.[16] On the basis of our update of their analysis, which incorporates newly available evidence (Table 2), nearly all the relevant criteria have been met, with the exception of the presence of experimental evidence. However, Hill emphasizes that meeting all nine criteria is not necessary[40]; instead, the criteria should serve as a framework to assess when the most likely interpretation of a relationship is causation.

ASSESSMENT OF CRITERIA

Thus, on the basis of a review of the available evidence, using both criteria that are specific for the evaluation of potential teratogens[9] and the Bradford Hill criteria[40] as frameworks, we suggest that sufficient evidence has accumulated to infer a causal relationship between prenatal Zika virus infection and microcephaly and other severe brain anomalies. Also supportive of a causal relationship is the absence of an alternative explanation; despite the extensive consideration of possible causes, researchers have been unable to identify alternative hypotheses that could explain the increase in cases of microcephaly that were observed first in Brazil and then retrospectively in French Polynesia, and now in preliminary reports that are being investigated in Colombia.[1,2,42]

Moving from a hypothesis that Zika virus is linked to certain adverse outcomes to a statement that Zika virus is a cause of certain adverse outcomes allows for direct communications regarding risk, both in clinical care settings and in public health guidance, and an intensified focus on prevention efforts, such as the implementation of vector control, the identification of improved diagnostic methods, and the development of a Zika virus vaccine.[44] In addition, after recognizing a causal relationship between Zika virus infection and adverse pregnancy and birth outcomes, we can focus research efforts on other critical issues: First, understanding the full spectrum of defects caused by congenital Zika virus infection; if Zika virus is similar to other teratogens, an expansion of the phenotype would be expected (e.g., with the congenital rubella syndrome, the phenotype was expanded from cataracts to include other findings such as hearing loss, congenital heart defects, and microcephaly).[11] Second, quantifying the relative and absolute risks among infants who are born to women who were infected at different times during pregnancy. Third, identifying factors that modify the risk of an adverse pregnancy or birth outcome (e.g., coinfection with another virus, preexisting immune response to another flavivirus, genetic background of the mother or fetus, and severity of infection). Addressing these issues will improve our efforts to minimize the burden of the effects of Zika virus infection during pregnancy.

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Declines in Unintended Pregnancy in the United States, 2008–2011

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ABSTRACT

BACKGROUND

The rate of unintended pregnancy in the United States increased slightly between 2001 and 2008 and is higher than that in many other industrialized countries. National trends have not been reported since 2008.

METHODS

We calculated rates of pregnancy for the years 2008 and 2011 according to women's and girls' pregnancy intentions and the outcomes of those pregnancies. We obtained data on pregnancy intentions from the National Survey of Family Growth and a national survey of patients who had abortions, data on births from the National Center for Health Statistics, and data on induced abortions from a national census of abortion providers; the number of miscarriages was estimated using data from the National Survey of Family Growth.

RESULTS

Less than half (45%) of pregnancies were unintended in 2011, as compared with 51% in 2008. The rate of unintended pregnancy among women and girls 15 to 44 years of age declined by 18%, from 54 per 1000 in 2008 to 45 per 1000 in 2011. Rates of unintended pregnancy among those who were below the federal poverty level or cohabiting were two to three times the national average. Across population subgroups, disparities in the rates of unintended pregnancy persisted but narrowed between 2008 and 2011; the incidence of unintended pregnancy declined by more than 25% among girls who were 15 to 17 years of age, women who were cohabiting, those whose incomes were between 100% and 199% of the federal poverty level, those who did not have a high school education, and Hispanics. The percentage of unintended pregnancies that ended in abortion remained stable during the period studied (40% in 2008 and 42% in 2011). Among women and girls 15 to 44 years of age, the rate of unintended pregnancies that ended in birth declined from 27 per 1000 in 2008 to 22 per 1000 in 2011.

CONCLUSIONS

After a previous period of minimal change, the rate of unintended pregnancy in the United States declined substantially between 2008 and 2011, but unintended pregnancies remained most common among women and girls who were poor and those who were cohabiting. (Funded by the Susan Thompson Buffett Foundation and the National Institutes of Health.)

THE RATE OF UNINTENDED PREGNANCY in a population is a central measure of reproductive health; it indicates the extent to which women and couples can determine freely whether and when they have children. In addition to supporting individual autonomy, there is also a clear public health justification for reducing the rate of unplanned pregnancy: women and girls who have unintended pregnancies that result in births are more likely than those who intended to become pregnant to have inadequate or a delayed initiation of prenatal care, to smoke and drink during pregnancy, and to have premature and low-birth-weight infants; they are also less likely to breast-feed. Increased risks of physical and mental health problems have also been reported in children of women who have unplanned pregnancies.[1-9] Many U.S. policies and programs have recognized these relationships and focus on reducing the rate of unintended pregnancy and associated adverse health outcomes.[10-12]

Although the rate of unintended pregnancy in the United States decreased between the late 1980s and the mid-1990s,[13] it plateaued by 2001[14] and increased slightly between 2001 and 2008, the most recent year for which estimates are available.[15] The rate of unintended pregnancy in the United States is substantially higher than that in other highly industrialized regions such as Western Europe.[16] We used U.S. data on pregnancy intentions, released in December 2014 by the National Center for Health Statistics (NCHS), to calculate the incidence of unintended pregnancy in 2011.

METHODS

STUDY DESIGN AND KEY MEASURES

The methods we used for this analysis are similar to those used in previously published studies.[15,17] Among all U.S. females and key population subgroups, we determined the total number of pregnancies that ended in birth, miscarriage (i.e., fetal loss or stillbirth), and induced abortion and calculated the percentages of each of these pregnancy outcomes that were unintended; we then divided the total number of unintended pregnancies by the population of women and girls 15 to 44 years of age to obtain a rate of unintended pregnancy per 1000 in this age group.

DATA SOURCES AND DEFINITIONS

The numbers of U.S. births, miscarriages, and abortions reported or estimated in 2011 and 2008 were derived from several sources. The numbers of births were obtained from NCHS,[18,19] which tabulates data from birth certificates to obtain birth counts at the national level. Because there is no recognized best estimate of the number — or method to obtain the number — of miscarriages in a given year, we followed a procedure that was established by researchers at NCHS[20] using that center's National Survey of Family Growth (NSFG), a nationally representative in-home survey that collects information on pregnancy and childbearing: we calculated the ratio of miscarriages to births that were reported in the NSFG and multiplied that ratio by the actual number of U.S. births to obtain our estimates of the number of miscarriages. The total number of abortions, including both surgical and medication abortions, for each year was obtained from a periodic census of all known abortion providers that was conducted by the Guttmacher Institute.[21] This census is considered to be the most comprehensive source of data on the incidence of abortion in the United States.[22]

Pregnancy intention was defined according to a respondent's answers to a series of retrospective survey questions about her desire to become pregnant right before each pregnancy occurred. If she reported that she did not want to become pregnant at the time the pregnancy occurred, but wanted to become pregnant in the future, the pregnancy was categorized as mistimed. If a respondent reported that she did not want to become pregnant then or at any time in the future, the pregnancy was categorized as unwanted. We classified a pregnancy as unintended if it was either mistimed or unwanted; an intended pregnancy was one that was desired at the time it occurred or sooner.

Data on pregnancy intentions (often called intendedness) were obtained from two nationally representative sources. The percentages of births and miscarriages that resulted from unintended pregnancies were calculated from the 2011–2013 NSFG. We evaluated 1975 pregnancies that ended between 2009 and 2013 (with 2011 as the central or reference year), as reported by the respondents; a respondent could report more than one pregnancy. The percentages of abortions that followed unintended con-

ceptions were calculated from the 2008 Abortion Patient Survey that was conducted by the Guttmacher Institute.[23] This paper-and-pencil survey gathered information from a representative sample of 9493 women who had abortions in the United States and is the most recent data set available of its kind. The questions about pregnancy intention in the Abortion Patient Survey were modeled on those in the NSFG. For both data sets, the pregnancy outcomes were weighted to represent all pregnancies in the United States in 2011.

STATISTICAL ANALYSIS

The percentages of births, miscarriages, and abortions that resulted from unintended pregnancies were applied to the counts of each respective pregnancy outcome and then summed to determine the total number of unintended pregnancies. To calculate rates, we obtained population counts according to age and according to race and ethnic group from the U.S. Census Bureau.[24] All other distributions of population subgroups were derived from the Annual Social and Economic Supplements of the U.S. Census Bureau's Current Population Survey,[25] except for religious affiliation, which was derived from the NSFG. Poor females were defined as those with incomes below 100% of the federal poverty level, and low-income females were those whose incomes were between 100% and 199% of the federal poverty level.

When calculating the percentage of unintended pregnancies that ended in abortion, we excluded miscarriages in order to assess only pregnancies in which the outcome was determined by the respondent. The rates of unintended pregnancy according to educational attainment were limited to women 20 years of age or older; this age cutoff excluded most females who had not yet completed schooling, yet still included young women, who have had historically high rates of unintended pregnancy. We also updated the rates of unintended pregnancy for 1981, 1987, 2001, and 2008 — years that the NSFG was fielded — to take into account updated population estimates and recent improvements in our analytic approach. Data on pregnancy intendedness were also collected in the 1995 survey of the NSFG but were excluded owing to concerns about the accuracy of the pregnancy intendedness data from that year.[26]

We performed analyses at an aggregate level and separately for each population subgroup: we combined data on pregnancy intention, pregnancy outcomes, and populations from several different sources to calculate rates, which made it difficult to assess the reliability of our estimates and of the change over time. Because most of the uncertainty around the rate estimates was attributable to the percentage of pregnancies that were unintended (since the numbers of pregnancies and population denominators are based largely on generally complete census data), we performed a supplementary analysis to calculate 95% confidence intervals for the percentage of pregnancies that were unintended using a merged data set that combined the sample of births and miscarriages from the NSFG with the sample of abortions from the Abortion Patient Survey. We then used this range of percentages to calculate the 95% confidence intervals around the rate estimates. Although these percentages are expected to be less accurate than the ones calculated in the aggregate manner, the 95% confidence intervals around these percentages should represent the variance around the rate estimates.

The above approach uses two different data sources for pregnancy intention. We also used a single data set, the NSFG, to calculate a test statistic for the change between 2008 and 2011 in the percentage of pregnancies that were unintended. Using the NSFG alone for all pregnancy outcomes allows for a simple calculation of the test statistic. Abortions are underreported in the NSFG, and therefore the percentages calculated using this approach were expected to be lower than those in our main analysis. Nonetheless, we considered this analysis of trends to be reasonable, because the underreporting of abortions has not changed substantially over time.[27,28]

RESULTS

FINDINGS AT THE NATIONAL LEVEL

In 2011, a total of 6.1 million pregnancies occurred in the United States (Table 1); 45% of these pregnancies (2.8 million) were unintended, as compared with 51% of the pregnancies in 2008. There were 45 unintended pregnancies for every 1000 women and girls 15 to 44 years of age in 2011, as compared with a rate of 54 per 1000 women and girls 15 to 44 years of age in

Table 1. Number of Pregnancies, Percentage That Were Unintended, Pregnancy Rates, and Percentage Change in the Rate of Unintended Pregnancies among All U.S. Females, 2008 and 2011.*

Characteristic	No. of Pregnancies, 2011 (in Thousands)		Percentage of Pregnancies That Were Unintended		Pregnancy Rate†				% Change in Rate of Unintended Pregnancy, 2008 to 2011
					Total		Unintended		
	Total	Unintended	2008	2011	2008	2011	2008	2011	
All females	6138	2779	51	45	106	98	54	45	−18
Age group‡									
15–19 yr	574	430	82	75	70	55	57	41	−28
15–17 yr	173	124	91	72	39	28	36	20	−44
18–19 yr	402	305	77	76	115	93	88	71	−20
20–24 yr	1494	878	64	59	163	138	104	81	−22
25–29 yr	1650	691	45	42	168	157	76	66	−13
30–34 yr	1440	444	35	31	141	141	49	43	−12
≥35 yr	967	328	39	34	48	47	19	16	−15
Relationship status									
Currently married	3084	731	31	24	119	121	36	29	−21
Never married, not cohabiting	1181	954	82	81	54	45	43	36	−16
Formerly married, not cohabiting	378	262	68	69	67	77	46	54	17
Cohabiting	1494	831	63	56	320	254	198	141	−29
Income as a percentage of the federal poverty level									
<100%	2131	1286	65	60	209	184	137	112	−18
100–199%	1373	709	55	52	152	111	85	58	−32
≥200%	2635	784	38	30	67	68	26	20	−20
Educational attainment§									
Not a high school graduate	813	363	54	45	187	162	101	73	−28
High school graduate or GED equivalent	1358	738	52	54	116	109	60	59	−2
Some college or associate's degree	1785	813	53	46	105	101	55	46	−16
College graduate	1595	428	31	27	94	95	29	25	−14
Race and ethnic group¶									
White non-Hispanic	3190	1201	42	38	89	86	38	33	−13
Black non-Hispanic	1101	699	69	64	132	122	92	79	−15

Hispanic	1387	691	56	50	140	116	79	58	−26
Religious affiliation								
Protestant	2803	1274	50	45	103	93	52	43	−19
Mainline Protestant	1329	703	53	53	106	95	57	51	−11
Evangelical Protestant	1473	571	48	39	101	91	48	35	−27
Catholic	1427	661	49	46	109	102	54	48	−11
Other	598	205	44	34	94	109	42	38	−10
None	1311	639	59	49	113	101	68	50	−26

* Numbers may not sum to group totals because of rounding. GED denotes General Educational Development.
† Rates are reported as the number of pregnancies per 1000 women and girls 15 to 44 years of age.
‡ Girls younger than 15 years of age were excluded because of insufficient data. For the category 35 years of age or older, the numerator is the number of pregnancies among women 35 years of age or older and the population denominator is the number of women 35 to 44 years of age.
§ Calculations by educational attainment were limited to women 20 years of age or older.
¶ Race and ethnic group were self-reported. Data from women and girls who reported their race or ethnic group as "other" are not included here.

2008, which corresponds to an 18% decline over this period (Table 1). This was the first substantial decline since at least 1981 (Fig. 1). The rate of intended pregnancy increased slightly from 51 to 53 per 1000 women and girls 15 to 44 years of age (data not shown); as a result, the overall rate of pregnancy decreased from 106 to 98 per 1000 women and girls 15 to 44 years of age.

In 2011, the percentage of unintended pregnancies (excluding miscarriages) that ended in abortion was 42% (Table 2). This percentage changed little from 2008, when it was 40%. The rate of births that resulted from unintended pregnancies declined from 27 to 22 per 1000 women and girls 15 to 44 years of age during the period studied.

FINDINGS FOR POPULATION SUBGROUPS

The decline in rates of unintended pregnancy was seen in almost every demographic group we examined (Table 1). For example, the rate declined in every age group. However, the highest rate of unintended pregnancy in 2011 was seen among women 20 to 24 years of age, followed by women 18 to 19 and women 25 to 29 years of age. The percentage of unintended pregnancies that ended in abortion did not vary substantially according to age group, although the percentage increased between 2008 and 2011 among girls 15 to 17 years of age; as a result, the pattern of births that resulted from unintended pregnancies reflected that of unintended pregnancy, with the highest rates observed among women 18 to 29 years of age and declines in every age group.
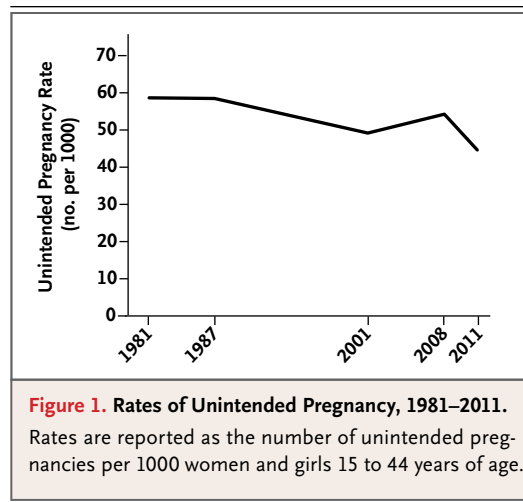
The rate of unintended pregnancy varied ac-

Figure 1. Rates of Unintended Pregnancy, 1981–2011.
Rates are reported as the number of unintended pregnancies per 1000 women and girls 15 to 44 years of age.

Table 2. Percentage of Unintended Pregnancies That Ended in Abortion and Rate of Unintended Pregnancies That Ended in Birth for All U.S. Females, 2008 and 2011.

Characteristic	Percentage of Unintended Pregnancies That Ended in Abortion*		Rate of Unintended Pregnancies That Ended in Birth†	
	2008	2011	2008	2011
All females	40	42	27	22
Age group‡				
15–19 yr	37	38	30	21
15–17 yr	35	43	19	10
18–19 yr	38	37	47	37
20–24 yr	41	44	53	40
25–29 yr	42	42	38	33
30–34 yr	41	42	24	21
≥35 yr	45	46	8	7
Relationship status				
Currently married	20	23	24	18
Never married, not cohabiting	57	56	16	14
Formerly married, not cohabiting	67	54	12	19
Cohabiting	39	41	101	72
Income as a percentage of the federal poverty level				
<100%	41	38	70	60
100–199%	37	44	45	28
≥200%	43	48	12	9
Educational attainment§				
Not a high school graduate	27	35	61	40
High school graduate or GED equivalent	40	38	31	31
Some college or associate's degree	48	49	24	20
College graduate	48	47	13	11
Race and ethnic group¶				
White non-Hispanic	36	36	20	17
Black non-Hispanic	50	50	40	33
Hispanic	37	40	43	31
Religious affiliation				
Protestant	34	36	28	23
Mainline Protestant	40	39	29	26
Evangelical Protestant	27	32	28	20
Catholic	44	48	26	22
Other	39	39	20	19
None	49	49	29	22

* Pregnancies that ended in miscarriage were excluded.
† Rates are reported as the number of unintended pregnancies per 1000 women and girls 15 to 44 years of age.
‡ Girls younger than 15 years of age were excluded because of insufficient data. For the category 35 years of age or older, the numerator is the number of pregnancies among women 35 years of age or older and the population denominator is the number of women 35 to 44 years of age.
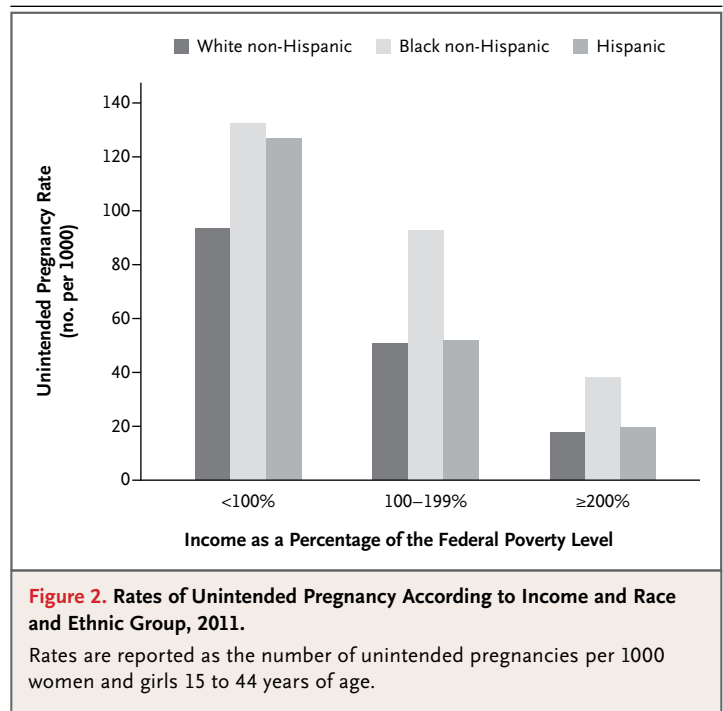§ Calculations by educational attainment were limited to women 20 years of age or older.
¶ Race and ethnic group were self-reported. Data from women and girls who reported their race or ethnic group as "other" are not included here.

cording to relationship status. Women who were married had the lowest rate of unintended pregnancy in 2011; by contrast, the rate among those who were unmarried but cohabiting was more than quadruple that among those who were married. However, the rate declined sharply between 2008 and 2011 among women who were cohabiting and to a lesser extent among those who were married or never married; those who were formerly married were the only group that had an increase in the rate of unintended pregnancy between 2008 and 2011. When an unintended pregnancy occurred, women who were married were much less likely to have an abortion than were those who were unmarried.

We found a strong inverse association between both income level and educational attainment and the rate of unintended pregnancy. However, the rate of unintended pregnancy declined between 2008 and 2011 in every income and education group, with the largest declines occurring among poor females and those who did not have a high school education. As a result, the absolute differences by income and education narrowed between 2008 and 2011. In addition to having higher rates of unintended pregnancy, poor and less-educated females were less likely to have induced abortions to end unintended pregnancies; as a result, the income and education disparities in the rate of unintended pregnancies that ended in birth were even greater than the disparities in the unintended pregnancy rate. Nevertheless, the rate of births that resulted from unintended pregnancies declined in virtually every income and education group.

There were substantial disparities in the rates of unintended pregnancy in 2011 according to race and ethnic group, even after income was accounted for (Fig. 2). However, the rate of unintended pregnancy declined between 2008 and 2011 in all racial and ethnic groups, with the largest decline among Hispanics. In 2011, the percentage of unintended pregnancies that ended in abortion was highest among blacks, and the rate of birth resulting from unintended pregnancies was lower among whites than among both blacks and Hispanics.

The rates of unintended pregnancy and of births resulting from unintended pregnancies also declined between 2008 and 2011 among women and girls of every religious affiliation assessed. In both years, these rates were highest

Figure 2. Rates of Unintended Pregnancy According to Income and Race and Ethnic Group, 2011.

Rates are reported as the number of unintended pregnancies per 1000 women and girls 15 to 44 years of age.

among mainline Protestants and among those with no religious affiliation.

Figure 3 shows that there have been declines in rates of unintended pregnancy in the most recent period across all strata of age, income, and race and ethnicity; this represents a change in the overall pattern since 1981. The greatest reductions were noted among women 20 to 24 years of age, poor and low-income women and girls, and Hispanics.

SUPPLEMENTARY ANALYSIS

In the supplementary analysis to assess the variance around our estimates (Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org), we found a decline in the percentage of reported pregnancies that were unintended, from 46% in 2008 to 39% in 2011 (P=0.01). Similarly, the supplementary analysis yielded a point estimate and a 95% confidence interval for the rate of unintended pregnancies of 45 (95% confidence interval [CI], 41 to 49) per 1000 women and girls 15 to 44 years of age in 2011, as compared with a rate of 54 (95% CI, 51 to 58) per 1000 women and girls 15 to 44 years of age in 2008. The confidence intervals do not overlap, which corroborates the finding of a decline.

Population subgroups with larger point esti-

Figure 3. Rates of Unintended Pregnancy According to Key Sociodemographic Characteristics, 1981–2011.

Rates are reported as the number of unintended pregnancies per 1000 women and girls 15 to 44 years of age.

DISCUSSION

After a long period of minimal change, the rate of unintended pregnancy in the United States declined substantially between 2008 and 2011. The rate of 45 unintended pregnancies per 1000 in 2011 was the lowest level seen in at least three decades. The decline occurred in nearly all demographic groups, including those defined by age, income, education, race and ethnicity, and religious affiliation.

The decline we observed corroborates the findings of a recent study[29] that examined rates of unintended pregnancy at the state level; this study used a different source for girls' and women's reports of pregnancy intention — the Pregnancy Risk Assessment Monitoring System of the Centers for Disease Control and Prevention — to produce state-specific estimates. In that study, declines of 5% or more between 2006 and 2010 occurred in 28 of 41 states that had data for both years.

Our analysis did not address factors that might explain the decline between 2008 and 2011, but several possible factors should be considered. Changes in sexual behavior are unlikely to have been a major driver. The incidence of sexual activity tends not to change much among adults,[30] and among women 18 to 19 years of age, the decline in the rate of unintended pregnancy occurred despite virtually no change over the course of the period studied in the percentage who reported ever having sex[31]; because younger teens have relatively few pregnancies, any change in their behavior would have relatively little effect on the overall rate of unintended pregnancy. Changes in the composition of the population are also not likely to explain the decline in the rate of unintended pregnancy; in fact, there is evidence that the percentage of the population composed of women and girls with higher rates of unintended pregnancy, such as those who were poor or Hispanic, increased over time,[24,25,32] and the decline in the rate of unintended pregnancy occurred despite this increase.

Change in the desire for pregnancy may have contributed to the decline in the rate of unintended pregnancies. Surveys of women in 2009 during the recession indicated that many women intended to reduce or delay their childbearing because of changing economic conditions.[33] As Americans recovered from the recession, it is
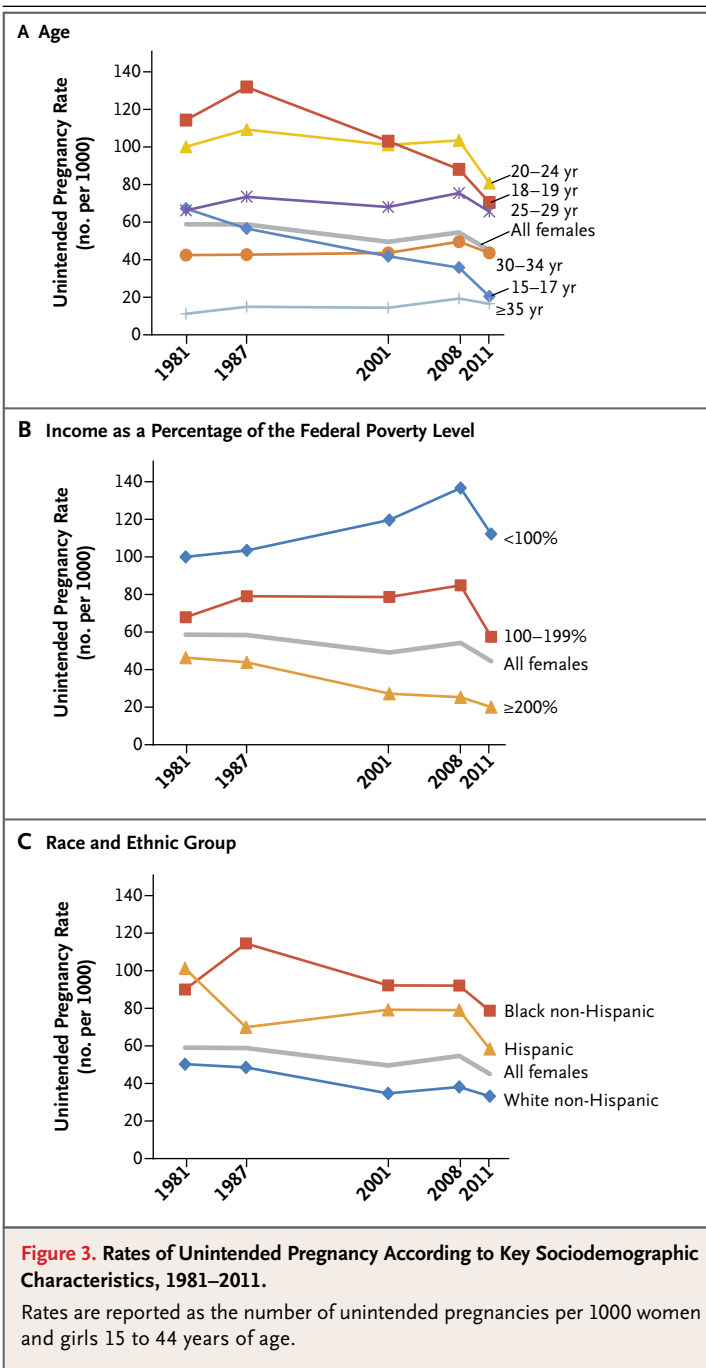
mates for the rate of unintended pregnancy generally had wider 95% confidence intervals. The results of the supplementary analysis supported the finding of differences in rates of unintended pregnancy across strata of age, relationship status, income, education, and race and ethnicity; the results did not support a finding of clear differences in the rates across strata of religious affiliation.

possible that there was a corresponding increase in desired pregnancy, which would have led to a shift away from unplanned pregnancies; our analyses show that there was a small increase in the rate of intended pregnancy between 2008 and 2011.

A likely explanation for the decline in the rate of unintended pregnancy is a change in the frequency and type of contraceptive use over time. Evidence shows that the overall use of any method of contraception among women and girls at risk for unintended pregnancy increased slightly between 2008 and 2012.[34,35] More important, the use of highly effective long-acting methods, particularly intrauterine devices, among U.S. females who used contraception increased from 4% to 12% between 2007 and 2012,[36] and this increase occurred in almost all demographic groups.[37,38] In a 2012 study, women and girls at high risk of unintended pregnancy who had free access to and used highly effective methods of contraception had much lower rates of unintended pregnancy than did those who used other methods, including commonly used methods such as the oral contraceptive pill.[39]

Although the differences in rates of unintended pregnancy across demographic groups narrowed over time, large disparities were still present in 2011. In particular, poor, black, and Hispanic women and girls continued to have much higher rates of unintended pregnancy than did whites and those with higher incomes. Much more progress can be made in eliminating these disparities. The rate of unintended pregnancy in Western Europe is 40% lower than the rate in the United States,[16] and the rate associated with higher incomes in the United States is similar to the rate among all women in Western Europe.

The observed decrease in the rate of unintended pregnancy preceded the implementation of several provisions in the Affordable Care Act that should improve coverage for contraceptive services, including the option for young people up to 26 years of age to remain on their parents' health insurance plans and a provision that requires insurance plans to cover contraception at no out-of-pocket cost. If these provisions lead to greater use of contraception overall or to increased use of highly effective methods among those who want them, the rate of unintended pregnancy could continue to decline.

A limitation of our study is that we used socioeconomic and other demographic information on women and girls from the 2008 Abortion Patient Survey to estimate both the 2008 and 2011 counts of women and girls who had abortions by characteristic. These counts might have changed through 2011. For example, the percentage of abortion patients who were poor increased from 2000 to 2008,[23] and it is possible that this percentage continued to increase from 2008 to 2011. If an increase in this percentage occurred from 2008 to 2011, the number of poor women and girls who had an unintended pregnancy in 2011, as well as the rate of unintended pregnancy, could have been underestimated; thus, the decline in the rate of unintended pregnancy among poor women and girls would be overestimated, and the decline in the rate of unintended pregnancy among those with higher incomes would be underestimated.

Our findings show a substantial decline in the rate of unintended pregnancy in the United States between 2008 and 2011, to a historic low. Nonetheless, nearly half of all pregnancies in 2011 were still unintended, and major disparities remained among women and girls according to socioeconomic status and race and ethnic group.

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The Zika Contraception Access Network: a feasibility programme to increase access to contraception in Puerto Rico during the 2016–17 Zika virus outbreak

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Summary

Background Prevention of unintended pregnancy is a primary strategy to reduce adverse pregnancy and birth outcomes related to Zika virus infection. The Zika Contraception Access Network (Z-CAN) aimed to build a network of health-care providers offering client-centred contraceptive counselling and the full range of reversible contraception at no cost to women in Puerto Rico who chose to prevent pregnancy during the 2016–17 Zika virus outbreak. Here, we describe the Z-CAN programme design, implementation activities, and baseline characteristics of the first 21124 participants.

Methods Z-CAN was developed by establishing partnerships between federal agencies, territorial health agencies, private corporations, and domestic philanthropic and non-profit organisations in the continental USA and Puerto Rico. Private donations to the National Foundation for the Centers for Disease Control and Prevention (CDCF) secured a supply of reversible contraceptive methods (including long-acting reversible contraception), made available to non-sterilised women of reproductive age at no cost through provider reimbursements and infrastructure supported by the CDCF. To build capacity in contraception service provision, doctors and clinic staff from all public health regions and nearly all municipalities in Puerto Rico were recruited into the programme. All providers completed 1 day of comprehensive training in contraception knowledge, counselling, and initiation and management, including the insertion and removal of long-acting reversible contraceptives (LARCs). Z-CAN was announced through health-care providers, word of mouth, and a health education campaign. Descriptive characteristics of programme providers and participants were recorded, and we estimated the factors associated with choosing and receiving a LARC method. As part of a Z-CAN programme monitoring plan, participants were invited to complete a patient satisfaction survey about whether they had obtained free, same-day access to their chosen contraceptive method after receiving comprehensive counselling, their perception of the quality of care they had received, and their satisfaction with their chosen method and services.

Findings Between May 4, 2016, and Aug 15, 2017, 153 providers in the Z-CAN programme provided services to 21124 women. 20110 (95%) women received same-day provision of a reversible contraceptive method. Whereas only 767 (4%) women had used a LARC method before Z-CAN, 14259 (68%) chose and received a LARC method at their initial visit. Of the women who received a LARC method, 10808 (76%) women had used no method or a least effective method of contraception (ie, condoms or withdrawal) before their Z-CAN visit. Of the 3489 women who participated in a patient satisfaction survey, 3068 (93%) of 3294 women were very satisfied with the services received, and 3216 (93%) of 3478 women reported receiving the method that they were most interested in after receiving counselling. 2382 (78%) of 3040 women rated their care as excellent or very good.

Interpretation Z-CAN was designed as a short-term response for rapid implementation of reversible contraceptive services in a complex emergency setting in Puerto Rico and has served more than 21000 women. This model could be replicated or adapted as part of future emergency preparedness and response efforts.

Funding National Foundation for the Centers for Disease Control and Prevention.

Introduction

Prevention of unintended pregnancy is a primary strategy to reduce adverse pregnancy and birth outcomes related to Zika virus infection.[1,2] Puerto Rico has the highest number of symptomatic Zika virus infections in the USA and US territories, including infections in women.[3] Additionally, 65% of pregnancies in Puerto Rico are unintended, and about 138000 of the 715000 women aged 15–44 years in Puerto Rico are at risk for unintended pregnancy.[4] 5–10% of the pregnancies with laboratory-confirmed Zika virus infection that were reported to the US Zika Pregnancy Registry resulted in a fetus or infant with Zika-virus-associated birth defects, and the full range of adverse development outcomes is not yet

Research in context

Evidence before this study
We searched PubMed for articles published on or before April 1, 2016, using the terms "Contraceptive Choice Project", "Zika and family planning", and "Zika and contraception". The Contraceptive CHOICE Project was a prospective cohort study of 10 000 women of reproductive age in St Louis, MO, USA, who wanted to prevent pregnancy and initiate a new method of contraception. The study was designed to introduce and promote the use of long-acting reversible contraception (LARC) methods, and the results showed that 65% of participating women chose LARC methods when cost, provider, and facility barriers were removed. In a report from April 1, 2016, early in Puerto Rico's 2016–17 Zika virus outbreak, women in the country were shown to have a high unmet need for contraception, high incidence of unintended pregnancy, poor access to contraception, and the highest number of Zika infections in the USA and US territories. We did not identify any studies that described a contraception-focused programme as part of the response to the Zika virus outbreak.

Added value of this study
The Zika Contraception Access Network (Z-CAN) is the first to describe the large-scale implementation of a comprehensive programme to rapidly expand access to contraceptives during a major public health emergency response. The programme was implemented quickly and was able to serve more women than previous projects based on expansion of contraceptive access. Z-CAN included introduction to and education about LARC methods for both providers and patients with no previous exposure to or experience with these newer contraceptive methods.

Implications of all the available evidence
This large and rapidly established contraception programme could be replicated in other areas with serious and complex public health emergencies to ensure that unintended births are averted. Although this programme was developed to prevent unintended pregnancies and birth defects associated with Zika virus infection, avoiding unintended pregnancy is an important strategy for a wide variety of public health responses, particularly in view of frequent disruptions in care and services in emergency settings.

known.[5] The threat of severe birth defects associated with Zika virus infection during pregnancy underscores the importance of contraception to prevent unintended pregnancies. However, a review of existing data and in-depth interviews with key informants early in the Zika virus outbreak in March, 2016, demonstrated that contraceptive access in Puerto Rico was limited by reduced availability of the full range of reversible methods, high out-of-pocket costs, insufficient provider reimbursement, logistical barriers that limit same-day provision, lack of patient education, and shortage of providers trained in insertion, removal, and management of long-acting reversible contraception (LARC), which includes intrauterine devices and contraceptive implants.[4] LARC is a highly effective, safe, cost-effective, and user-friendly method of contraception that reduces unintended pregnancy and abortion.[6–9] In 2002–14, LARC use in the USA increased from 2·4% to 14·3% of women using contraception.[10] However, LARC use in Puerto Rico was low before the Zika virus outbreak, with estimates indicating that less than 1% of women using contraception used a LARC method.[4]

Recognising the importance of contraceptive access during the Zika virus outbreak, the National Foundation for the Centers for Disease Control and Prevention (CDCF), with technical assistance from the Centers for Disease Control and Prevention (CDC) and in collaboration with a diverse group of stakeholders and private donors, established the Zika Contraception Access Network (Z-CAN) in Puerto Rico. Z-CAN was a short-term response (from May, 2016, to September, 2017) for rapid implementation of reversible contraceptive services in a complex emergency setting. Z-CAN aimed to build a network of health-care providers trained in client-centred contraceptive counselling and same-day provision of the full range of reversible contraceptive methods (including LARC) at no cost to women who choose to delay or avoid pregnancy, and to raise awareness in women and families of contraception as a primary prevention measure to reduce adverse pregnancy and birth outcomes related to Zika virus infection. In addition to access barriers, a history of coerced sterilisation and concern for unethical testing of oral contraceptives in Puerto Rico were important considerations in programme design.[11,12]

Here we describe the Z-CAN programme design and implementation activities and the baseline characteristics of the first 21 124 women served through Z-CAN.

Methods
Programme design and implementation
Z-CAN was designed to address gaps in contraceptive access and service provision in Puerto Rico as a preventive measure to reduce the effect of Zika virus on infants. The development of Z-CAN included several strategies to rapidly reduce access barriers to contraception in Puerto Rico's health system, strengthen infrastructure to support the Z-CAN programme, and work towards the sustainability of reversible contraceptive services after the Z-CAN programme ends (figure 1).
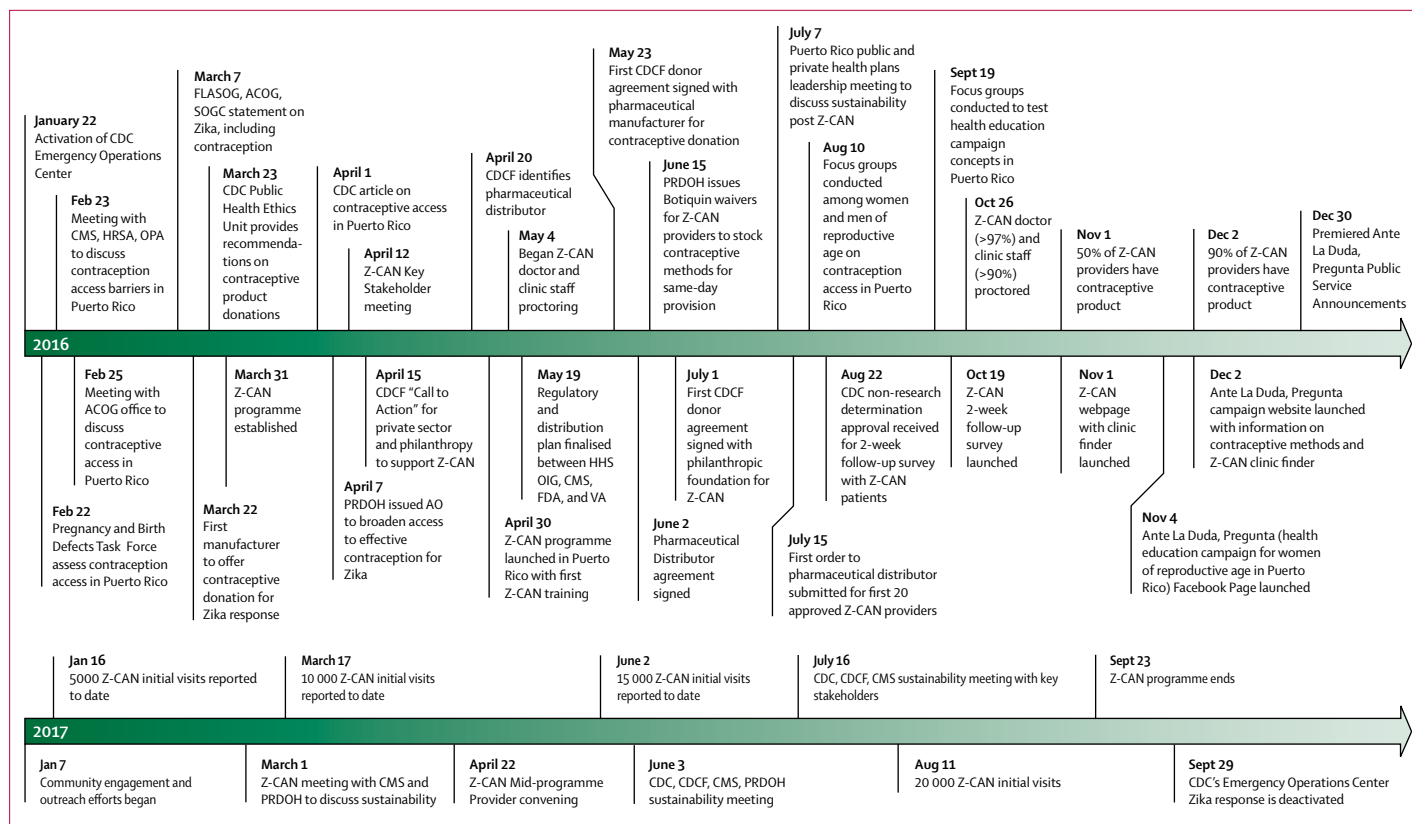
January 22
Activation of CDC Emergency Operations Center

Feb 23
Meeting with CMS, HRSA, OPA to discuss contraception access barriers in Puerto Rico

March 7
FLASOG, ACOG, SOGC statement on Zika, including contraception

March 23
CDC Public Health Ethics Unit provides recommendations on contraceptive product donations

April 1
CDC article on contraceptive access in Puerto Rico

April 12
Z-CAN Key Stakeholder meeting

April 20
CDCF identifies pharmaceutical distributor

May 4
Began Z-CAN doctor and clinic staff proctoring

May 23
First CDCF donor agreement signed with pharmaceutical manufacturer for contraceptive donation

June 15
PRDOH issues Botiquin waivers for Z-CAN providers to stock contraceptive methods for same-day provision

July 7
Puerto Rico public and private health plans leadership meeting to discuss sustainability post Z-CAN

Aug 10
Focus groups conducted among women and men of reproductive age on contraception access in Puerto Rico

Sept 19
Focus groups conducted to test health education campaign concepts in Puerto Rico

Oct 26
Z-CAN doctor (>97%) and clinic staff (>90%) proctored

Nov 1
50% of Z-CAN providers have contraceptive product

Dec 2
90% of Z-CAN providers have contraceptive product

Dec 30
Premiered Ante La Duda, Pregunta Public Service Announcements

2016

Feb 25
Meeting with ACOG office to discuss contraceptive access in Puerto Rico

Feb 22
Pregnancy and Birth Defects Task Force assess contraception access in Puerto Rico

March 31
Z-CAN programme established

March 22
First manufacturer to offer contraceptive donation for Zika response

April 15
CDCF "Call to Action" for private sector and philanthropy to support Z-CAN

April 7
PRDOH issued AO to broaden access to effective contraception for Zika

May 19
Regulatory and distribution plan finalised between HHS OIG, CMS, FDA, and VA

April 30
Z-CAN programme launched in Puerto Rico with first Z-CAN training

July 1
First CDCF donor agreement signed with philanthropic foundation for Z-CAN

June 2
Pharmaceutical Distributor agreement signed

July 15
First order to pharmaceutical distributor submitted for first 20 approved Z-CAN providers

Aug 22
CDC non-research determination approval received for 2-week follow-up survey with Z-CAN patients

Oct 19
Z-CAN 2-week follow-up survey launched

Nov 1
Z-CAN webpage with clinic finder launched

Nov 4
Ante La Duda, Pregunta (health education campaign for women of reproductive age in Puerto Rico) Facebook Page launched

Dec 2
Ante La Duda, Pregunta campaign website launched with information on contraceptive methods and Z-CAN clinic finder

Jan 16
5000 Z-CAN initial visits reported to date

March 17
10 000 Z-CAN initial visits reported to date

June 2
15 000 Z-CAN initial visits reported to date

July 16
CDC, CDCF, CMS sustainability meeting with key stakeholders

Sept 23
Z-CAN programme ends

2017

Jan 7
Community engagement and outreach efforts began

March 1
Z-CAN meeting with CMS and PRDOH to discuss sustainability

April 22
Z-CAN Mid-programme Provider convening

June 3
CDC, CDCF, CMS, PRDOH sustainability meeting

Aug 11
20 000 Z-CAN initial visits

Sept 29
CDC's Emergency Operations Center Zika response is deactivated

Figure 1: Zika Contraception Access Network (Z-CAN) major milestones, 2016–17
CDC=Centers for Disease Control and Prevention. CMS=Centers for Medicare and Medicaid Services. HRSA=Health Resources and Service Administration. OPA=Office of Population Affairs. FLASOG=Federacion Latinoamericana de Sociedades de Obstetricia y Ginecologia. ACOG=American College of Obstetricians and Gynecologists. SOGC=The Society of Obstetricians and Gynecologists. PRDOH=Puerto Rico Department of Health. AO=Administrative Order. HHS OIG=Health and Human Services Office of the Inspector General. FDA=US Food and Drug Administration. VA=Veterans Administration.

The development of strong partnerships was crucial in the design and implementation of Z-CAN. The programme was built with a network of partners including federal agencies, territorial health agencies, private corporations, and domestic philanthropic and non-profit organisations in the continental USA and Puerto Rico. Private donors provided product commitments to CDCF for the full range of reversible contraceptive methods (including LARC methods). CDCF established a plan for contraception procurement and distribution adherent to US Food and Drug Administration (FDA) and territorial guidelines and for private donations through CDCF-supported provider reimbursement and infrastructure costs to ensure contraception was available to women at no cost.

The gaps in contraceptive access and service provision[4] meant that it was necessary to build provider and staff capacity in contraception knowledge, counselling, and initiation and management, including the insertion and removal of LARC. Z-CAN recruited doctors and clinic staff (nurses and clinic administrators) from all public health regions and nearly all municipalities on the island who practised in private and publicly funded clinics and who were interested in receiving training in the provision of contraception.[13] Doctors and clinic staff were not recruited from municipalities with no community health centres, government facilities, or private practices providing women's health care. Doctors and staff were recruited through the Puerto Rico section of the American College of Obstetricians and Gynecologists, Puerto Rico Obstetrics and Gynecology, the Puerto Rico Department of Health, the Puerto Rico Primary Care Association, the Puerto Rico Health Insurance Administration, and Medicaid-managed care organisations. Before Z-CAN, none of the participating clinics routinely provided levonorgestrel-releasing intrauterine devices or contraceptive implants, and access to copper intrauterine devices was very limited. A 1-day comprehensive training course offered participants an overview of Zika virus (including the risk of sexual transmission and the importance of condom use for disease prevention), a tested curriculum on client-centred contraceptive counselling, didactic information about the full range of reversible contraceptives, a review of evidence-based contraceptive guidelines,[14,15] practical training in insertion and removal of intrauterine devices (providers were

observed on three to five simulations),[13] an FDA-approved etonogestrel implant training, and a overview of Z-CAN policies and procedures.

Provider reimbursement for these services was previously identified as barriers to contraception access.[4] Through Z-CAN, private donations were used to provide a level of provider reimbursement that was commensurate with Medicaid reimbursement rates in the continental USA. This reimbursement covered client-centred contraceptive counselling for women and their partners, if desired, and method provision. If a LARC was provided, the reimbursement fee was bundled to include both insertion and removal at the time of the insertion visit to ensure that women could have their LARC devices removed when desired at no cost.

After initial training, a Z-CAN staff member and a family planning specialist proctored providers and clinic staff to ensure delivery of high-quality care. Proctoring visits consisted of: direct observation of contraceptive counselling, at least one insertion of an intrauterine device, and staff interaction with patients; review of data collection, inventory tracking, and billing procedures; and a clinic audit to ensure that supplies, space, equipment, and security were sufficient to participate in Z-CAN. If provider, staff, and clinic met all readiness criteria, they were authorised to receive contraceptive products and to begin offering Z-CAN services.

Data collection and analysis

Women learned of Z-CAN through providers, word of mouth, and a health education campaign involving community engagement activities, Z-CAN materials, posters in health centres, a campaign website, and a Facebook page. Non-sterilised women of reproductive age were eligible to receive Z-CAN services, irrespective of age or insurance status. All Z-CAN services were provided free of charge.

At the initial Z-CAN visit, women were assigned a unique identification number. Providers and clinic staff recorded women's demographic information, reproductive and contraception histories, and their chosen contraceptive method. Data were submitted without personal identifying information to the Z-CAN programme and entered into a REDCap database hosted on a secure server.[16]

The data presented here are descriptive characteristics of programme providers and women receiving Z-CAN services. To examine factors associated with choosing and receiving a LARC method, we estimated unadjusted and adjusted prevalence ratios with 95% CI. Data were analysed using SAS-callable SUDAAN version 11.0.0 to account for clustering of patients within clinic-provider dyads.

The CDC's Public Health Ethics Committee (PHEC) provided internal consultation during the programme and project design to ensure no conflicts of interest existed and to address any ethical concerns.[17] The Public Health Ethics Conflict of Interest Work Group,

part of the CDC Zika Response Emergency Operations Center and comprised of individuals from the PHEC, reviewed the Z-CAN programme proposal during its design phase and recommended that the programme offer the full range of reversible contraceptive methods and have measures in place to prevent coercion of women.

As part of the Z-CAN programme monitoring plan, women were invited to participate in a 10 min self-administered online survey within 2 weeks of their initial visit. Z-CAN-trained clinic staff collected contact information from women who did not opt out of being contacted for future surveys. Women were invited to participate in the survey via email or text message; those without online access could complete the survey on the telephone with programme staff. The survey measured whether participants received free same-day access to the contraceptive method of their choice after receiving comprehensive counselling, patient perception of the received quality of care, and satisfaction with their chosen method and services. Perception of quality of care was measured using the validated interpersonal quality of family planning care scale,[18] comprised of 11 items measured using a five-point Likert scale (a score of 1 means poor; a score of 5 means excellent; appendix). No personal identifiers were collected, and unique identification numbers were used to merge survey responses with initial visit data. Women were considered non-respondents if they did not complete the survey within 3 weeks after confirmed receipt of email or text message invitation and after up to three outreach attempts. Responses were collected through Survey Monkey online software, and respondents received a US$10 electronic gift card. We used SAS version 9.3 to compare baseline characteristics of survey respondents and non-respondents.

The Z-CAN programme and patient satisfaction survey were determined by CDC to be non-research public health practice activities and thus exempt from Institutional Review Board review. The programme did not obtain consent from women served by Z-CAN providers. The women received a letter at their initial visit that described the follow-up contact planned for programme monitoring purposes and were given the opportunity to opt out. Women who did not opt out were invited to participate in the patient satisfaction survey. If a woman chose to participate in the survey, she did so by consenting to the survey within the online environment.

Role of the funding source

See **Online** for appendix

Results

Training for providers took place between April 30, 2016, and Dec 6, 2016. 177 doctors, including nine resident doctors training in obstetrics and gynaecology, each participated in one of the eight Z-CAN training sessions. Of those who completed training, 153 practising doctors (141 obstetrician gynaecologists and 12 family doctors or paediatricians) agreed to participate in Z-CAN, completed proctoring visits, and received contraceptive supplies to provide Z-CAN services. The characteristics of providers are listed in table 1. 139 clinics across the island participated in the Z-CAN project (figure 2). The Z-CAN programme design, scale-up, and implementation occurred rapidly across the island, and the first Z-CAN contraception services were offered on May 4, 2016.

As of Aug 15, 2017, data were available for 21 124 women who had attended an initial visit in the Z-CAN programme (table 1). The mean age of participants was 26 years (SD 6·66).

The distribution of contraception methods used by women before and after joining the Z-CAN programme is shown in figure 3. Before their initial Z-CAN visit, most women used either no method or one of the least effective contraceptive methods (condoms, sponge, withdrawal, spermicide, or fertility awareness methods), and only a small proportion of women used one of the most effective methods (male sterilisation, intrauterine device, or implant; figure 3). At their visit, more than 14 259 (68%) women chose and received a LARC method and 5250 (25%) women chose oral contraceptive pills or other moderately effective hormonal contraception (eg, depot medroxyprogesterone acetate injection). Of the 959 (5%) women who did not receive a contraceptive method, the most common reasons were being undecided on method preference or not ready to receive the method that day, pregnancy could not be ruled out, or the desired method was not in stock (table 1). Of the 14 259 women who chose and received a LARC method, 7167 (50%) women received a levonorgestrel-releasing intrauterine device, 5031 (35%) women received an etonogestrel implant, and 2061 (14%) women received a copper intrauterine device. Women were more likely to choose and receive a LARC method if they had a college degree, had no insurance, had at least one livebirth, used a most effective contraceptive method before Z-CAN, and saw a Z-CAN provider in private practice or a public health or academic clinic, after adjustment for all other characteristics (table 2). Women aged 25 years or more and women using a moderately effective contraceptive method before Z-CAN were less likely to choose and receive a LARC method. Results were similar when the analysis was restricted to women who received a contraceptive method at their initial visit.

The satisfaction survey began on Oct 28, 2016. By July 21, 2017, 9829 women had received invitations to complete the patient satisfaction survey, and 3489 (36%) women had responded (2482 women

	n/N (%)
Provider characteristics	
Provider type	
Obstetrician-gynaecologist	141/153 (92%)
Family doctor	10/153 (7%)
Paediatrician	2/153 (1%)
Practice type	
Private practice	102/153 (67%)
Community health centre*	38/153 (25%)
Public health clinic†	3/153 (2%)
Academic clinic‡	10/153 (7%)
Participant characteristics	
Age, years	
≤20	4539/21 124 (22%)
21–24	6057/21 124 (29%)
25–34	7759/21 124 (37%)
≥35	2558/21 124 (12%)
Relationship status	
Single	8887/21 124 (42%)
Married or partnered	11 979/21 124 (57%)
Education	
≤12 years	7895/21 124 (37%)
College degree	11 024/21 124 (52%)
Graduate degree	1941/21 124 (9%)
Insurance status	
Private or other	8813/21 124 (42%)
Public	10 786/21 124 (51%)
None	1111/21 124 (5%)
Previous livebirth	
0	7762/21 124 (37%)
≥1	12 491/21 124 (59%)
Breastfeeding at time of initial visit	
No	17 213/21 124 (82%)
Yes	3350/21 124 (16%)
Did not want to conceive in the next year	20 829/21 124 (95%)
Received same-day services	20 110/21 124 (95%)
Did not receive a contraceptive method at initial visit	959/21 124 (5%)
Undecided or not ready	410/959 (43%)
Might be pregnant	217/959 (23%)
Desired method out of stock	97/959 (10%)
Medical reason	83/959 (9%)
Reason not specified	78/959 (8%)
Did not want a contraceptive method	37/959 (4%)
Continuing current method	26/959 (3%)
Pregnant	11/959 (1%)

Proportions might not add up to 100% because of missing data. *Funded by the Health Resources and Services Administration. †Funded by the Puerto Rico Department of Public Health. ‡Affiliated with the University of Puerto Rico.

Table 1: Characteristics of Zika Contraception Access Network (Z-CAN) providers and the first 21 124 women enrolled in the Z-CAN programme, as of Aug 15, 2017
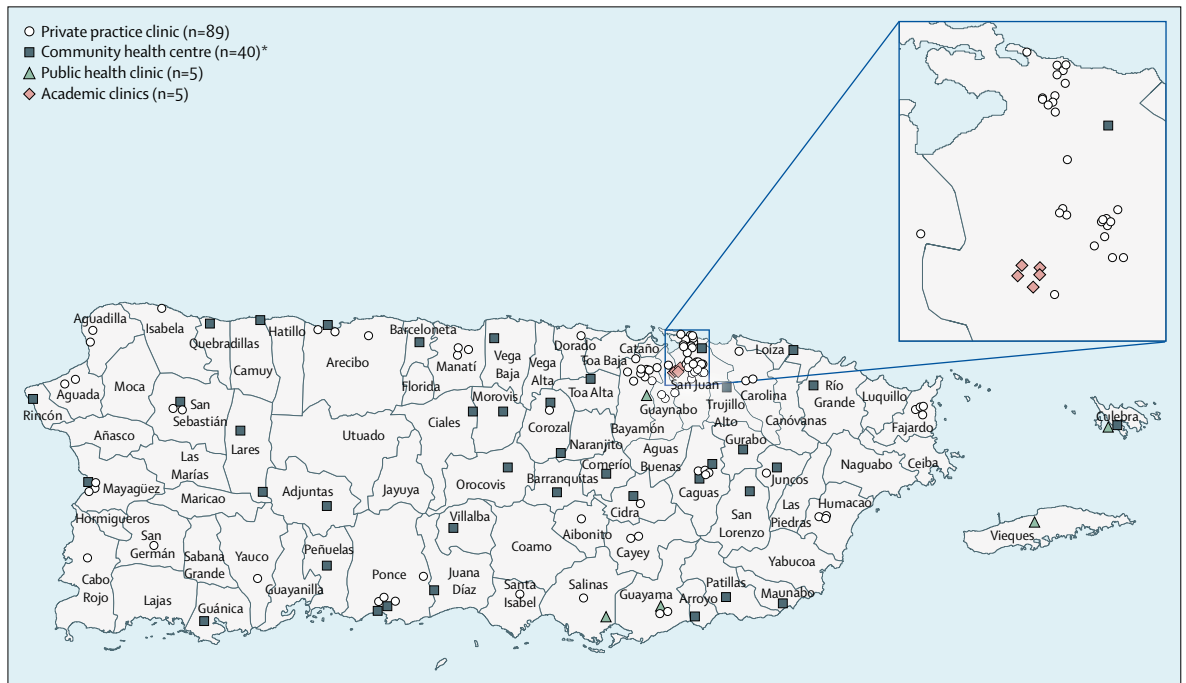
Figure 2: Puerto Rico Zika Contraception Access Network clinics
*Includes 17 community health centres and 23 satellite clinics. Source: Zika Contraception Access Network as of Sept 23, 2017.
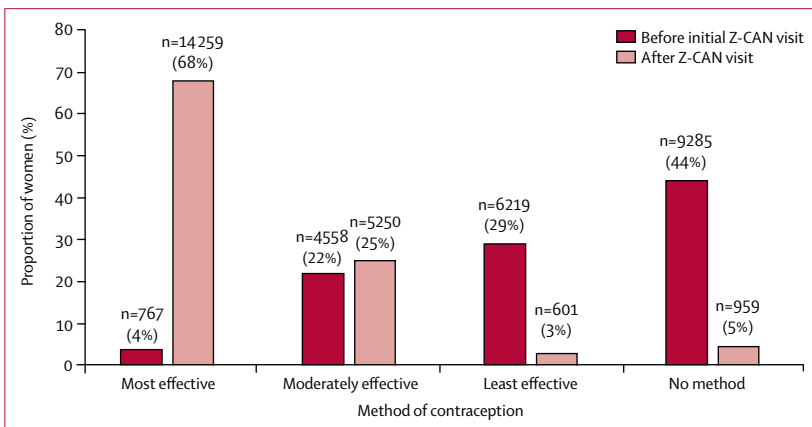

Figure 3: Contraceptive method use by women before and after their initial visit to a Zika Contraception Access Network (Z-CAN) provider in Puerto Rico, as of Aug 15, 2017 (N=21 124)
Proportions might not add up to 100% because of missing data. Most effective contraceptive methods include intrauterine devices, implants, and partner sterilisation. Less than 1% of women using these methods will get pregnant during the first year of typical use. Moderately effective contraceptive methods include injectables, pills, patch, ring, and diaphragm. 6–12% of women using these methods will get pregnant during the first year of typical use. Least effective birth control methods include male and female condoms, withdrawal, sponge, fertility awareness methods, and spermicides. Least effective birth control methods have a failure rate of 18 or more pregnancies per 100 women who use these methods each year. The Centres for Disease Control and Prevention have produced an overview of the effectiveness of family planning methods. Methods provided by Z-CAN included intrauterine devices, implants, injectables, pills, patch, ring, and male condoms.

For the **effectiveness of family planning methods** see https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf

responded by email invitation, 1006 women responded by text message invitation, and one woman responded by phone administration). We were able to link initial visit data to survey data for 3439 (99%) respondents.

Respondents differed from non-respondents with respect to age, insurance status, and type of method received; compared with non-respondents, respondents overall were slightly older, had private insurance, and chose a more effective method during their visit. 3489 women participated in the patient satisfaction survey, but not all women completed every question of the survey. 3068 (93%) of the 3294 women who answered the question about their satisfaction with services were very satisfied, 203 (6%) women were somewhat satisfied, and 23 (1%) women were not satisfied. 3216 (93%) of the 3478 women who answered the question about receiving the method they were most interested in after receiving counselling did receive the method they were most interested in. Of the 3040 women who completed every item on the 11-item interpersonal quality of family planning care scale, 2382 (78%) respondents rated their care as excellent or very good on all 11 items. Results from individual items measuring quality of care are summarised in the appendix.

Discussion

In Puerto Rico, the combination of a high incidence of Zika virus infection, a high incidence of unintended pregnancy, and low use of highly effective contraception necessitated programmatic efforts to improve contraceptive access as a primary prevention strategy to reduce adverse pregnancy and birth outcomes related to Zika virus infection. The Z-CAN programme shows the feasibility of implementing a programme to increase

access to the full range of reversible contraception, including LARC methods, within a complex public health response. Z-CAN also shows that it is possible to build capacity quickly with standardised and targeted training sessions and limited mentoring of committed providers and to provide high-quality, comprehensive contraceptive services in an emergency response.

Contraception has an important role in the Zika response because Zika virus infection during pregnancy increases the risk for microcephaly and other severe birth defects.[2] Contraception could be a key response strategy in other public health emergencies in which prenatal exposures pose a severe risk to pregnant women and their infants.[19] Guidance for rapid reproductive health assessment and programme implementation in emergency settings is available, but existing tools position contraception services as post-emergency activities rather than services to be implemented in the emergency phase.[20] Z-CAN shows that with concerted effort, commitment, dedicated resources, and recognition of the benefits of giving women the option to prevent pregnancy during a time of crisis, it is possible to prioritise and implement effective contraceptive provision early in an emergency response.

Contraceptive use and provision in Puerto Rico before the Z-CAN programme was limited by policy, financial, and logistical barriers.[4,21] Most of the 21124 women seen by the Z-CAN programmme chose and received a LARC method, and most of these women were not using an effective method of contraception before Z-CAN; these findings suggest that when barriers to access are removed (eg, cost, limited service points, and lack of providers), most women who wanted to prevent pregnancy during the Zika virus outbreak chose a highly effective method of contraception. The choice of a LARC method was more likely in women who had previously given birth than in nulliparous women. Intrauterine devices are generally safe for all women, including nulliparous women.[14] Providers might have misconceptions about the safety of intrauterine devices in nulliparous women, which have been shown to be associated with infrequent provision,[22] emphasising the opportunity for providers to include LARC methods in counselling and eligibility determinations for all women seeking contraception. Although use of LARC methods by women using contraception in the USA is low (14%),[10] our findings are consistent with those from other demonstration projects[9,23] that removed barriers to LARC access such as cost, provider availability, geographic access, and comprehensive contraception counselling. Women who chose a short-acting method were given up to 6 months advanced supply. Women who perceived a return visit to receive additional contraceptive supplies as a barrier might have inadvertently been incentivised to choose a LARC method. However, results from the patient satisfaction survey suggested that most women left their initial Z-CAN visit with the method they were most

	LARC (n=14 259)	Other contraceptive method (n=6810)	Unadjusted prevalence ratio, 95% CI	Adjusted prevalence ratio, 95% CI*
Age, years				
≤20	2930/14 125 (21%)	1594/6734 (24%)	Referent	Referent
21–24	4176/14 125 (30%)	1868/6734 (28%)	1·07, 1·03–1·10†	1·00, 0·97–1·03
25–34	5305/14 125 (38%)	2435/6734 (36%)	1·06, 1·02–1·10†	0·93, 0·90–0·97†
≥35	1714/14 125 (12%)	837/6734 (12%)	1·04, 0·98–1·10	0·85, 0·80–0·92†
Relationship status				
Single	5717/14 106 (41%)	3148/6709 (47%)	Referent	Referent
Married or partnered	8389/14 106 (60%)	3561/6709 (53%)	1·09, 1·04–1·14†	0·99, 0·95–1·04
Education				
≤12 years	5258/14 094 (37%)	2617/6712 (39%)	Referent	Referent
College degree	7585/14 094 (54%)	3411/6712 (51%)	1·03, 1·00–1·07	1·04, 1·01–1·08†
Graduate degree	1251/14 094 (9%)	684/6712 (10%)	0·97, 0·91–1·03	1·02, 0·96–1·08
Insurance status				
Private or other	5827/13 970 (42%)	2968/6689 (44%)	Referent	Referent
Public	7326/13 970 (52%)	3429/6689 (51%)	1·03, 0·97–1·09	0·97, 0·91–1·02
None	817/13 970 (6%)	292/6689 (4%)	1·11, 1·05–1·18†	1·11, 1·05–1·17†
Previous livebirth				
0	4301/13 688 (31%)	3431/6511 (53%)	Referent	Referent
1 or more	9387/13 688 (69%)	3080/6511 (47%)	1·35, 1·27–1·44†	1·40, 1·31–1·48†
Currently breastfeeding				
No	11 271/13 884 (81%)	5892/6626 (89%)	Referent	Referent
Yes	2613/13 884 (19%)	734/6626 (11%)	1·19, 1·14–1·24†	1·03, 0·99–1·08
Effectiveness of contraceptive method used before Z-CAN‡				
None	6357/14 097 (45%)	2909/6683 (44%)	Referent	Referent
Least	4451/14 097 (32%)	1757/6683 (26%)	1·05, 0·98–1·11	1·05, 0·99–1·11
Moderately	2666/14 097 (19%)	1874/6683 (28%)	0·86, 0·82–0·89†	0·90, 0·86–0·94†
Most	623/14 097 (4%)	143/6683 (2%)	1·19, 1·12–1·25†	1·13, 1·06–1·21†
Clinic type				
Community health clinic	2154/14 259 (15%)	1521/6810 (22%)	Referent	Referent
Private practice or other	12 105/14 259 (85%)	5289/6810 (78%)	1·19, 1·06–1·33†	1·19, 1·07–1·33†

Data are n/N (%) unless indicated otherwise. LARC=long-acting reversible contraceptive. *Each characteristic in the table was adjusted for all other characteristics. †95% CI does not include 1. ‡Least effective contraceptive methods include condoms for men and women, withdrawal, sponge, fertility awareness methods, and spermicides. Moderately effective contraceptive methods include injectables, pills, patch, ring, and diaphragm. Most effective contraceptive methods include intrauterine devices, implants, and partner sterilisation. Sterilised women were not eligible for Z-CAN services.

Table 2: Factors associated with choosing and receiving a LARC method among the first 21 124 women enrolled in the Zika Contraception Access Network (Z-CAN) programme, as of Aug 15, 2017

interested in receiving. In the context of the Zika virus outbreak, improved access to contraception has the potential to decrease unintended pregnancies and the number of adverse pregnancy and birth outcomes related to Zika virus infection.[1,4,24]

On the basis of results from multiple large-scale programmes and research studies to reduce barriers to contraceptive access, we anticipated that Z-CAN services would lead to an increase in LARC use. Because of their many advantages, including high effectiveness, safety, reversibility, user ease, high user satisfaction, and cost-effectiveness, LARC methods are crucial in public

health efforts to decrease unintended pregnancies. However, issues of perceived or actual provider coercion of women to choose LARC methods (or refuse LARC removals), particularly based on age, race, and class, have been reported.[25,26] The historical context of unethical contraceptive practices and research in Puerto Rico and concerns for reproductive coercion with LARC provision were important considerations in programme design. An important element of the Z-CAN training and proctoring for all providers and clinic staff was to develop competency in delivering high-quality, patient-centred contraceptive counselling that facilitated autonomous decision making.[13] Respondents to the satisfaction survey indicated high satisfaction with Z-CAN services, and nearly all women received the method they were most interested in after counselling, suggesting that participants received high-quality and patient-centred services through Z-CAN. The Z-CAN programme evaluation will include additional follow-up surveys of women participating in the programme to further assess quality of and satisfaction with Z-CAN services.

Through partnership and collaboration with a diverse group of stakeholders, Z-CAN reduced barriers to contraception as part of the public health response to the Zika virus outbreak and expanded the capacity of Puerto Rico's health-care system to integrate same-day access to contraceptive services into normal clinic practice. Z-CAN efforts to build sustainability with key stakeholders include building the capacity of a broad network of providers who can provide access to contraception, raising awareness in women of reproductive age in Puerto Rico about the availability of contraceptive methods, expanding the number of contraceptive service access sites, eliminating prior authorisation requirements and cost-sharing in health insurance plans, and discussing continued availability of LARC methods in Puerto Rico through pricing negotiations and development of a sustainable supply chain with manufacturers. Although the total cost to implement, sustain, or replicate the Z-CAN programme is difficult to calculate, the most expensive aspects of the programme were provision of the contraceptive methods (almost all of which were donated in the case of Z-CAN) and provider reimbursement for services. Different contexts will have different cost challenges, but the financing requirements of these crucial aspects might be substantial and should be considered in programme design and sustainability planning. Successful sustainability will be achieved if the elimination of the most pressing barriers addressed by Z-CAN is maintained.

This programme has several strengths. To our knowledge, Z-CAN is the first contraception access programme developed as a primary prevention strategy to mitigate the effect of a Zika virus outbreak, and it is the first contraception access programme as a primary intervention to prevent adverse pregnancy and birth

outcomes in the context of a public health emergency response. The Z-CAN programme contains important elements of both rapid programme design and implementation and sustainability planning and can be adapted to other settings in which improving contraceptive access could enhance the response to an emergency. The strong partnerships between programme teams and stakeholders in Puerto Rico and the high demand for contraceptive services also strengthened the programme.

The Z-CAN programme and this study also have several limitations. Although Z-CAN had broad coverage across the island, the programme was not able to provide services in municipalities without health-care infrastructure, so some women had to travel outside their municipality to access care. Because of the rapid design and implementation of Z-CAN and the specific threat of Zika virus to maternal and child health, our results are not readily generalisable to non-emergency situations. The response rate to the patient satisfaction survey was low, and the results of the survey might not be generalisable to all women who received Z-CAN services. The programme was implemented to serve women throughout the risk period for Zika virus transmission, while working towards sustainability of high-quality and accessible contraceptive services. Although the design and implementation phases were relatively fast, rate-limiting steps (eg, design of a procurement and distribution system for donated contraceptive methods) slowed the delivery of services in the early phases of the programme. In view of the challenges of procurement and payment of LARC methods, reaching a level of sustainability of contraceptive services that closely mimics Z-CAN will probably be difficult.[21]

Z-CAN was designed as a short-term response for rapid implementation of contraceptive services in a complex emergency setting. Z-CAN has established an extensive network of providers in Puerto Rico and has served more than 21000 women seeking to prevent pregnancy during the risk period for Zika virus infection. The programme might have prevented unintended pregnancies and birth defects related to Zika virus infections during the outbreak. Mosquito-borne transmission of Zika virus has reached 95 countries worldwide and all but two countries in the Latin America Caribbean Region.[27] On the basis of these preliminary results, Z-CAN is a model programme that could be replicated or adapted in these settings as part of emergency preparedness and response efforts. Additionally, Z-CAN's design and implementation could be refined and adapted in other non-emergent settings, in which increased access to contraception could improve health outcomes.

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Estimating Contraceptive Needs and Increasing Access to Contraception in Response to the Zika Virus Disease Outbreak — Puerto Rico, 2016

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Zika virus is a flavivirus transmitted primarily by *Aedes* species mosquitoes. Increasing evidence links Zika virus infection during pregnancy to adverse pregnancy and birth outcomes, including pregnancy loss, intrauterine growth restriction, eye defects, congenital brain abnormalities, and other fetal abnormalities (*1,2*). The virus has also been determined to be sexually transmitted.* Because of the potential risks associated with Zika virus infection during pregnancy, CDC has recommended that health care providers discuss prevention of unintended pregnancy with women and couples who reside in areas of active Zika virus transmission and do not want to become pregnant.[†] However, limitations in access to contraception in some of these areas might affect the ability to prevent an unintended pregnancy. As of March 16, 2016, the highest number of Zika virus disease cases in the United States and U.S. territories were reported from Puerto Rico.[§] The number of cases will likely rise with increasing mosquito activity in affected areas, resulting in increased risk for transmission to pregnant women. High rates of unintended and adolescent pregnancies in Puerto Rico suggest that, in the context of this outbreak, access to contraception might need to be improved (*3,4*). CDC estimates that 138,000 women of reproductive age (aged 15–44 years) in Puerto Rico do not desire pregnancy and are not using one of the most effective or moderately effective contraceptive methods,[¶,**] and therefore might experience an unintended pregnancy. CDC and other federal and local partners are seeking to expand access to contraception for these persons. Such efforts have the potential to increase contraceptive access and use, reduce unintended pregnancies, and lead to fewer adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy. The assessment of challenges and resources related to contraceptive access in Puerto Rico might be a useful model for other areas with active transmission of Zika virus.

CDC, the Puerto Rico Department of Health, and partners used a comprehensive approach, including key informant interviews and review of existing data, to gather information on contraception services in Puerto Rico, including information on rates of unintended pregnancy, contraceptive use, contraceptive access, and barriers to provision and use of contraception. Discussions were conducted with federal partners, including the Center for Medicare and Medicaid Services, the Office of Population Affairs, and the Health Resources and Services Administration (HRSA). Key stakeholders and family planning providers in Puerto Rico were also consulted, including the Puerto Rico Department of Health, the Puerto Rico Chapter of the American College of Obstetricians and Gynecologists (ACOG), Title X federal family planning grantees, and the Puerto Rico Health Insurance Administration.

Because current data regarding contraceptive use prevalence in Puerto Rico are not available, the number of women in Puerto Rico who desire effective contraception was estimated using several data sources. The estimated number of women of reproductive age (15–44 years) in 2014 was obtained from the U.S. Census Bureau.[††] To determine the number of women of reproductive age who are not using one of the most effective or moderately effective contraceptive methods and who might therefore have an unintended pregnancy, a series of assumptions were made. Based on national results from the 2013 Youth Risk Behavior Surveillance System, 50% of women aged 15–19 years were assumed to be sexually experienced, and among these, 90% were assumed not to desire pregnancy and not to be using one of the most effective or moderately effective contraceptive methods.[§§,¶¶] Among women aged 20–44 years, 65% were assumed to be sexually active, not infertile, not currently pregnant, and not currently desiring to become pregnant (*5*). The number of women aged 20–44 years who might have an unintended pregnancy was estimated by assuming that 65% were not sterilized (*6*), and

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* http://www.cdc.gov/mmwr/volumes/65/wr/mm6508e2.htm.
† http://www.cdc.gov/mmwr/volumes/65/wr/mm6505e2.htm.
§ http://www.cdc.gov/zika/geo/united-states.html.
¶ http://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf.
** Most effective = sterilization, intrauterine device, contraceptive implant; moderately effective = injectable contraceptive, oral contraceptive, contraceptive patch, or contraceptive vaginal ring.

†† http://www.census.gov.
§§ http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6304a1.htm.
¶¶ Estimated number of sexually active women aged 15–19 years who might have an unintended pregnancy = (no. women aged 15–19 years) x (50% sexually active) x (90% not desiring pregnancy, not infertile, not using effective contraception).

that among those, 33% are not using one of the most effective or moderately effective reversible contraceptive methods (5).***

To estimate the percentage distribution of desired contraceptive methods that might be needed in Puerto Rico, data from the Contraceptive CHOICE project, which was designed to remove the financial barriers to contraception, offer all methods and emphasize the most effective methods of birth control, and reduce unintended pregnancy in the St. Louis, Missouri area during 2007–2011,††† was used. In this project, women desiring reversible contraception were offered any Food and Drug Administration–approved contraceptive method at no cost along with counseling to promote the use of long-acting reversible contraceptive (LARC) methods (intrauterine devices [IUDs] and hormonal contraceptive implants), because these are the most effective reversible methods. Seventy-five percent of the general study population and 72% of adolescents aged 15–19 years chose a LARC method, resulting in decreases in adolescent and unintended pregnancy (7,8). Demonstration projects in Iowa and Colorado, also designed to increase use of LARC methods, have similarly resulted in increased use of LARCs and decreases in unintended pregnancy.§§§,¶¶¶ Assuming a distribution of desired methods similar to that observed in the CHOICE project (7,8), if barriers to access were removed, the total number of contraceptive products needed in Puerto Rico to supply all women of reproductive age who are currently not using one of the most effective or moderately effective contraceptive methods and who do not want to become pregnant was estimated.

Approximately 715,000 women aged 15–44 years reside in Puerto Rico, and there were approximately 34,000 births in 2014 (3). A 2008 hospital-based survey of postpartum women in Puerto Rico indicated that 65.5% of pregnancies were unintended in Puerto Rico, compared with 51% in a probability sample of the general U.S. population (the 50 U.S. states and the District of Columbia), according to the 2008 National Survey of Family Growth (4,9). In 2014, among women aged 15–19 years, the birth rate was almost twice as high (40/1,000) in Puerto Rico as in the U.S. overall (24/1,000) (3).

The most recent population-based estimates of contraceptive use in Puerto Rico, from a 2002 Behavioral Risk Factor Surveillance System survey, found that among women aged 18–44 years who used contraception, tubal ligation was the most frequently reported method, used by 46% of women,

followed by oral contraceptives (19%), condoms (11%), calendar-based contraceptive methods (10%), vasectomy (6%), depot medroxyprogesterone acetate (DMPA) (3%), and IUDs (1%) (6). More recent information on services provided by La Asociación Puertorriqueña Pro Bienestar de la Familia (PROFAMILIA), a private non-profit organization that provides reproductive health care to a largely low income population in Puerto Rico, indicated that among approximately 44,000 women receiving contraceptive care in 2009, 80% received oral contraceptives, 8% received the transdermal contraceptive patch, 6% received condoms, 3% received DMPA, and <1% received an IUD (4).

Women access contraception at various sites in Puerto Rico, including community health clinics, private medical offices, university clinics, and Title X family planning clinics (Manuel Vargas, MD, MPH, Puerto Rico Department of Health; Claritsa Malave, MD, MPH, HRSA; personal communications, 2016). Despite the availability of these resources, barriers exist to providing optimal contraceptive coverage. Key stakeholders in Puerto Rico identified the need for increased contraceptive supplies, family planning delivery sites, training for providers on LARC insertion, education for women and men on effective contraception to reduce unintended pregnancy, and decreased financial and administrative barriers for providers and patients (Manual Vargas, MD, MPH, Puerto Rico Department of Health; Claritsa Malave, MD, MPH, HRSA; Nabal Bracero, MD, ACOG Puerto Rico Section; Ramon Sanchez, MD, MPH, Clinica Preven; Blanca Cuevas, MS, PROFAMILIA; personal communications, 2016). Coverage for all contraceptive methods by federal and private insurers is not universal in Puerto Rico. Certain contraceptive methods can be unaffordable for providers and patients, which has resulted in limited availability of more effective contraceptive options such as LARCs that have higher up-front costs (Manuel Vargas, MD, MPH, Puerto Rico Department of Health; personal communication, 2016). In addition, the cost of IUD and hormonal implant insertion might not be fully covered by public or private insurance, which might also deter women from seeking LARCs. Because of cost, these methods are often not available in physician offices or pharmacies, and therefore most women receive oral contraceptives, DMPA, or condoms. A lack of availability in hospitals has also led to missed opportunities for postpartum initiation of LARCs (Nabal Bracero, MD, MPH, ACOG Puerto Rico Section; personal communication, 2016). The number of health care providers who offer contraception, specifically IUDs and contraceptive implants, has been limited by lack of training and reimbursement (Nabal Bracero, MD, MPH, ACOG Puerto Rico Section; Manuel Vargas, MD, MPH, Puerto Rico Department of Health; personal communications, 2016).

*** Estimated number of sexually active women aged 20–44 years who might have an unintended pregnancy = (no. women aged 20–44 years) x (65% sexually active, not infertile, not currently pregnant, not desiring pregnancy) x (65% not sterilized) x (33% not using effective reversible contraception).
††† http://www.choiceproject.wustl.edu.
§§§ http://www.astho.org/Maternal-and-Child-Health/Long-Acting-Reversible-Contraception/Iowa-Initiative-Title-X-Issue-Brief/.
¶¶¶ https://www.colorado.gov/pacific/cdphe/reducing-unintended-pregnancy.

Women typically do not choose LARC methods because of this lack of availability, as well as a general lack of knowledge about these methods (Ramon Sanchez, MD, MPH, Clinica Preven; personal communication, 2016).

Among the 715,000 women of reproductive age in Puerto Rico, an estimated total of 138,000, or nearly 1 in 5 women, including 55,000 aged 15–19 years and 83,000 aged 20–44 years, do not want to become pregnant, are not using one of the most effective or moderately effective contraceptive methods, and could therefore have an unintended pregnancy. Applying the distribution of methods observed in the CHOICE project, there is an estimated unmet need for IUDs for 68,000 women, hormonal contraceptive implants for 33,000 women, DMPA for 11,000 women, oral contraceptives for 14,000 women, vaginal rings for 9,000 women, and contraceptive patches for 3,000 women (Table). The estimated needs for a year are 68,000 IUDs, 33,000 hormonal contraceptive implants, 44,000 DMPA doses, 168,000 oral contraceptive pill packs, 108,000 vaginal rings, and 36,000 contraceptive patches.

Discussion

Reducing the rate of unintended pregnancy is a public health priority because unintended pregnancies can be associated with delayed entry into prenatal care, decreased smoking cessation, and increased incidence of low birthweight (10), with attendant negative health consequences for mother and infant. Prevention of unintended pregnancies in the context of a Zika virus outbreak is especially important to reducing the likelihood of congenital infections. Removing barriers to contraception, such as cost, access, and lack of knowledge, can lead to increased use of the most effective contraceptive methods and reduced rates of unintended pregnancy, which would result in fewer adverse pregnancy and birth outcomes associated with Zika virus disease during pregnancy.

CDC and other partners have initiated multiple approaches to address some of these barriers. Current information on contraceptive use and unmet need is important, and efforts are underway to conduct reproductive health surveys in Puerto Rico to obtain this information. Approaches to increasing access to effective contraceptive methods at no or reduced cost are being explored. Education of providers is being conducted through outreach sessions designed to disseminate information about prevention of adverse outcomes associated with Zika virus infection during pregnancy. Training of providers on insertion of IUDs and contraceptive implants can be implemented using resources from professional organizations such as ACOG and the University of Puerto Rico. Ongoing education about effective use of contraception can be enhanced through health care providers, counselors in community health centers, home visiting nurses, and schools.

The findings in this report are subject to at least four limitations. First, no recent information was available regarding the proportion of women of reproductive age in Puerto Rico using specific contraceptive methods. Therefore, estimates of contraceptive need were derived from 2002 data, highlighting the urgent need for reproductive health surveys in Puerto Rico and other Zika-affected areas to better estimate unmet contraceptive need. Second, contraceptive preferences were extrapolated from the CHOICE project, and might not represent preferences in Puerto Rico or other populations, because of demographic and cultural differences. However, demonstration projects from other populations in the United States have similarly demonstrated high preference for LARC methods when common barriers, including cost, availability, and knowledge, were removed. Third, pregnancy intentions might change as a result of the Zika virus outbreak; therefore assumptions about pregnancy desires might not be accurate. Finally, most of the information on contraceptive access and barriers was obtained by nonsystematic personal communications with key leaders and stakeholders.

TABLE. Estimated contraception needs required to supply all women who desire to avoid pregnancy,* by contraceptive method — Puerto Rico, 2016

| | Age group (yrs) | | | | | |
| | 15–19 | | 20–44 | | | Total no. of contraceptives needed for 1 yr supply |
Contraceptive method	Percent distribution[†]	Approximate no. of women	Percent distribution[§]	Approximate no. of women	Total no. of women	
Intrauterine devices	37	20,000	58	48,000	68,000	68,000
Contraceptive implants	35	19,000	17	14,000	33,000	33,000
Depot medroxyprogesterone acetate	9	5,000	7	6,000	11,000	44,000
Oral contraceptives	12	7,000	9	7,000	14,000	168,000
Contraceptive vaginal ring	5	3,000	7	6,000	9,000	108,000
Contraceptive patch	2	1,000	2	2,000	3,000	36,000
Total	100	55,000	100	83,000	138,000	457,000

* Includes women who are sexually active, fertile, and not sterilized nor using one of the most effective or moderately effective reversible contraceptive methods.
† Percent of contraceptive methods = distribution observed in CHOICE project for women aged 15–19 years (http://www.nejm.org/doi/pdf/10.1056/NEJMoa1400506).
§ Percent of contraceptive methods = distribution observed in CHOICE project for women aged 20–44 years (http://europepmc.org/articles/pmc4216614).

Summary

What is already known about this topic?

Zika virus infection during pregnancy has been linked to adverse pregnancy and birth outcomes, including pregnancy loss, intrauterine growth restriction, and congenital brain abnormalities. As of March 2016, Puerto Rico had the highest number of cases of Zika virus disease in the United States and its territories. Women residing in areas with active Zika virus transmission who do not desire pregnancy need access to effective and affordable contraception.

What is added by this report?

Approximately two thirds of pregnancies in Puerto Rico are unintended. An estimated 138,000 women of reproductive age (15–44 years) in Puerto Rico do not desire pregnancy and are not using an effective contraceptive method. Access to contraception is constrained by limited availability, especially of highly effective long-acting reversible contraceptives, high cost, incomplete insurance coverage, and lack of trained providers. To adequately prevent unintended pregnancies, there is an estimated need for IUDs for 68,000 women, contraceptive implants for 33,000 women, depot medroxyprogesterone acetate for 11,000 women, oral contraceptives for 14,000 women, vaginal rings for 9,000 women, and contraceptive patches for 3,000 women.

What are the implications for public health practice?

Removing barriers to contraception, such as cost, limited access, and lack of knowledge, could lead to increased use of highly effective contraceptive methods and reduced rates of unintended pregnancy, resulting in fewer adverse pregnancy and birth outcomes in the context of a Zika virus disease outbreak. This assessment of the resources and challenges in Puerto Rico related to contraceptive access might be a useful model for other areas with active transmission of Zika virus.

A collaborative and coordinated response is required from federal and local partners as well as other stakeholders, such as academic and professional organizations, private insurance companies, schools, and community leaders, to ensure access to contraception for women who desire to avoid pregnancy during the Zika outbreak in Puerto Rico and other affected areas. Increasing reimbursement and reducing costs for contraceptive services would support access. Efforts to increase opportunities for health care provider training on LARC insertion are needed. Education opportunities should be increased through health care providers, health educators, community leaders, schools, and other outreach mechanisms. This assessment of resources and challenges related to contraceptive access performed for Puerto Rico might be a useful model for other areas with active transmission of Zika virus.

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Cost-effectiveness of Increasing Access to Contraception during the Zika Virus Outbreak, Puerto Rico, 2016

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We modeled the potential cost-effectiveness of increasing access to contraception in Puerto Rico during a Zika virus outbreak. The intervention is projected to cost an additional $33.5 million in family planning services and is likely to be cost-saving for the healthcare system overall. It could reduce Zika virus–related costs by $65.2 million ($2.8 million from less Zika virus testing and monitoring and $62.3 million from avoided costs of Zika virus–associated microcephaly [ZAM]). The estimates are influenced by the contraception methods used, the frequency of ZAM, and the lifetime incremental cost of ZAM. Accounting for unwanted pregnancies that are prevented, irrespective of Zika virus infection, an additional $40.4 million in medical costs would be avoided through the intervention. Increasing contraceptive access for women who want to delay or avoid pregnancy in Puerto Rico during a Zika virus outbreak can substantially reduce the number of cases of ZAM and healthcare costs.

Zika virus infection during pregnancy can cause microcephaly with severe brain damage in the fetus (referred to here as Zika virus–associated microcephaly [ZAM]) and is linked to pregnancy loss and to problems in infants, including eye defects, hearing loss, and impaired growth (*1*). Zika virus is a flavivirus transmitted primarily by infected *Aedes* species mosquitos (*2*). Zika virus can also be sexually transmitted (*3*). Puerto Rico has the largest number of Zika virus disease cases in the United States and its territories (*4*) and, based on extrapolations from the experiences of other countries with Zika virus outbreaks, will probably experience large numbers of Zika virus–exposed pregnancies (*5*).

A primary strategy to reduce Zika virus–associated adverse pregnancy outcomes is to assist women who want to delay or avoid pregnancy. An estimated 65% of pregnancies in Puerto Rico are unintended (unwanted or mistimed), compared with 45% in the continental United States (*2,6*). Women in Puerto Rico face multiple barriers to contraceptive use, including high out-of-pocket costs, a shortage of contraceptive supplies, lack of education about options, and a limited number of family planning delivery sites (*2*).

In response to the Zika virus outbreak, the Centers for Disease Control and Prevention and other federal and local partners are seeking to improve access to contraception for women in Puerto Rico who desire it but encounter barriers to accessing the full range of contraception methods, including long-acting reversible contraceptives (LARCs). The objective of this analysis was to estimate the potential cost-effectiveness of increasing access to contraception in Puerto Rico during the 2016 Zika virus outbreak.

Methods

We constructed a decision tree cost-effectiveness model for a target population of 163,000 women who at the time of the intervention are sexually active with a male partner, fertile, not desiring pregnancy within the next 12 months, and not using permanent contraception methods (e.g., tubal ligation and vasectomy) (online Technical Appendix Table and Figure 1, http://wwwnc.cdc.gov/EID/article/23/1/16-1322-Techapp1.pdf). In the no intervention scenario, no changes in contraceptive use distributions from the status quo are expected to occur. In the intervention scenario, women in Puerto Rico are assumed to

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have same-day access to contraception methods, including LARC, with no out-of-pocket costs. In addition, healthcare providers would be trained to provide client-centered contraceptive counseling and outreach so that women have the information they need to make an informed choice on the contraception method that is best for them. The model specifies contraceptive method use distribution, unintended pregnancy events, and the frequency of ZAM (online Technical Appendix Figure 1).

We assumed an intervention in place throughout a year-long Zika virus outbreak in Puerto Rico. We evaluated the costs and outcomes of increased access to contraception compared with no intervention (i.e., status quo). Output measures included numbers of ZAM cases prevented, including stillbirths, elective terminations, and live-born infants, and healthy life years (HLY) gained. Economic benefits of the intervention included avoided costs from ZAM cases prevented and costs avoided for monitoring for Zika virus–exposed pregnancies and infants born from Zika virus–infected mothers. In addition, the avoided cost of prenatal, delivery, postpartum, and neonatal care associated with avoided unwanted pregnancies was considered an economic benefit. In cost-effectiveness analyses, if total avoided cost exceeds the cost of an intervention that improves health, the intervention is considered cost-saving. For scenarios with positive net costs, we reported the incremental cost-effectiveness ratio (ICER), which is the net cost per HLY gained in comparison to the status quo.

Independent of Zika virus–exposed pregnancies and ZAM, unintended pregnancy is associated with adverse maternal and child health outcomes. Because roughly 60% of unintended pregnancies are classified as mistimed, which might result in a delayed rather than avoided pregnancy, with the same costs occurring later (7), we only estimated avoided medical costs from prevention of the 40% of unintended pregnancies presumed to be not desired at a later time irrespective of Zika virus infection. However, we included all ZAM cases prevented during the intervention period.

Contraception Use with and without the Intervention

We estimated the inputs for the decision-tree model and their sources (Table 1, http://wwwnc.cdc.gov/EID/article/23/1/16-1322-T1.htm). In the no intervention scenario, we took the distribution of women in the target population by use of different types of reversible contraceptives (or no use) from a 2002 survey administered in Puerto Rico and adjusted it to reflect the 36% decrease in fertility rates in Puerto Rico during 2002–2015 (8,23,24).

For the main intervention scenario, we assumed that 50% of no contraception users, 60% of less-effective contraceptive method users, and 100% of moderately effective contraceptive method users would visit a healthcare provider during the intervention period and be counseled about contraception use (Table 1). The first 2 percentages are roughly twice the percentages of women reported in the 2011–2013 US National Survey on Family Growth to have received contraceptive services (contraception or counseling) within the past year because we assumed that, during the Zika virus outbreak, more women and providers would discuss contraception; virtually all moderately effective method users were assumed to see providers to obtain contraceptive prescriptions.

For the main scenario, we also assumed, optimistically, that 50% of women in the target population who receive contraceptive services during the Zika virus outbreak would be willing to change to a more effective contraceptive method, evenly divided between moderately effective and highly effective methods. We applied data from the Contraceptive CHOICE Project (67% of participants used LARC and 33% used moderately effective methods) (9) to the 40% of women assumed to not want to be pregnant; we assumed 20% of other women not intending pregnancy would use LARC. We further assumed that 30% of moderately effective contraception users would also choose to use condoms (dual-method use) under the intervention, based on a study reporting dual-method use among persons at risk for HIV (25).

Epidemiologic Model Input Parameters

We calculated method-specific annual pregnancy rates by applying failure rates of contraception methods under typical use (10), in combination with information on estimated numbers of unintended pregnancies, to adjust for other factors influencing pregnancy risk (19). We estimated the proportion of fetal losses among unintended pregnancies from data for the Caribbean region, including Puerto Rico (12), and calculated the proportion of induced abortion among unintended pregnancies from a survey conducted in Puerto Rico in 2001 (the latest year for which data were available) (11). We assumed that the distribution of fetal loss and induced abortions in unintended pregnancies unaffected by ZAM would not be altered by the Zika virus outbreak or the intervention.

For adverse pregnancy and birth outcomes associated with Zika virus, we only considered ZAM and associated brain anomalies, including live births, stillbirths, and terminations attributable to prenatal diagnosis. Although Zika virus can cause brain lesions and dysfunction in fetuses and newborns who do not have microcephaly (26), we lacked the data to model their prevalence and cost. In the main analysis, we assumed 58 cases of ZAM per 10,000 live births (range 32–86/10,000) based on a modeling study that considered data from other mosquitoborne illnesses in Puerto Rico and Zika virus outbreaks in other locations (5). We assumed a pregnancy loss rate of 35% among Zika

virus–exposed fetuses with diagnosed birth defects based on cases in the US Zika Pregnancy Registry as of July 21, 2016 (*14*).

A summary measure of population health impact is healthy life expectancy at birth. We projected gains in HLY by multiplying total cases of ZAM prevented by 30.0, which is the average number of quality-adjusted life-years at birth in the United States for an infant without severe microcephaly (*15*) and the estimated loss in disability-adjusted life years from microcephaly (*27*). We multiplied 30.0 by the sum of live births and fetal losses associated with ZAM to calculate gains in HLY. We included fetal losses in the HLY calculations because in the absence of ZAM those pregnancies would have resulted in live births, with the same healthy life expectancy as other children (*15*).

Cost Parameters

We conducted the analysis from a healthcare system perspective that includes direct medically related costs regardless of payer. We used payments from private insurance because payments from Medicaid might underestimate the cost of healthcare (*28*). Intervention costs included program costs of training providers, patient educational materials, outreach/media campaigns on the availability of contraceptives services, and program coordination and the incremental costs of family planning services. The latter comprised the costs of contraception methods and related office visits and services (e.g., insertion and removal of LARC for new method users resulting from the intervention and the cost of more intensive counseling for all women receiving contraceptive services during the intervention). We took the 1-year costs for contraception methods from the literature (*16,29*) and based the other program costs on the estimated costs for a pilot program planned to increase access to contraception in Puerto Rico as part of the current Zika virus outbreak response (*30*). We did not apply a discount rate to intervention costs because of the time horizon of 12 months.

Zika virus–related costs prevented by this intervention were in 2 parts: 1) costs for Zika virus testing and monitoring for Zika virus–exposed pregnancies and infants, and 2) costs of ZAM cases (Table 1). The cost estimates for testing and monitoring presumed 100% adherence by clinicians and patients to recommendations (*20–22*).

The lifetime cost per live-born infant with ZAM includes direct medical and nonmedical costs. ZAM is among the most severe types of microcephaly and is associated with loss of brain tissue volume, increased fluid spaces, and intracranial calcifications. All 3 cases of live-born infants with ZAM in French Polynesia demonstrated severe neurologic outcomes with delayed cognitive development (*26*). On the basis of expert opinion, infants with ZAM who survive the neonatal period would be expected to have neurologic dysfunction consistent with severe cerebral palsy within 1–2 years of birth.

As a proxy for the medical cost of ZAM, we used the estimated cost of treating infants with microcephaly associated with a diagnosis of symptomatic congenital cytomegalovirus (CMV). We used the MarketScan Commercial Database (Truven Health Analytics) with a sample of ≈100 million US residents covered by employer-sponsored insurance at any time during 2009–2014. We used average costs for 4 newborn infants with diagnoses of microcephaly and CMV who survived and were enrolled in a health plan for ≥3 years. For the direct nonmedical cost of ZAM, we used the estimated cost for supportive care for children with severe congenital brain injury, both paid care and unpaid care. The total lifetime cost for surviving infants with ZAM was estimated at $3.8 million per infant, taking into account infant and child mortality and discounting of costs in future years at a 3% rate per year; the sum of undiscounted costs for children who survive to adulthood might reach $10 million.

We determined the estimated non–Zika virus–related medical costs associated with women's prenatal care, labor and delivery, and postpartum care for pregnancies ending in live birth and neonatal care from a study of US commercial health plan expenditures (*17*). Estimates for costs associated with pregnancies ending in induced abortion were based on our analyses of commercial claims data (Table 1).

Sensitivity Analyses

Because many parameters used in the model are uncertain, we conducted sensitivity analyses on selected parameters, including different scenarios for the baseline and postintervention contraception use distributions in Puerto Rico. We tested alternate baseline contraception use distributions in Puerto Rico for women at risk for unintended pregnancy by using the actual distribution of method use reported in 2002 (*8*) and among women attending Title X clinics in Puerto Rico in 2014 (*31*). For the postintervention contraception use distribution, we tested scenarios assuming different proportions of women receiving contraceptive services from a healthcare provider, different levels of willingness to switch to a more effective method, and different shares of moderately effective and highly effective methods among switchers. Other parameters evaluated during sensitivity analysis included the incidence of ZAM during the Zika virus outbreak in Puerto Rico, percentage of pregnancies with ZAM terminated, the cost of caring for a live-born infant with microcephaly, and the cost of the intervention.

We conducted sensitivity analyses in which we altered selected assumptions. In one, we annualized the cost of LARC devices considering the expected duration of method use. In another, we adjusted observed data on US healthcare and supportive care costs to the generally lower levels

of prices in Puerto Rico market by applying conversion factors of ratios of healthcare spending per capita and wages of nurse assistants between the United States and Puerto Rico (*32,33*). We also conducted a probabilistic sensitivity analysis by using Monte Carlo simulation (10,000 draws) that assumed different distributions for all the parameters used in the model (Table 1). All analyses were conducted using TreeAge Pro 2016 software (TreeAge Software, Williamstown, MA, USA) and Excel 2013 (Microsoft, Redmond, WA, USA). All costs were adjusted to 2014 US dollars by using the health component of the Personal Consumption Expenditures price index (*34*).

Results

In the main scenario, we predict the intervention would prevent 25 cases of ZAM among unintended pregnancies avoided, of which 16 would have resulted in live births (Table 2). The incremental intervention cost of US $33.5 million (i.e., $206 per member of target population) relative to no intervention (status quo) is more than offset by $65.2 million in avoided Zika virus–associated costs, $2.8 million from extra testing and monitoring for pregnant women and infants for Zika virus–exposed pregnancies avoided, and $62.3 million from ZAM cases prevented. The net savings from Zika virus–associated costs alone is $31.7 million.

The number of ZAM cases prevented and Zika virus–associated costs avoided are sensitive to the proportion of women receiving contraceptive services and the proportion of those women willing to switch to a more effective contraception method during the Zika virus outbreak (Figure; Table 3). If the proportions of women receiving contraception services are assumed to be the same as estimated for the continental United States in the National Survey of Family Growth for 2011–2013 (i.e., 21% among no contraception users, 33% among less-effective method users, and 97% among all moderately effective method users), 16 cases of ZAM are prevented, and the net savings is $15.4 million (Table 3). If 10% of women receiving contraceptive services switch to a more effective method, 6 cases of ZAM are prevented, and net saving is $2.8 million. If the intervention only shifts users of moderately effective methods to a highly effective method (no change in non-use or use of less-effective methods), 7 ZAM cases are prevented,

Table 2. Zika virus–associated microcephaly cases and costs, as well as additional costs associated with unwanted pregnancies, with and without intervention to increase access to contraception to women during the Zika virus outbreak, Puerto Rico, 2016, in main scenario*†‡

Parameter	Without intervention	With intervention	Difference
Prevention of ZAM and Zika virus–associated cost			
Total no. ZAM cases	99	74	−25
No. pregnancy terminations	28	21	−7
No. stillbirths	7	5	−2
No. live births	64	48	−16
Cost of family planning services (under intervention also includes program cost)	$38,269,679	$71,738,133	$33,468,454
Total Zika virus–associated cost	$256,578,162	$191,422,342	−$65,155,820
Costs of extra testing and monitoring for Zika virus during pregnancy and for infants exposed in utero during Zika virus outbreak§	$11,125,061	$8,303,158	−$2,821,903
Direct costs of ZAM¶	$245,453,101	$183,119,184	−$62,333,917
Pregnancy terminations	$139,343	$103,956	−$35,387
Stillbirths	$40,025	$29,861	−$10,165
Live births	$245,273,733	$182,985,368	−$62,288,366
Cost savings from Zika virus–associated cost avoided only#			−$31,687,366
Prevention of unwanted pregnancies			
No. of unwanted pregnancies**	11,995	8,949	−3,046
No. induced abortions	3,385	2,525	−860
No. spontaneous abortions and fetal deaths	1,679	1,253	−426
No. unwanted live births	6,856	5,117	−1,739
Medical cost for unwanted pregnancy	$159,074,573	$118,722,504	−$40,352,069
Net cost savings from avoiding both Zika virus–associated cost and unwanted pregnancy cost††			−$72,039,435

*ZAM, Zika virus–associated microcephaly.
†The numbers in the columns and rows might not exactly match because of rounding.
‡Target population size: 163,000 women who do not intend to become pregnant during Zika virus outbreak. Women of reproductive age in Puerto Rico who are sexually active with a male partner, fertile, not desiring pregnancy, and not using permanent contraception methods (e.g., tubal ligation and vasectomy).
§Only including cost of testing for Zika virus and monitoring for exposed infants without ZAM; testing costs for infants with ZAM are included in the direct costs of ZAM.
¶From healthcare system perspective, includes direct medical and medical-related costs, including supportive care for persons with ZAM, even if the cost might not be paid by healthcare payers or delivered by healthcare providers.
#Total Zika virus–associated cost avoided (absolute value) minus the additional cost of family planning service under intervention compared with no intervention.
**Unwanted pregnancies which are not desired in the future (assuming 60% of unintended pregnancies are mistimed), irrespective of Zika virus infection
††Absolute value of net medical cost for unwanted pregnancy plus absolute value of net cost savings from Zika virus–associated costs avoided.
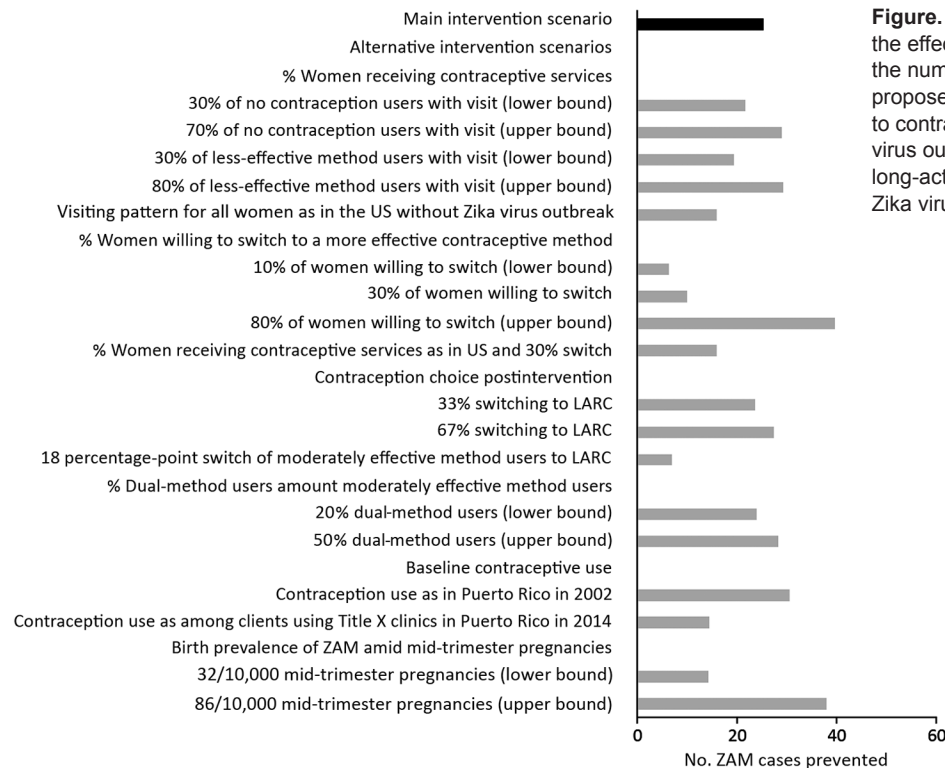
Figure. Sensitivity analysis indicating the effect of changes of assumptions on the number of ZAM cases prevented in a proposed intervention to increase access to contraception to women during the Zika virus outbreak, Puerto Rico, 2016. LARC, long-acting reversible contraceptive; ZAM, Zika virus–associated microcephaly.

with an ICER of $24,608/HLY gained. Increasing the proportion of dual-method users increases the number of cases of ZAM prevented and net savings attributable to higher contraception effectiveness. The results are also sensitive to the prevalence of ZAM among mid-trimester pregnancies, the percentage of ZAM cases resulting in live-born infants, lifetime cost per live-born infant with ZAM, and the intervention cost. If we adjust US cost estimates for lower prices in Puerto Rico while keeping intervention costs at US prices, net savings are $1.7 million. In all but 1 of the scenarios tested, the intervention is cost-saving.

A probabilistic sensitivity analysis scatter graph shows that most of the model simulations result in ICERs in the lower right quadrant with lower costs and better health outcomes (online Technical Appendix Figure 2). Specifically, the intervention is cost-saving in 92.11% of the 10,000 iterations, and in 98.10% of the iterations, the intervention has an ICER of <$20,000/HLY gained.

The intervention is also predicted to prevent $40.4 million in medical costs from unwanted pregnancies avoided in the main scenario (Table 2). In many sensitivity analyses, the cost avoided from these unwanted pregnancies prevented alone is greater than the intervention cost. The larger the numbers of no contraception users and less-effective method users receiving contraceptive services and willing to switch to more effective methods, the greater the magnitude of cost savings from unwanted pregnancies avoided (Table 3).

Discussion

The results of our modeling analysis suggest that increasing access to effective contraception in the context of the 2016 Zika virus outbreak for women in Puerto Rico who do not intend to become pregnant could proportionally reduce the number of unintended pregnancies and cases of ZAM by 25%. The intervention is cost-saving (negative net cost) when considering the benefits from preventing ZAM and avoiding Zika virus–exposed pregnancy costs in the main scenarios and in most of the scenarios we tested. In scenarios in which the intervention is not cost-saving, it is still cost-effective relative to accepted cost-effectiveness thresholds (*35*). The World Health Organization suggests that interventions that cost <3 times the gross domestic product per capita per HLY (equivalent to $150,000 in the United States and $60,000 in Puerto Rico) are cost-effective and those costing less than gross domestic product per capita are highly cost-effective (*36*). When considering additional benefits from preventing unintended pregnancies not desired at a later time, the intervention is cost-saving in all scenarios. Previous studies have shown that expanding access to contraception, especially LARC, is cost-saving (*16,37,38*). Likewise, our findings suggest that this intervention could be cost-saving or cost-effective within the context of a public health emergency response.

Our study has several limitations. First, we project the effects of a hypothetical intervention in place in

Table 3. Sensitivity analyses indicating the number of ZAM cases prevented and Zika virus–associated costs avoided in proposed intervention to increase access to contraception to women during Zika virus outbreak, Puerto Rico, 2016*

Parameter	No. ZAM cases prevented	Incremental intervention cost, millions	Zika virus–associated cost avoided, millions	Total incremental cost,† millions	Cost per HLY gained	Additional cost avoided from UP, millions
Main scenario	25	$33.5	$65.2	–$31.7	CS	$40.4
% Women receiving contraceptive services from healthcare provider; main scenario, 50% of no method users, 60% of less-effective method users, and 100% of moderately effective method users						
30% of no method users‡	22	$32.4	$55.8	–$23.5	CS	$34.6
70% of no method users	29	$34.6	$74.5	–$39.9	CS	$46.1
30% of less-effective method users	19	$26.0	$50.0	–$24.0	CS	$31.0
80% of less-effective method users	29	$38.5	$75.2	–$36.8	CS	$46.6
% Women receiving contraceptive services as in NSFG 2011–2013§	16	$25.2	$40.6	–$15.4	CS	$25.1
% Women willing to change to more effective method;¶ main scenario value: 50%						
10%	6	$13.0	$15.8	–$2.8	CS	$9.7
30%	16	$23.2	$40.5	–$17.3	CS	$25.0
80%	39	$48.8	$102.2	–$53.3	CS	$63.3
% Women receiving contraceptive services from healthcare provider as in NSFG 2011–2013 with 30% of them willing to change to a new method	10	$18.2	$25.7	–$7.6	CS	$15.9
Use of highly effective methods among switchers; main value 50%						
67%	27	$38.4	$69.9	–$31.5	CS	$43.3
33%	23	$28.5	$60.4	–$31.8	CS	$37.4
Contraception switching pattern reported in Colorado Family Planning Initiative#	7	$21.8	$17.0	$4.8	$24,608	$10.5
Dual-method use; 30% of moderately effective method users in main scenario						
20% of moderately effective users	24	33.1	61.3	–$28.2	CS	$38.0
50% of moderately effective users	28	34.1	−72.9	–$38.7	CS	$45.1
Contraception use distribution at baseline						
As reported in 2002 BRFSS survey**	30	33.6	−78.4	–$44.8	CS	$48.6
As in Title X clinics in 2014††	14	$30.1	$36.7	–$6.6	CS	$22.7
Rate of ZAM among all live-born infants; main scenario value 58/10,000						
32/10,000	14	$33.5	$37.5	–$4.0	CS	$40.4
86/10,000	38	$33.5	$96.3	–$62.8	CS	$40.3
Lifetime costs for microcephaly; main scenario value $3.8 million						
$1.9 million	25	$33.5	$33.5	0	CN‡‡	$40.4
$2.2 million	25	$33.5	$39.5	–$6.1	CS	$40.4
$5.5 million	25	$33.5	$93.5	–$60.0	CS	$40.4
Termination of pregnancy with ZAM						
20%	25	$33.5	$72.8	–$39.3	CS	$40.4
50%	25	$33.5	$44.1	–$10.6	CS	$40.3
Cost of the program other than providing the contraception at no cost to patients; main scenario value $39/person						
$0/person	25	$27.1	$65.2	–$38.0	CS	$40.4
$100/person	25	$43.4	$65.2	–$21.8	CS	$40.4
Annualized LARC device cost	25	$17.5	$65.2	–$47.7	CS	$40.4
Puerto Rico costs§§	25	$30.8	$32.5	–$1.7	CS	$14.4
Discount rate						
0%	25	$33.5	$105.4	–$72.0	CS	$40.4
5%	25	$33.5	$52.9	–$19.4	CS	$40.4

*BRFSS, Behavioral Risk Factor Surveillance System; CN, cost-neutral; CS, cost-saving; HLY, healthy life years; LARC, long-acting reversible contraceptive; NSFG, National Survey of Family Growth; UP, unwanted pregnancy; ZAM, Zika virus–associated microcephaly.
†Total incremental cost is the additional cost of contraception minus Zika virus–associated cost avoided.
‡30% of no contraception users, 60% of less-effective contraceptive method users, 100% of moderately effective contraceptive method users seeking contraceptive services from healthcare provider during the Zika virus outbreak.
§Based on NSFG 2011–2013, among women of reproductive age who are sexually active, did not intend to become pregnant, and were not using permanent contraceptive methods, 21% of no contraception users, 33% of less-effective contraceptive method users, 97% of moderately effective contraceptive method users, and 94% of dual-method users had at least 1 contraceptive service visit in the last 12 months (in total 50%).
¶Based on Title X Family Planning annual report for 2007–2015 in Colorado, 30% of clients who visited Title X clinics switched to a new method.
#Eighteen percentage points of users of moderately effective methods are assumed to switch to highly effective methods, of whom 21% were dual-method users.
**Contraception distribution in Puerto Rico in 2002 15.9% no method, 41.6% less-effective methods, 40.2% moderately effective methods, and 2.4% highly effective methods.
††In 2014, in Title X clinics in Puerto Rico, 20% of women at risk for unintended pregnancy used less-effective methods, 77% used moderately effective methods, and 2% used highly effective methods.
‡‡Intervention cost equals to the medical savings from ZAM cases prevented.
§§Conversion factor of 0.36 applied to pregnancy and ZAM medical costs based on the ratio of per capita medical expenditure in Puerto Rico and in the United States in 2012 as in Portela et al. 2015 (32); conversion factor of 0.72 applied to costs of supportive care for live-born infants with ZAM, based on the ratio of annual salary for assistant nurses in Puerto Rico and in the United States (33).

Puerto Rico during the 2016 Zika virus outbreak. However, the qualitative results would apply in future outbreaks. Second, the baseline contraception use distribution is based on a 2002 survey; the current distribution in Puerto Rico might be different. Third, uncertainty exists about the effect of the proposed intervention on postintervention contraceptive use distribution; however, the sensitivity analyses indicate that different distributions of LARC types among switchers does not have a substantial influence on the results. Fourth, our study assumes that women have full access to healthcare providers. In areas with limited access to providers, the effectiveness of the intervention might be lower, although Puerto Rico has a similar ratio of physicians to population as the United States as a whole (39), and despite a loss of physicians in recent years, Puerto Rico has a network of providers, federally qualified health clinics, and Title X providers in rural and urban areas. Fifth, the distribution of outcomes of unintended pregnancies in Puerto Rico is uncertain. We lack data on miscarriage and induced abortion rates in Puerto Rico and so did not have sufficient data to model uncertainty in these parameters. The rates of stillbirth and pregnancy termination among pregnancies with ZAM in Puerto Rico are also unknown. Our assumed percentage of live births among pregnancies with recognized ZAM (65%) compares with a 38% rate reported in French Polynesia during the 2013 Zika virus outbreak (11). Sixth, pregnancy intentions and use of contraception among women in Puerto Rico might differ during the Zika virus outbreak compared to preoutbreak periods. Seventh, our analysis does not consider possibly higher rates of fetal loss and induced abortion among women infected by Zika virus during early pregnancy or brain abnormalities or conditions related to Zika virus not involving microcephaly. Eighth, the assumed Zika virus testing costs assume 100% adherence to recommended testing practices; the actual cost savings taking nonadherence into account would be lower. Ninth, the cost estimates of ZAM cases in live-born infants do not include costs of managing mental health conditions among parents of affected infants. Tenth, using private insurance payments might overstate the healthcare cost of treating ZAM. However, if the cost of ZAM exceeds $1.9 million, the intervention is still cost-saving. Finally, if efforts to prevent transmission of Zika virus in Puerto Rico are effective, the rate of infection in pregnancy and the incidence of ZAM relative to that projected could be reduced.

Despite its limitations, our study has several strengths. First, the study is based on the most current available information. Second, the contraception scenarios are based on real-world programs and have resulted from consultation with subject matter experts. Third, expenditure data from a large sample of US residents with commercial health insurance were used to calculate the potential medical cost of ZAM on the basis of combinations of diagnostic codes for virus-associated microcephaly, although costs might be lower for similar children with public insurance. Finally, sensitivity analyses give consistent results indicating expected net cost savings associated with an intervention that would increase access to contraception in response to the Zika virus outbreak in Puerto Rico.

Zika virus can cause devastating birth defects, and infants born with ZAM and their families will require lifelong support. Avoiding unintended pregnancies is a critical intervention to mitigate the effects of ZAM. Efforts to prevent adverse Zika virus–related pregnancy outcomes in Puerto Rico are especially important because of limited resources (40). Our analyses suggest that increasing access to a full range of contraception among women in Puerto Rico who want to delay or avoid becoming pregnant during a Zika virus outbreak would be a cost-saving strategy to reduce the effects of ZAM. The magnitude of cost savings is even greater when considering the avoided cost of unwanted pregnancies prevented.

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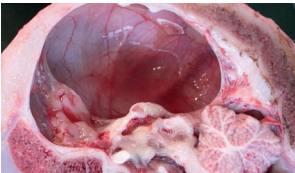
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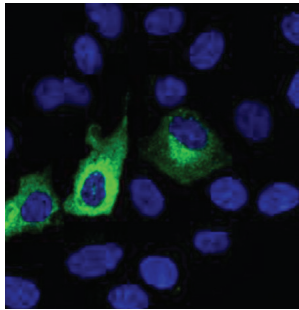
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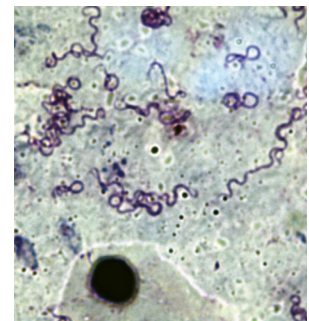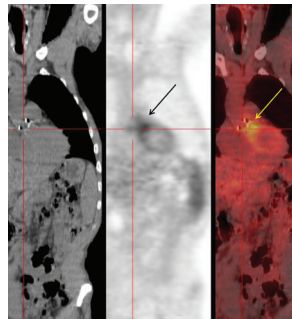
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GYNECOLOGY

Three-year continuation of reversible contraception

Justin T. Diedrich, MD, MSCI; Qiuhong Zhao, MS; Tessa Madden, MD, MPH;
Gina M. Secura, PhD; Jeffrey F. Peipert, MD, PhD

OBJECTIVE: The objective of this analysis was to estimate the 3-year continuation rates of long-acting reversible contraceptive (LARC) methods and to compare these rates to non-LARC methods.

STUDY DESIGN: The Contraceptive CHOICE Project (CHOICE) was a prospective cohort study that followed 9256 participants with telephone surveys at 3 and 6 months, then every 6 months for 2—3 years. We estimated 3-year continuation rates of baseline methods that were chosen at enrollment. The LARC methods include the 52-mg levonorgestrel intrauterine device; the copper intrauterine device, and the subdermal implant). These were then compared to rates to non-LARC hormonal methods (depot medroxyprogesterone acetate, oral contraceptive pills, contraceptive patch, and vaginal ring). Eligibility criteria for this analysis included participants who started their baseline chosen method by the 3-month survey. Participants who discontinued their method to attempt conception were censored. We used a Cox proportional hazard model to adjust for confounding and to estimate the hazard ratio for risk of discontinuation.

RESULTS: Our analytic sample consisted of 4708 CHOICE participants who met inclusion criteria. Three-year continuation rates were 69.8% for users of the levonorgestrel intrauterine device, 69.7% for copper intrauterine device users, and 56.2% for implant users. At 3 years, continuation was 67.2% among LARC users and 31.0% among non-LARC users ($P < .001$). After adjustment for age, race, education, socioeconomic status, parity, and history of sexually transmitted infection, the hazard ratio for risk of discontinuation was 3-fold higher among non-LARC method users than LARC users (adjusted hazard ratio, 3.08; 95% confidence interval, 2.80—3.39).

CONCLUSION: Three-year continuation of the 2 intrauterine devices approached 70%. Continuation of LARC methods was significantly higher than non-LARC methods.

Key words: contraception, continuation, intrauterine device, long-acting reversible contraception, subdermal implant

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L ong-acting reversible contraceptive (LARC) methods are highly effective and have high user satisfaction.[1] Their use has increased in the United States over the past 2 decades; approximately 8.5% of women who use contraception report current use of a LARC method.[2] In fact, a recent report demonstrated a nearly 5-fold increase in LARC methods over the last decade.[3] LARC users are likely to be highly satisfied with their method at 12 and 24

EDITORS' ★ CHOICE

months.[4,5] However, data are lacking regarding continuation of LARC methods at 3 years in the United States. Some of the previous studies that assessed longer-term continuation randomly assigned women to a contraceptive method and included women from many different countries.[6,7] The largest study was performed by Sivin et al.[8] This multinational study randomly assigned women to the

levonorgestrel-20 (the predecessor to the current levonorgestrel-containing intrauterine device [LNG-IUD]) and the TCu380Ag (the predecessor to the current copper-intrauterine device [Cu-IUD]). Cumulative continuation at 3 years was 49% among LNG-20 users and 59% among TCu380Ag users. Other prospective studies found 3-year continuation rates of 67—78% among users of Cu-IUDs.[9,10] Continuation of LNG-IUD has been reported at 73—80% at 3 years.[11,12]

5,090 women in 1st cohort who were followed 36 months

→ Excluded: did not start method by 3 months

185 women censored for pregnancy intention

4,708 included in analysis

Flow chart of participants included in analysis.

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

Subdermal implants have international continuation rates of 30—53%.[12-15]

This analysis was performed to estimate the rates of 36-month continuation of the baseline contraceptive method that was chosen and to compare continuation rates of LARC and non-LARC methods at enrollment into the Contraceptive CHOICE Project. In addition, we explored baseline characteristics that are associated with discontinuation of contraceptive methods. We hypothesized that 36-month continuation rates for the LARC methods would exceed 60% and that continuation would be significantly higher for LARC methods than non-LARC methods.

MATERIALS AND METHODS

In 2007, the Contraceptive CHOICE Project (CHOICE) began recruiting women for a prospective observational cohort study. The goal of the study was to reduce the unintended pregnancy rate in the St. Louis, MO, area by promoting the most effective methods of contraception and eliminating the cost barrier to all forms of contraception. The methods have been reported in detail[16] but are described briefly below. The Human Research Protection Office at Washington University in St. Louis approved the study protocol before study recruitment.

Participants were referred to CHOICE through their health care providers, posted flyers, and word of mouth. Recruitment sites included local health care centers, 2 abortion care providers, and a university-associated clinical research center. Inclusion criteria included women who (1) were 14—45 years of age, (2) desired reversible contraception and were willing to start a new method, (3) were sexually active with a male partner or intended to be within 6 months, (4) who lived in or received reproductive care in the St. Louis area, and (5) were able to consent in English or Spanish. Women were excluded if they desired pregnancy in the next 12 months or were had had hysterectomy or permanent sterilization. Recruitment of the 9256 participants began in 2007 and was completed in 2011. All participants provided written informed consent before study enrollment.

All potential participants heard a standardized introduction to LARC methods; upon enrollment, they received additional contraceptive counseling.[17] LARC methods included the LNG-IUD, the Cu-IUD, and the 3-year subdermal implant. The contraceptive counseling reviewed all reversible methods in order of effectiveness from most to least effective. After a baseline interview, participants completed screening for sexually transmitted infections, received their contraceptive of choice at no cost, and were followed for 2 or 3 years, depending on the timing of enrollment. Follow-up telephone interviews were performed at 3 and 6 months then every 6 months thereafter for the duration of study participation. At the enrollment visit, each participant chose her baseline method. When possible, they would start that method immediately. In certain cases (such as when pregnancy could not be ruled out reasonably), the patient received a bridge method until they returned for the initiation of their chosen method. Bridge methods included depot medroxyprogesterone acetate (DMPA), oral contraceptive pills (OCPs), combined contraceptive patch, vaginal ring, or condoms. Participants were able to switch methods at any time during the follow-up period. For the purposes of this analysis, if a participant switched her method, we considered this a
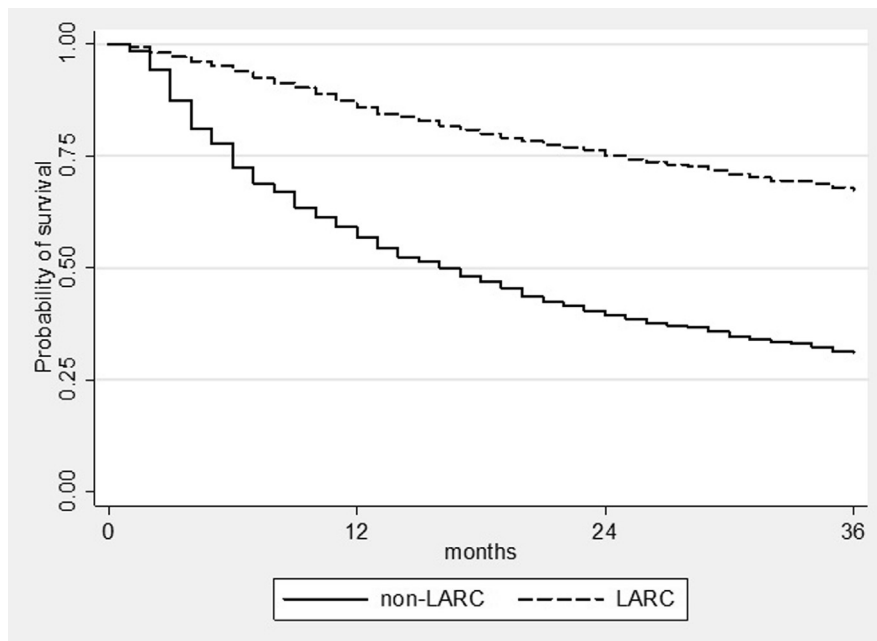
Kaplan-Meier Survival Curve of long-acting reversible contraceptive methods and non-long-acting reversible contraceptive methods.

LARC, long-acting reversible contraceptive method.

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

TABLE 1
Baseline characteristics of analytic sample, stratified by contraceptive method and age

Variable	Overall (n = 4708)	Non-long-acting reversible contraceptive method (n = 1505)	Long-acting reversible contraceptive method (n = 3203)	P value
Age, y[a]	25.2 ± 5.7	24.0 ± 5.0	25.7 ± 5.9	< .001
Race, n (%)				.668
Black	2243 (47.7)	723 (48.1)	1520 (47.5)	
White	2100 (44.6)	659 (43.8)	1441 (45.0)	
Other	364 (7.7)	122 (8.1)	242 (7.6)	
Education, n (%)				< .001
≤High school	1661 (35.3)	472 (31.4)	1189 (37.1)	
Some college	1987 (42.2)	666 (44.3)	1321 (41.3)	
College graduate	1058 (22.5)	366 (24.3)	692 (21.6)	
Body mass index, n (%)				< .001
Underweight	144 (3.1)	72 (4.9)	72 (2.3)	
Normal	1895 (41.2)	718 (49.2)	1177 (37.4)	
Overweight	1206 (26.2)	333 (22.8)	873 (27.8)	
Obese	1357 (29.5)	336 (23.0)	1021 (32.5)	
Low socioeconomic status, n (%)[b]				< .001
No	2088 (44.4)	776 (51.6)	1312 (41.0)	
Yes	2618 (55.6)	728 (48.4)	1890 (59.0)	
Insurance, n (%)				< .001
None	2031 (43.5)	683 (46.0)	1348 (42.4)	
Private	2081 (44.6)	711 (47.9)	1370 (43.0)	
Public	556 (11.9)	91 (6.1)	465 (14.6)	
Parity, n (%)				< .001
0	2225 (47.3)	988 (65.6)	1237 (38.7)	
1	1150 (24.4)	290 (19.3)	860 (26.8)	
2	819 (17.4)	149 (9.9)	670 (20.9)	
3+	514 (10.9)	78 (5.2)	436 (13.6)	
Unintended pregnancies, n (%)				< .001
0	1599 (34.0)	704 (46.9)	895 (28.0)	
1	1292 (27.5)	423 (28.2)	869 (27.2)	
2	780 (16.6)	188 (12.5)	592 (18.5)	
3+	1027 (21.9)	187 (12.5)	840 (26.3)	

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.   (continued)

discontinuation of the baseline method. Women who received the implant were told that it was approved for up to 3 years of use. If a participant had the device removed and reinserted within the same month, it was not considered a discontinuation. Follow-up interviews focused on method use, complaints, complications, side-effects, method troubleshooting, reasons for method discontinuation, and pregnancies. CHOICE participants have unrestricted access to device removal, even after CHOICE ended.

This analysis included women who chose a LARC or a non-LARC method (DMPA, OCPs, contraceptive patch, or vaginal ring), started using their method

TABLE 1
Baseline characteristics of analytic sample, stratified by contraceptive method and age (continued)

Variable	Overall (n = 4708)	Non-long-acting reversible contraceptive method (n = 1505)	Long-acting reversible contraceptive method (n = 3203)	P value
History of abortion at baseline, n (%)				< .001
No	2870 (61.0)	969 (64.4)	1901 (59.4)	
Yes	1838 (39.0)	536 (35.6)	1302 (40.6)	
History of sexually transmitted infection at baseline				.011
No	2869 (61.0)	957 (63.6)	1912 (59.7)	
Yes	1836 (39.0)	547 (36.4)	1289 (40.3)	

[a] Data are given as mean ± SD; [b] Includes trouble paying for basic necessities or receiving government subsidies in the form of food stamps or welfare.

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

TABLE 2
Kaplan-Meier estimates of 1-, 2-, and 3-year continuation of baseline method chosen

Variable	Continuation, % (95% confidence interval)		
	1 Year	2 Year	3 Year
Overall	76.7 (75.4—77.9)	64.2 (62.6—65.5)	56.2 (54.5—57.5)
Intrauterine device			
Levonorgestrel	87.3 (85.8—88.6)	76.7 (74.8—78.5)	69.8 (67.6—71.8)
Copper	84.3 (80.7—87.3)	76.2 (72.1—79.9)	69.7 (65.1—73.7)
Implant	81.7 (78.3—84.7)	68.7 (64.7—72.3)	56.2 (51.8—60.3)
Depot medroxyprogesterone acetate	57.1 (51.6—62.3)	39.3 (33.8—44.7)	33.2 (26.9—37.7)
Oral contraceptive pill	60.6 (56.3—64.6)	42.2 (37.9—46.5)	31.5 (27.3—35.8)
Ring	54.3 (49.7—58.6)	37.5 (33.1—41.9)	30.0 (25.8—34.4)
Patch	48.2 (38.3—57.4)	35.0 (25.7—44.5)	28.4 (19.5—37.9)
Long-acting reversible contraceptive	85.8 (84.5—87.0)	75.2 (73.6—76.7)	67.2 (65.4—68.9)
Non-long-acting reversible contraceptive	55.8 (54.2—59.4)	39.5 (36.9—42.1)	31.0 (28.5—33.5)
Adolescents, 14—19 y			
Long-acting reversible contraceptive	82.1 (78.0—85.6)	68.0 (63.0—72.5)	52.6 (47.2—57.7)
Non-long-acting reversible contraceptive	48.5 (42.1—54.6)	34.5 (28.5—40.6)	23.1 (17.6—29.0)
Adults, 20—45 y			
Long-acting reversible contraceptive	86.3 (85.0—87.6)	76.2 (74.5—77.8)	69.2 (67.4—71.0)
Non-long-acting reversible contraceptive	58.6 (55.7—61.3)	40.5 (37.7—43.4)	32.6 (29.8—35.4)

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

by their 3-month survey, and completed their 36-month follow-up survey or had another data source that verified continuation or discontinuation at 3 years. Continuation rates at 3 years were estimated for each method. LARC methods were compared with non-LARC methods and were stratified by age (14—19 and 20—45 years old). Descriptive analyses were performed to describe demographic characteristics of participants with the use of chi-square test or *t*-test, where appropriate. Normality was assessed for continuous variables. The time-to-event for this survival analysis was calculated from method initiation to the time point when the participant discontinued her contraceptive method. If she was lost to follow up, she was censored at her last time of contact with CHOICE. Participants were censored if they discontinued a contraceptive method to attempt pregnancy. Kaplan-Meier survival functions were used to estimate continuation rates among different methods. We used Cox proportional hazard models to estimate hazard ratios for risk of contraceptive method discontinuation for characteristics that were associated with discontinuation. We defined *confounders* as variables that changed the estimate of hazard ratio for a contraceptive method by ≥10% when they were included in the model. Confounding variables and significant factors from univariable analysis or variables that were set a priori were

included in the final multivariable model to evaluate their effect size. The alpha level was set at .05. Stata software (version 11; StataCorp, College Station, TX) was used for all analyses.

RESULTS

Of 9256 CHOICE participants, the first 5090 were observed for 3 years. In this cohort, 382 women were excluded because they did not start their chosen baseline method by the 3-month survey. There were a total of 4708 participants (92%) who were observed for 3 years and were included in this analysis. A flow diagram of included participants is shown in Figure 1. There were 185 women (4%) who were censored because of discontinuation for desire to conceive or pregnancy.

Demographic and reproductive characteristics are shown in Table 1. Mean age of participants in this analysis was 25 years; 48% were black; 35% had a high school education or less; 34% received public assistance; 44% had no health insurance; and 12% reported public insurance. Overall, 47% were nulliparous, and 66% reported at least 1 unintended pregnancy at baseline. There were 662 adolescents in our cohort: 405 used LARC methods and 257 used non-LARC methods. In our stratified analysis by LARC vs non-LARC methods, we noted that LARC users were older, had higher parity, were more likely to have public insurance, and were more likely to have a history of an unintended pregnancy.

Continuation at 1, 2, and 3 years for each contraceptive method is listed in Table 2. We stratified continuation by LARC and non-LARC methods. At 3 years, continuation was 67.2% among LARC users and 31.0% among non-LARC users (P < .001) (Figure 2). The highest continuation was among IUD users, with 69.8% continuation among LNG-IUD users and 69.7% among Cu-IUD users. Non-LARC methods had lower rates of continuation that range from 28—33% at 3 years. Among adolescents 14—19 years old, 3-year continuation was lower for all methods compared with women 20—45 years old and was lowest among non-LARC methods (52.6% for adolescents who

TABLE 3
Univariable analysis of risk factors for discontinuation of baseline contraceptive method at 3 years

Variable	Univariable model	
	Hazard ratio	95% Confidence interval
Contraceptive method		
Oral contraceptive pill		Reference
Intrauterine device		
Levonorgestrel	0.30	0.27—0.35
Copper	0.31	0.26—0.38
Implant	0.48	0.40—0.56
Depot medroxyprogesterone acetate	1.01	0.85—1.20
Patch	1.21	0.94—1.56
Ring	1.12	0.96—1.30
Age, y		
14—19	1.55	1.38—1.74
20+		Reference
Race		
Black	1.20	1.09—1.32
White		Reference
Other	1.30	1.10—1.54
Education		
≤High school		Reference
Some college	0.93	0.84—1.03
College graduate	0.82	0.73—0.93
Body mass index		
Underweight	1.18	0.92—1.51
Normal		Reference
Overweight	0.91	0.82—1.02
Obese	0.78	0.70—0.87
Low socioeconomic status[a]		
No		Reference
Yes	0.95	0.87—1.04
Insurance		
None	1.07	0.97—1.18
Commercial		Reference
Public	1.04	0.90—1.20
Parity		
0	1.38	1.27—1.51
1+		Reference

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.   (continued)

TABLE 3
Univariable analysis of risk factors for discontinuation of baseline contraceptive method at 3 years (continued)

Variable	Univariable model	
	Hazard ratio	95% Confidence interval
Previous unintended pregnancies		
0		Reference
1+	0.79	0.72—0.87
History of sexually transmitted infection		
No		Reference
Yes	1.13	1.03—1.24

a Defined as trouble paying for basic needs (food, housing, medical care, transportation) or receiving government aid (food stamps, welfare).

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

TABLE 4
Multivariable analysis of risk factors for discontinuation of baseline contraceptive method at 3 years

Variable	Multivariable model	
	Hazard ratio	95% Confidence interval
Contraceptive method		
Oral contraceptive pills		Reference
Intrauterine device		
Levonorgestrel	0.31	0.27—0.36
Copper	0.33	0.27—0.40
Implant	0.44	0.37—0.52
Depot medroxyprogesterone acetate	0.93	0.78—1.11
Patch	1.17	0. 91—1.52
Ring	1.16	1.00—1.35
Contraceptive duration		
Long-acting reversible contraceptive		Reference
Non-long-acting reversible contraceptive	3.08	2.80—3.39
Age, y		
14—19	1.33	1.16—1.53
20+		Reference
Race		
Black	1.12	1.01—1.25
White		Reference
Other	1.26	1.07—1.50
Education		
≤High school		Reference
Some college	0.93	0.84—1.04
College/graduate	0.85	0.74—0.98

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.   (continued)

used LARC and 23.1% for non-LARC methods). By 3 years, 54.6% of adolescents continued the LNG-IUD; 49.5% continued the Cu-IUD, and 50.8% continued the subdermal implant.

Univariable analysis of risk factors for discontinuation is shown in Table 3; the multivariable model is shown in Table 4. After adjustment for age, race, education, low socioeconomic status, parity, and history of sexually transmitted infection, the hazard ratio for discontinuation was >3 times higher among non-LARC method users (adjusted hazard ratio, 3.08; 95% confidence interval, 2.80—3.39) than LARC users. Participants 14-19 years old at baseline were more likely to discontinue at 3 years compared with women ≥20 years old (adjusted hazard ratio, 1.33; 95% confidence interval, 1.16—1.53). Compared to those with a high school education or less, college graduates reported a lower risk of discontinuation (adjusted hazard ratio, 0.85; 95% confidence interval, 0.74—0.98).

Participants discontinued their baseline methods for a variety of reasons (Table 5). Of LNG-IUD users who discontinued this method, approximately 19% did so because of bleeding changes; 25% reported "I did not like how it made me feel." The most common reasons for Cu-IUD users to stop their method was bleeding changes (35%) and cramping (17%). Forty-five percent of implant discontinuers reported bleeding changes; 28% reported that they did not like how they felt. Among non-LARC methods, 33% of DMPA users who stopped this method reported general side-effects as the most common reason for discontinuation. Forty-two percent of OCP users who discontinued reported logistical reasons, such as the pill being hard to remember to take or hard to get. Of patch discontinuers, 41% reported side-effects. Twenty-seven percent of women who discontinued the ring reported side-effects; 24% reported logistical issues.

COMMENT
Continuation rates for LARC methods at 1, 2, and 3 years are significantly higher than non-LARC methods. After adjustment for confounding variables, the

TABLE 4
Multivariable analysis of risk factors for discontinuation of baseline contraceptive method at 3 years (continued)

Variable	Multivariable model	
	Hazard ratio	95% Confidence interval
Low socioeconomic status[a]		
No		Reference
Yes	1.05	0.95—1.17
Parity		
0	1.10	0.98—1.23
1+		Reference
History of sexually transmitted disease		
No		Reference
Yes	1.21	1.10—1.34

[a] Low socioeconomic status is defined as trouble paying for basic needs (food, housing, medical care, transportation) or receiving government aid (food stamps, welfare)

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

choice of a shorter-acting method and younger age were associated with increased discontinuation.[1,4,18,19] Teens 14—19 years of age were more likely to discontinue than women of ≥20 years old. However, of those adolescents who chose LARC methods, more than one-half were still using their method at 3 years compared with one-fifth of adolescents who were using their non-LARC methods at 3 years. Even among women who were using short-acting methods, 3-year continuation was relatively high. Those who used OCPs, DMPA, patch, and ring had continuation rates of 28—33%.

Relatively few previous studies have estimated continuation beyond 1 year among women in the United States who chose their contraceptive method rather than being randomly assigned to a method. Furthermore, this analysis was conducted with the data from the CHOICE cohort with a high follow-up rate in which only 19% of participants were lost to follow up at 3 years. Our cohort had continuation rates that were consistent with other prospective trials. The 70% continuation of both LNG- and Cu-IUDs was consistent with the previously reported 67—80%.[9-12] The 56% continuation of implants was higher than the previously reported 30—53%.[12-15]

It is very plausible that women who are interested in long-term (>2 years) protection from pregnancy are more likely to select IUDs and the implant; women who are less certain about their need or desire for long-term contraception would select non-LARC methods. However, we still believe our estimates of 3-year continuation are important for contraceptive counseling. High continuation rates reflect high satisfaction with LARC methods.[5]

The major limitation of CHOICE is that it is a convenience sample within 1 geographic region. Participants were required to start or switch to a different

TABLE 5
Reasons for discontinuation of baseline contraceptive method in Contraceptive CHOICE Project

Variable	Long-acting reversible contraception, n (%)			Non-long-acting reversible contraception, n (%)			
	Levonorgestrel-intrauterine device	Copper-intrauterine device	Implant	Depo medroxyprogesterone acetate	Oral contraceptive pill	Patch	Ring
Bleeding changes	136 (19.1)	75 (35.2)	133 (45.5)	58 (25.6)	49 (12.3)	4 (4.8)	39 (10.4)
Pain	82 (11.5)	37 (17.4)	8 (2.7)	4 (1.8)	3 (0.8)	2 (2.4)	9 (2.4)
Did not like "side-effects"	181 (25.4)	20 (9.4)	81 (27.7)	76 (33.5)	62 (15.6)	34 (41.0)	100 (26.7)
Desired pregnancy	67 (9.4)	22 (10.3)	17 (5.8)	4 (1.8)	8 (2.0)	3 (3.6)	15 (4.0)
Method failed	9 (1.3)	3 (1.4)	0	2 (0.9)	25 (6.3)	4 (4.8)	11 (2.9)
Expulsion/came off /fell out	96 (13.5)	26 (12.2)	—	—	—	5 (6.0)	14 (3.7)
Difficult to use	0	0	0	0	0	0	20 (5.3)
Logistics[a]	0	0	0	22 (9.7)	169 (42.5)	14 (16.9)	89 (23.7)
All others	142 (19.8)	30 (14.1)	53 (18.2)	61 (26.7)	82 (20.6)	17 (20.5)	78 (20.8)
Totals	713	213	292	227	398	83	375

[a] Time, hard to get, remember.

Diedrich. Three-year contraceptive continuation. Am J Obstet Gynecol 2015.

contraceptive method at enrollment, which may also limit generalizability. An important consideration in this analysis is our assessment of 3-year continuation of the subdermal implant. This may be an inappropriate cut-off to measure continuation and satisfaction if women undergo implant removal because of the approaching "expiration" of the device at 3 years (the Food and Drug Administration-approved duration of use).[20] Another limitation is that data on side-effects, continuation, and expulsion were self-reported through phone follow up instead of at clinic visits.

Regardless of age, sociodemographic markers, and education, women who use LARC methods report high continuation rates at 3 years. OCPs and condoms continue to be the reversible contraceptive methods most commonly used by women in the United States.[3] It is time for a paradigm shift: LARC methods should be considered first-line contraceptives for women of all ages, given that satisfaction, continuation, and effectiveness have been shown to be superior to non-LARC methods.[1,4,5,21] ∎

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With Pills, Patches, Rings, and Shots: Who Still Uses Condoms? A Longitudinal Cohort Study

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Abstract

Purpose—To describe women's condom use patterns over time and assess predictors of dual method use 12 months after initiating hormonal contraceptives.

Methods—We conducted a prospective cohort study among women aged 15–24 years initiating oral contraceptive pills, patch, ring, or depot medroxyprogesterone and attending public family planning clinics. Participants completed questionnaires at baseline and 3, 6, and 12 months after enrollment. We used multivariable logistic regression to assess baseline factors associated with dual method use at 12 months among 1,194 women who were sexually active in the past 30 days.

Results—At baseline, 36% were condom users, and only 5% were dual method users. After initiation of a hormonal method, condom use decreased to 27% and remained relatively unchanged thereafter. Dual method use increased to a peak of 20% at 3 months but decreased over time. Women who were condom users at baseline had nearly twice the odds of being a dual method user at 12 months compared with nonusers (adjusted odds ratio [AOR] = 2.01, 95% CI: 1.28–3.14). Women who believed their main partner thought condoms were "very important," regardless of perceived sexually transmitted infection risk or participant's own views of condoms, had higher odds of dual method use (AOR = 2.89, 95% CI: 1.47–5.71).

Conclusions—These results highlight a potential missed opportunity for family planning providers. Providers focus on helping women initiate hormonal methods, however, they may improve outcomes by giving greater attention to method continuation and contingency planning in the event of method discontinuation and to the role of the partner in family planning.

Keywords

Dual method; Contraception; Adolescent; Young adult; Condoms; Sexually transmitted diseases; Depot medroxyprogesterone acetate; Oral contraceptives; Contraceptive patch; Vaginal ring

Between 1996 and 2006, pregnancy rates among teenaged women (aged 15–19 years) in the United States decreased by nearly 33%, yet as of 2006 (the most recent year for which data

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are available) an estimated 82% of these were unintended [1–3]. Sexually experienced teens and young adults have unintended pregnancy rates more than twice the national figure (69 per 1,000) for sexually active women of childbearing age, with the highest rates (162 per 1,000) among 18–19 year olds [4]. In addition to disproportionately high rates of unintended pregnancy, women aged 15–24 years also experience high rates of sexually transmitted infections (STIs). Although comprising only 25% of the sexually active population, teens and young adults are responsible for more than half of gonorrhea infections and nearly 75% of chlamydia infections [5]. Unintended pregnancy and STIs remain high, despite widespread use of contraceptives. Between 2006 and 2010, more than 86% of never-married female teens and 93% of never-married male teens had used a contraceptive method at last sex. Of this, condom use accounted for 75% and 52% by men and women, respectively [1].

Dual method use, defined as the use of a contraceptive method plus condoms, has been promoted as an effective way to mitigate the burden of both unintended pregnancy and STIs in teens and young adults. Although the prevalence of dual method use among teens has been found to be as high as 20%, when young adults are included, dual method use is as low as 8.3% [1,6]. Our understanding of factors associated with increased dual method use is very limited. Much of the prior research on dual method use has been cross-sectional, which is inadequate to assess the temporal relationship between factors that might contribute to dual method use [7–10]. In addition, few studies have been designed to analyze continued condom use at the time that women initiate hormonal contraception. Finally, many prior studies have been hampered by methodological flaws, including small sample sizes [7,9–12], differing lengths of follow-up for women using different methods [12], inconsistent definitions of dual method use including ineffective methods such as abstinence or withdrawal [7], and inconsistent definitions of discontinuation (discontinuation of condoms or the hormonal method), limiting the inferences to be drawn and generalizability of this prior research [13].

We examined condom use patterns over time in a large cohort of high-risk young women initiating hormonal contraception, including relatively newer contraceptive methods not previously studied: the transdermal patch and the vaginal ring. Additionally, we sought to identify predictors of dual method use over a 1-year period to inform strategies for increasing dual method use.

Materials and Methods

Subjects

Data for this study were collected as part of a larger study on factors associated with method discontinuation and pregnancy among adolescents and young women initiating hormonal contraception; detailed description of the study methods are described elsewhere [14]. In the original cohort, women initiating hormonal contraceptives, either the pill, patch, ring, or depot medroxyprogesterone, were recruited from four Planned Parenthood clinics in Northern California (Vallejo, Richmond, East Oakland, and Hayward) between September 2005 and July 2008. The study was designed specifically to examine newer short acting hormonal method use and therefore women using other effective methods including long acting reversible contraceptive (LARC) methods at baseline were not enrolled. Women, however, could switch to any method including LARCs over the 1-year follow-up period, although few did this. Women who presented for reproductive health care were screened consecutively. Eligibility criteria included being between 15 and 24 years old, not married, able to read English or Spanish, not pregnant (self-report) or desiring pregnancy within the next year, and able to provide written informed consent and comply with study procedures. Women could not have previously used the method they were initiating at the visit. Research staff collected data from enrolled participants via self-administered electronic questionnaires

at baseline and 3, 6, and 12 months. All participants provided written informed consent. Given that minors can consent to contraceptive services in California without parental consent and that attempting to obtain parental consent could have compromised the adolescents' guarantee of confidential services, parental consent was not required. The study was approved by the Committee on Human Research at the University of California, San Francisco.

Measures

The primary outcome measure was dual method use at 1 year. Dual method use was defined as condom use plus an effective contraceptive method. Effective contraceptive methods included the pill, patch, ring, implant, or IUD. Effective contraceptive method use was determined from questions about method used at last sex and continued use of the hormonal method initiated at baseline. Women were considered condom users if the percent of time they reported using a condom divided by the number of times they reported having sex in the past 30 days was equal to or greater than 80%. We based our definition of a condom user on evidence from a recent cohort study that demonstrated that using a proportion of protected acts (number of times a condom was used divided by the number of vaginal sex acts during a typical month in the past 3 months) was more predictive of pregnancy incidence than other measures (since last visit, at last sex, or frequency measure), although no one method was most predictive of STI/HIV incidence [15].

Independent variables considered for the analysis included those found to be associated with dual method use in previous studies as well as variables informed by the Health Belief Model, which states that individuals weigh the costs and benefits of a health-related behavior before attempting behavior change, and the Theory of Planned Behavior, which takes into account subjective norms around the behavior based on attitudes of individuals close to the person [16,17]. We grouped variables into the following categories: sociodemographic characteristics, reproductive history, and attitudes toward condom use.

Sociodemographic characteristics collected at baseline included age, neighborhood income, race and ethnicity, education, and employment status. Sexual and reproductive history measures included prior pregnancies and STIs, partner concurrency (having sex with a man other than main partner), and length of time they had sex with their main partner (0–3 months, 4–6 months, 7–12 months, >12 months, and no sex yet). Perceived STI risk in the next 3 months was measured on a Likert scale (not at all likely, a little likely, somewhat likely, very likely, don't know). Participant's beliefs toward condom use were derived from responses to a series of questions with answers on a Likert scale. The items were "Condoms should always be used, even if the girl uses birth control like the pill, patch, ring, or the shot" and "A girl does not need to use condoms if she gets checked at the clinic often" (responses for both questions included: strongly agree, agree, neither, disagree, and strongly disagree). Assessment of the attitudes of the woman and her partner toward condoms was obtained from the following questions: "How important do you think it is for your main partner to use condoms when he has sex with you? FOR HIM is it…" and "How important is it for YOU to use condoms when you have sex with your main partner?" (responses included: not at all important, somewhat important, very important, and don't know). For women who reported condom use at last sex, reason for condom use was also asked (responses included: STI prevention, pregnancy prevention, both, or don't know).

Data analysis

Analysis was limited to the subset of women from the original study cohort who reported having sex in the past 30 days at baseline. Women were divided into those who were condom users at baseline and those that were not. Comparisons between condom users and

non-condom users at baseline were made using chi-square analyses. Bivariate analyses (chi-square) were conducted using sociodemographic, reproductive history, and attitude variables at baseline to model dual method use at 12 months. Multivariable logistic regression was used to examine factors associated with dual method use at 12 months. Variables chosen for the multivariable model were based on results from bivariate analyses ($p < .05$), potential confounders, prior research, and Health Belief Model/Theory of Planned Behavior. Attrition analyses were conducted comparing baseline characteristics including sociodemographics and reproductive history between those lost to follow-up and those who remained in the study. Two separate sensitivity analyses were done for the multivariable model, the first assuming those lost to follow-up were dual method users and the second assuming they were not. Statistical significance level was set to $p < .05$. All analyses were conducted using STATA 11 (Stata Corporation, College Station, TX).

Results

Of the 1,387 women enrolled at baseline in the cohort, we excluded 193 subjects for the following reasons: 134 women had not had sex in the past 30 days and 59 women were missing data on predictor variables. This resulted in 1,194 women who were eligible for analysis. The cohort was racially/ethnically diverse, with 61% describing themselves as either Latina or African-American. Nearly two thirds of women were ages 15 to 19 and more than half lived in a low-income neighborhood. At baseline, 36% of women were condom users and 5% were dual method users. Condom users at baseline were more likely to have been in a monogamous relationship of shorter duration and have a main partner with positive views of condoms, with a lower likelihood of a prior pregnancy than those who did not use condoms at baseline as seen in Table 1.

Contraceptive and condom use over time was dynamic with women experiencing dramatic changes in both as represented in Figure 1. After initiation of hormonal methods at baseline, overall condom use (condoms only or with a contraceptive method) dropped from 36% to 27% by 3 months. During the same period, dual method use increased from 5% to a peak of 20%. Over the 12 months, as women discontinued hormonal methods, there was a substantial decrease in dual method use, an increase in condom only use, and little change in overall condom use. Among condom users at baseline who discontinued condom use after initiating an effective method and were no longer using that method at 1 year, 46% switched back to condoms.

In the bivariate analysis of factors associated with dual method use at 12 months, being a consistent condom user at baseline was associated with an odds ratio (OR) of 2.4 (95% CI: 1.6–3.6). Type of hormonal method chosen at baseline was not significantly associated with dual method use nor was a prior pregnancy or history of an STI. Women who said their partner thought condoms were "very important" or did not know how their partners felt about condom use were more likely to be dual method users than women who said their partner thought condoms were "not at all important" (OR 3.5, 95% CI: 1.9–6.3 and 2.5, 95% CI: 1.3–4.8, respectively). In the multivariable model (adjusted for age, race/ethnicity, clinic site), both baseline condom use and main partner's views of condoms remained significant. Those who thought it was "very likely" that they would get an STI in the next 3 months were significantly less likely to be dual method users at 1 year (OR .5, 95% CI: .3–.99), as seen in Table 2.

To determine whether those lost to follow-up may have affected our results, we conducted sensitivity analyses that demonstrated that predictors of dual method use did not differ significantly when those lost to follow-up were assumed not to be dual method users. When

those lost to follow-up were considered dual users however, only condom use at baseline remained a significant predictor of dual method use (data not shown).

Discussion

This study highlights the dynamic nature of the tradeoff between hormonal methods and condom use in women initiating hormonal contraception as well as the influence of the male partner on dual method use longitudinally. A tradeoff is a phenomenon whereby women initially use condoms, begin a hormonal contraceptive, and subsequently discontinue condom use. This was observed in the current study when, as women initiated a range of effective hormonal contraceptives, dual method use increased; however, overall condom use suffered as a result. This finding is consistent with the tradeoff between condom use and hormonal methods demonstrated in a prior study [18]. The longitudinal nature of this study allowed us to follow condom use over time as women initiated and later discontinued hormonal contraception. By 12 months, the modest gains in dual method use were diminished. What is important about this study is that we were able to demonstrate that not only did women trade off condoms for hormonal methods, but as they discontinued the hormonal methods, more than half (54%) failed to resume condom use, resulting in an ultimate tradeoff of condoms for no method. This outcome is far from ideal. Given the realities of the tradeoff between condoms and hormonal contraception, the use of condoms, not only for STI protection but also as a backup method when hormonal contraception is discontinued, should be underscored. Additionally, with the understanding that many women discontinue these hormonal methods over time, promotion of long-acting reversible contraception, including copper and progestin-releasing IUDs and implants, is essential.

Overall condom use decreased by nearly one third from baseline to 12 months, and although hormonal method discontinuation was significant, there was a net gain in effective hormonal contraceptive use. It should be noted that even on the most fertile day, the risk of a woman becoming pregnant is less than half her risk of acquiring gonorrhea from an infected partner [19]. At the same time, the risk of an STI only exists when a partner is infected, whereas the risk of pregnancy (although varying in likelihood throughout a woman's cycle) is present with virtually all partners. Therefore, one might argue that it is possible for a subset of women, those in committed monogamous relationships for instance, the tradeoff may be justified. Unfortunately, we know from multiple studies that adolescents and young adults often underestimate their risk of STIs [20,21]. Of note, having a high perceived risk of an STI in the next 3 months was independently associated with reduced odds of being a dual method user. Although it is counterintuitive, we speculate that other factors influence contraceptive behaviors. In particular, gender-based power may explain why even though women know they are at high risk, they have less agency in their relationships to negotiate condom use and therefore have lower odds of dual method use [22].

Because of small sample size and the observational design of the study, we were unable to compare STI acquisition rates among those that made the tradeoff compared with those that did not. Although a recent analysis of a randomized intervention to increase dual method use also failed to find a significant difference in biologic outcomes (STI and unintended pregnancy incidence), the study found that those with the highest level of adherence had the lowest incidence of STIs and unintended pregnancy [23]. Further studies are needed to assess STI acquisition in the setting of initiation of hormonal methods.

Our results also highlight the strong influence that a woman's main partner has on her decision to be a dual method user, irrespective of her own views about dual method use. This again may be related to the concept of relationship power imbalance and its impact on a woman's ability to negotiate condom use. Many of the associations observed in prior studies

(age, African-American race, type of hormonal method initiated, partner concurrency, prior pregnancy, and STIs) were not observed in our bivariate models. Partner's attitude toward condom use, in addition to condom use at baseline, were the only other significant predictors after controlling for numerous other factors. This is consistent with findings from previous research and highlights the importance of recognizing the role of the partner in contraceptive choice [9,12,24]. Providers should inquire about partner attitudes about condom use and work with women to develop techniques to address this component of the decision around dual method use. Interestingly, women who reported they didn't know their partner's attitudes about condoms were also more likely to report dual method use, suggesting that as long as partners do not actively voice opposition to condoms, women are more likely to use them along with another method. The need for the involvement of the partner in family planning was emphasized in a recent study of adult women attending public family planning clinics, which found that nearly two thirds of respondents were interested in some form of partner involvement in their reproductive health planning [25]. It is clear from our findings that the role of the partner is significant and that women do not make contraceptive decisions in isolation. Providing couples-centered counseling may represent a way to improve contraceptive, and more specifically, dual method use.

Our study has limitations that affect the interpretation of the data. Although our follow-up rate was high at 88%, there were some differences in women who were lost to follow-up. Women with follow-up data were more likely to be in school or working full time than those who were lost to follow-up, indicating that our final study population may have been lower risk. However, our sensitivity analysis demonstrated that even if none of those who were lost to follow-up were dual method users, our results would be the same. The data were obtained by self-report, which is susceptible to social desirability bias; however, the majority of the data was collected by computer, which has been shown to improve reliability for sensitive questions [26]. This study included a diverse group of women from urban and suburban public family planning clinics in Northern California; it may not be generalizable to other populations but this population represents an important demographic as they are at high risk for experiencing unintended pregnancy and STIs.

Despite these limitations, this study provides a dynamic view of condom use among women initiating hormonal methods and identifies key factors that could be addressed during family planning visits to improve dual method use among women.

These results highlight a potential missed opportunity for family planning providers. With a focus on getting women to initiate hormonal methods for pregnancy prevention, it is unclear whether ample attention is given to method continuation and contingency planning in the event of method discontinuation. Increasing dual method use is challenging as both hormonal contraceptive use and condom use are complex behaviors with multiple mediating factors that many women may have difficulty negotiating; that being said, it is crucial that providers stress the importance of dual method use.

Acknowledgments

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IMPLICATIONS AND CONTRIBUTION

In our efforts to increase the use of hormonal contraceptives, condom use suffers and contraceptive continuation is not optimal. This study highlights the large need for effective interventions to improve long-term condom and contraceptive use among adolescent and young adult women and their partners.
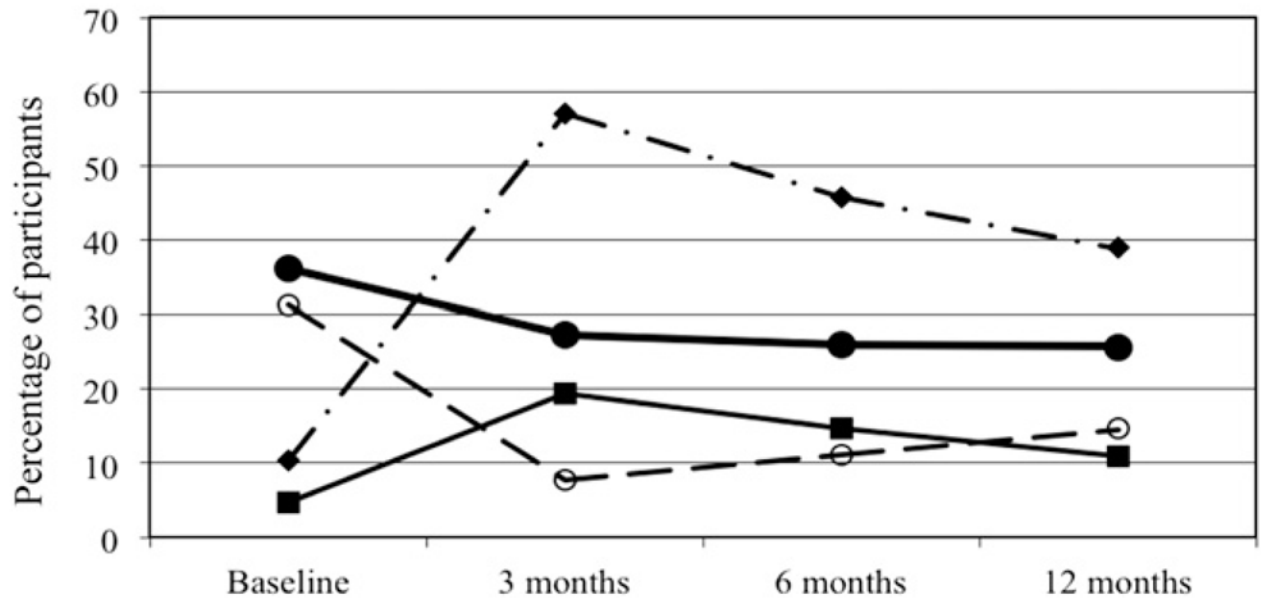
Figure 1.
Condom use over time with the initiation of hormonal methods. ━●━ Hormonal methods only.[a] ━■━ Overall condom use.[b] ─♦─ Dual method use. ─○─ Condom only. [a]Also includes small percentage of women (1.8%) using other effective methods (intrauterine devices, implants). [b]Includes condom only and dual method use.

Table 1

Characteristics of participants by condom use status at baseline

Characteristic	Total		Condom user		Non-condom user	
	N	**%**	**N**	**%**	**N**	**%**
	1,194		**432**	**36.2**	**762**	**63.8**
Sociodemographics						
Age (years) [**]						
15–17	413	34.6	170	39.4	243	31.9
18–19	391	32.8	146	33.8	245	32.2
20–24	390	32.7	116	26.9	274	36.0
Race/ethnicity (n = 1,194)						
White	133	11.1	59	13.7	74	9.7
Latina	320	26.8	105	24.3	215	28.2
African American/black	407	34.1	150	34.7	257	33.7
Asian/Pacific Islander	141	11.8	43	10.0	98	12.9
Multiracial/other	193	16.2	75	17.4	118	15.5
School and employment status (n = 1,194)						
In school or employed (full or part time)	996	83.4	371	85.9	625	82.0
Not working or in school	198	16.6	61	14.1	137	18.0
Clinic site (n = 1,194)						
Oakland	361	30.2	125	28.9	236	31.0
Hayward	312	26.1	120	27.8	192	25.2
Vallejo	139	11.6	49	11.3	90	11.8
Richmond	382	32	138	31.9	244	32.0
Low income neighborhood (n = 1,171) [a]	655	55.9	244	58.1	411	54.7
Reproductive history						
Method used at last sex (n = 1,190) [***]						
Pill	82	6.9	30	7.0	52	6.9
Patch	56	4.7	15	3.5	41	5.4
Ring	12	1.0	1	.2	11	1.4
DMPA	29	2.4	10	2.3	19	2.5

Characteristic	Total		Condom user		Non-condom user	
	N	%	N	%	N	%
	1,194		432	36.2	762	63.8
Other effective method[b]	1	.8	0	0	1	.1
None/withdrawal	993	83.4	366	84.9	627	82.6
Dual method users	56	4.7	56	13	0	0
Baseline method initiated (n = 1,194)[*]						
Pill	366	30.7	158	36.6	208	27.3
Patch	339	28.4	112	25.9	227	29.8
Ring	232	19.4	74	17.1	158	20.7
DMPA	257	21.5	88	20.4	169	22.2
Prior pregnancy (n = 1,194)[***]	586	49.1	165	38.2	421	55.2
Prior STI (n = 1,169)	255	21.8	83	19.7	172	23.0
Perceived STI risk in next 3 months with main partner (n = 1,194)						
Not at all/a little likely/somewhat	875	73.3	314	72.7	561	73.6
Very likely	319	26.7	118	27.3	201	26.4
Partner concurrency (sex with man other than main partner) (n = 1,194)[*]	170	14.2	47	10.9	123	16.1
Time had sex with main partner (months) (n = 1,194)[***]						
0–6	518	43.4	228	52.8	290	38.1
7–12	140	11.7	41	9.5	99	13.0
>12	352	29.5	97	22.5	255	33.5
No sex yet	184	15.4	66	15.3	118	15.5
Attitudes toward condom use						
Reason for condom use at last sex (n = 459)[c,**]						
Pregnancy prevention	188	41	133	37.7	55	51.9
STI/AIDS prevention	12	2.6	8	2.3	4	3.8
Both	255	55.6	211	59.8	44	41.5
Other	4	.9	1	.3	3	2.8
Main partner views of condoms (n = 1,008)[d,***]						
Very important	307	30.5	204	56.0	103	16.0
Somewhat important	327	32.4	115	31.6	212	32.9

Characteristic	Total		Condom user		Non-condom user	
	N	%	N	%	N	%
	1,194		**432**	**36.2**	**762**	**63.8**
Not at all important	321	31.8	43	11.8	278	43.2
Don't know	53	5.3	2	.5	51	7.9
Believes should always use condoms, even if on birth control (n = 1,187) ***						
Strongly agree	419	35.3	185	43.1	234	30.9
Agree	417	35.1	132	30.8	285	37.6
Neither	212	17.9	70	16.3	142	18.7
Disagree	119	10	33	7.7	86	11.3
Strongly disagree	20	1.7	9	2.1	11	1.5

DMPA = depot medroxyprogesterone; STI = sexually transmitted infection.

*
p < .05,

**
p < .01,

***
p < .001.

[a]Defined as living in a zip code where the proportion of families living below the federal poverty level is greater than the national average.

[b]Includes one woman who reported using a once-monthly injectable contraceptive.

[c]Asked of those who used a condom at last sex.

[d]Asked only of those with a main partner.

Table 2

Predictors of dual method use at 12 months

Variable	Unadjusted OR (95% CI)[a] N = 1,018	Adjusted OR (95% CI)[b] N = 1,012
Baseline condom use		
<80% of time	1 (reference)	1 (reference)
80% of time	2.40 (1.62–3.58)***	2.01 (1.28–3.14)**
Prior sexually transmitted infection[c]	1.35 (.93–1.96)	1.55 (.94–2.55)
Prior pregnancy	1.11 (.75–1.65)	1.18 (.73–1.88)
Perceived STI risk in next 3 months		
Not at all/a little/somewhat likely	1 (reference)	1 (reference)
Very likely	.89 (.56–1.42)	.54 (.30–.99)*
Partner concurrency (other than main)	.77 (.42–1.41)	.73 (.38–1.40)
Main partner views of condoms		
Not at all important	1 (reference)	1 (reference)
Somewhat important	1.65 (.86–3.20)	1.55 (.78–3.10)
Very important	3.45 (1.88–6.34)***	2.89 (1.47–5.71)**
Don't know	2.45 (1.25–4.81)*	2.99 (1.35–6.64)**
Believes should always use condoms, even if on birth control[d]		
Strongly disagree	1 (reference)	1 (reference)
Disagree	.29 (0.05–1.72)	.48 (.07–3.13)
Neither	.91 (019–4.27)	1.54 (.30–7.78)
Agree	.93 (.20–4.24)	1.41 (.29–6.89)
Strongly agree	.97 (.21–4.41)	1.07 (.22–5.15)

*
p < .05,

**
p < .01,

***
p < .001.

[a]
n = 1,018 as 176 women were missing data for dual method use at 12 months.

[b]
Adjusted for age, race/ethnicity, and clinic site.

[c]
Individuals who were missing on STI history were categorized as missing as to include in multivariable analysis.

[d]
n = 1,012 because of missing data.

Original article

The Developmental Association of Relationship Quality, Hormonal Contraceptive Choice and Condom Non-Use among Adolescent Women

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Abstract

Purpose: Consistent condom use is critical to efforts to prevent sexually transmitted infections among adolescents, but condom use may decline as relationships and contraceptive needs change. The purpose of this research is to assess changes in condom non-use longitudinally in the context of changes in relationship quality, coital frequency and hormonal contraceptive choice.

Methods: Participants were women (aged 14–17 years at enrollment) recruited from three urban adolescent medicine clinics. Data were collected at three-month intervals using a face-to-face structured interview. Participants were able to contribute up to 10 interviews, but on average contributed 4.2 interviews over the 27-month period. Independent variables assessed partner-specific relationship quality (five items; scale range 5–25; $\alpha = .92$, e.g., *this partner is a very important person to me*); and, number of coital events with a specific partner. Additional items assessed experience with oral contraceptive pills (OCP) use and injected depo medroxy-progesterone acetate (DMPA). The outcome variable was number of coital events without condom use during the past three months. Analyses were conducted as a three-level hierarchical linear growth curve model using HLM 6. The Level 1 predictor was time, to test the hypothesis that condom non-use increases over time. Level 2 predictors assessed relationship quality and coital frequency across all partners to assess hypotheses that participants' condom non-use increases over time as a function of relationship quality and coital frequency. Level 3 predictors assessed the participant-level influence of OCP or DMPA experience on time-related changes in condom non-use.

Results: A total of 176 women reported 279 sex partners and contributed 478 visits. Both average coital frequency and average condom non-use linearly increased during the 27-month follow-up. At any given follow-up, about 35% reported recent OCP use, and 65% reported DMPA use. HLM analyses showed that condom non-use increased as a function of time ($\beta = .12$; $p = .03$, Level 1 analysis). Increased condom non-use over time was primarily a function of increased coital frequency ($\beta = .01$; $p = .00$), although higher levels of relationship quality were associated with increased condom non-use at enrollment ($\beta = .44$; $p = .00$, Level 2 analysis). The temporal rise in condom non-use significantly increased among DMPA users ($\beta = .06$; $p = .00$) but not OCP users (Level 3 analysis) ($\beta = -.04$; $p = .06$).

Conclusions: Developmentally, relationship characteristics and coital frequency appear to have increasing weight in decisions about condom use. Hormonal contraceptive methods are not equivalently associated with the overall temporal decline in condom use. Future research associated with dual contraceptive/condom use should address differential factors associated condom use in combination with different hormonal methods. © 2006 Society for Adolescent Medicine. All rights reserved.

Keywords: Hormonal contraception; Condom use; Relationship quality

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The prophylactic functions of condoms include prevention of sexually transmitted infections (STI) as well as conception [1]. This dual function makes condoms unique among the contraceptive methods available to adolescents. However, many adolescents, especially women, prefer more reliable, coitus-independent contraceptive methods that do not reduce STI risk [2]. In fact, hormonal contraceptive methods may increase risk of some STI, making condom use even more important [3]. Thus, so-called "dual use" of coitus-independent contraception plus condom use with each coitus has become a public health standard [4]. This ideal has been difficult to achieve, however, and fewer than 25% of adolescent women consider themselves to be "dual users" [5,6]. Many adolescent women view dual use as a "trade-off" between intimacy and decreased perceived STI risk. These women are especially unlikely to use condoms in addition to hormonal contraceptive methods [7].

Issues surrounding pregnancy and STI prevention become additionally complex because choices about contraception and condom use are not static characteristics of adolescents or their sexual relationships. Condom use is more common with a new sexual partner, and during the early weeks of a relationship [8,9]. Adolescents discontinue condom use quickly, perhaps less than one month, suggesting that consistent condom use is a relatively short-lived characteristic of many sexual relationships [10]. Among adolescent women, condom use is less likely in partnerships characterized as relatively higher in emotional affiliations [11,12]. Although coital frequency is typically higher in more stable relationships, greater coital frequency appears to be associated independently with increased levels of non-condom use, even when relationship characteristics are controlled [12,13].

A final factor that may affect condom use is the specific type of coitus-independent contraceptive method. The most widely used methods—oral contraceptive pills (OCP) and depot medroxy-progesterone acetate (DMPA)–are similar in terms of contraceptive effectiveness but differ markedly in terms of method characteristics and user perceptions. For example, up to one-half of OCP users miss enough doses to place them at risk for pregnancy, with the implied need for a back-up contraceptive method [14]. Thus, the demand of daily pill-taking (and awareness of failures in pill-taking) mandates more attention to contraception and STI prevention issues while the certainty of contraceptive protection and prolonged intervals between DMPA injections may diminish such attention [15]. Therefore, accumulation of experience with a method such as DMPA may be associated with increasing levels of condom non-use, whereas OCP experience would be less likely to change levels of condom non-use.

Existing research lacks an understanding of the effects of developmental change in condom use and contraceptive behaviors. The average age of first sexual intercourse for American women is about age 16, thus a substantial portion of middle and late adolescent development may be accompanied by sexual activity [16]. By age 20, an average of five lifetime sex partners is reported. These partnerships are usually sequential, allowing for an accumulation of experience with romantic and sexual relationships, changing personal and interpersonal motivations for sex, and changes in motivations for contraception [17]. Condom use behaviors appear to decline over time, not only within a given relationship, but in each succeeding relationship [9,10].

These developmental contexts of hormonal contraception and condom use warrant a more detailed understanding of their development over time. The purpose of this research, then, is to evaluate the short-term (within three-month intervals) and long term (over 27 months) changes in condom non-use in the context of partner-specific relationship quality, partner-specific coital frequency, and hormonal contraceptive choice. A latent growth curve (LGC) approach using hierarchical linear modeling (HLM) is used to allow the examination of patterns of change (e.g., linear or non-linear) as well as testing of hypotheses about potential predictors of these changes. LGC allows individual and group change to be modeled by using a varying number and spacing of data points across time, which is indicative of these data [18]. This method also allows the information from all the sex partners during any time period to be incorporated and analyzed in a predictive model.

Methods

Study design and procedures

Data were collected as part of a larger longitudinal study of risk and protective factors (initiated in 1999) associated with sexually transmitted infections among women in middle adolescence. Briefly, the larger study consisted of an enrollment visit and follow-up clinic visits each three months during a 27-month study period (up to 10 visits total). At each visit, a structured face-to-face interview with trained research assistants provided detailed information regarding sexual and contraceptive behaviors in the previous three-month period. Informed consent was obtained from each participant and permission obtained from a parent or legal guardian. This research was approved by the institutional review board of Indiana University/Purdue University at Indianapolis – Clarian.

Participants were adolescent women receiving health care in three primary health clinics in Indianapolis. These clinics serve mostly African-American neighborhoods of lower- and middle-income residents in areas with high rates of teen pregnancy and sexually transmitted infections. For example, the proportion of African-Americans in census tracts served by participating clinics was 78%, and the median household income was $28,000. The 2004 Chlamydia rates for zip codes in which the participating clinics are located ranged from 469/100,000 to 1656/100,000. A

majority (> 75%) of female clinic patients are African-American, and a large majority of clinic patients receive some form of public assistance for health care (> 85%). Study participants resembled the racial-ethnic composition of participating clinics in that 87% of the sample reported race as African-American.

Clinic patients were eligible for study participation if they were aged between 14 and 17 years at enrollment, spoke English, and were not pregnant at enrollment. However, participants who became pregnant were continued in the study. The age range of 14–17 years was chosen because of high rates of initiation of sexual activity. Thus, lifetime sexual experience was not an enrollment requirement because many initially sexually inexperienced could be expected to become sexually active during the follow-up period. For this analysis, women who became pregnant or who were not using a hormonal contraceptive method were excluded.

Measures

The primary outcome measure was condom non-use, defined as the total number of coital events (during the previous three months) unprotected by condoms. We chose this measure as a reflection of potential exposure to STI that does not confound levels of condom non-use with levels of coital frequency [19].

Independent variables consisted of partner-specific relationship quality and partner-specific coital frequency and partner-independent measures of hormonal contraceptive choice. At enrollment and each follow-up visit, participants were asked to identify sex partners by first name or initial, last name, nickname, any contact information, and street address if known. This information was used to create unique partner identifiers in order to link relationship-specific attitudes and behaviors to their specific relationships.

Partner-specific variables included relationship quality and coital frequency. *Relationship quality* assesses positive emotional and affiliational aspects of a relationship. The additive index consists of five items coded as "strongly disagree," "disagree," "agree" or "strongly agree," (scale range 5–25; $\alpha = .92$) with higher scores indicative of greater relationship quality. Example items include *[this partner] is a very important person to me* and *I enjoy spending time with [this partner]*.

Coital frequency reflected the total number of coital events with a given partner. Coital frequency was assessed by asking "How many times in the past three months did you have sex?" Responses were recorded verbatim for each partner. Participants were asked for an approximate number, and "missing" was entered when a precise estimate was not provided. Information on all the sex partners in the past three months were used for this analysis in order to assess the total effects of relationship quality and coital frequency on the outcome measure.

The individual's experience with OCP or DMPA was assessed as the cumulative number of visits in which OCP or DMPA was reported as the method of contraception used in the previous three months. Values range from 0 to 10 with lower values representing less DMPA or OCP experience and higher values representing greater OCP or DMPA experience.

Statistical methods

Analyses were conducted as a three-level hierarchical linear growth curve (LGC) model using HLM 6 [20]. LGC analysis allows examination of patterns of change with repeated observations of nested variables and with a varying number of data points across time. In the current application, LGC is used to estimate individual growth trajectories of condom non-use by fitting a regression line to individual observations of condom non-use over time. The information from all the individual curves is used to create a summary measure of condom non-use. This summary measure is what is referred to as the "latent growth curve." The curve is latent because it captures group level growth based on the relationships between the observed measures across time [18].

The HLM approach to LGC conceptualizes time as nested within the individual. LGC with HLM allows examination of the influence of specific variables on these curves. Present analyses consisted of creating a taxonomy of nested models as suggested by other researchers employing the methodology [18]. These models are created by sequential addition of predictors, with examination of statistical significance of the predictors and changes in overall model fit. Improvements in fit were assessed by examination of the changes in pseudo-R^2, the deviance statistic, Akaike Information Criterion (AIC), and the Bayesian Information Criterion (BIC) [18]. The pseudo-R^2 represents changes in the percentage of unexplained variance as model components are added. The AIC and BIC assess model fit as a function of model complexity, with progressively smaller values for deviance, AIC and for BIC indicating better fit.

LGC produces two latent factors (the intercept and the slope), which together form the trajectory. The intercept is the start, or initial, value. The slope represents the rate of change, or growth, over time. A positive sign for the slope indicates an increase over time. A negative sign indicates a decrease over time. HLM assesses the influence of factors at different levels in the model on the intercept and slope. Here, condom non-use is assessed over time (measured by the sequence of three-month visits) and is specified as nested within partner-specific variables (i.e., relationship quality and coital frequency) because individual participants may have more than one partner during any given three-month period. Partner-specific variables are specified as nested within the duration of experience with a contraceptive method choice because a given method applies equally to all partners. Thus (in the language of LGC), the Level 1

Table 1
Descriptive statistics for Level 1, Level 2 and Level 3

Variable name	Mean	SD	Minimum	Maximum
Visit-specific variables (Level 1; n = 478 visits)				
Condom nonuse	6.95	14.38	0	60.00
Time	—	—	0 months (enrollment)	27 months
Partner-specific variables (Level 2; n = 275 partners)				
Relationship quality	18.53	4.22	6.00	25.00
Coital frequency	7.57	10.86	0	60.00
Participant-specific variables (Level 3; n = 175 participants)				
Hormonal contraceptive experience				
DMPA	2.33	2.59	0	10.00
OCP	1.24	1.67	0	10.00

Note: Sample represents 176 participants (Level 3 variables) with 278 sexual partners (Level 2 variables) and 478 visits (Level 1 variables).
* 4.10 per partner.

predictor was time, to test the hypothesis that condom non-use increases over time (i.e., during each three-month period over the 27 months). In the taxonomy of models, these analyses represent temporal change in condom non-use without assessment of influence by other predictors (see Time Only model, Table 2).

Level 1 generates individual change trajectories (intercept and slope) for each outcome of interest (here condom non-use). At Level 1 an *individual* growth model of condom non-use at time t with partner i for participant j is in the form:

$$Y_{1ij} \equiv \gamma_{0ij} + \gamma_{1ij}(\text{Time})_{tij} + e_{tij}$$

where Y_{tij} is the condom non-use at time t with partner i for adolescent j; γ_{0ij} represents the expected level of condom non-use for adolescent j at Time zero (i.e., the initial status or intercept); γ_{1i} is the rate of change in the condom non-use during the three-month interval with partner i for adolescent j; (Time)$_{tij}$ is 0, 1, 2, 3, 4, ...12; γ_{2ij} is the rate of change with partner i for adolescent j; and, e_{tij} represents the within-person residual.

Level 2 predictors were coital frequency (with each partner) and relationship quality (with each partner) to assess hypotheses that participants' condom non-use increases over time as a function of partner-specific coital frequency and partner-specific relationship quality. Level 2 generates partner level change trajectories (mean intercept, intercept variance, mean slope, slope variance). The general unconditional Level 2 model with fixed effects and no covariates is:

$$\gamma_{0ij} = \gamma_{00j} + r_{0ij}$$

$$\gamma_{1ij} = \gamma_{10j} + r_{1ij}$$

where γ_{0ij} is the condom non-use for adolescent j with partner i at time zero; δ_{1ij} is the condom non-use rate of change over the length of the study; γ_{10j} is the mean rate of change across each partner for adolescent j; r_{1ij} and r_{2ij} are random errors (associated with the intercept and subsequent slope).

Three Level 2 models were evaluated: partner-specific coital frequency only; partner-specific relationship quality only; and simultaneous inclusion of both coital frequency and relationship quality.

Level 3 captures the variability between adolescents. In this case, Level 3 captures the variability between the groups (DMPA or OCP) to which the adolescents belong. The general conditional Level 3 model with fixed effects and no covariates:

$$\gamma_{00j} = \gamma_{000} + u_{00j}$$

$$\gamma_{10j} = \gamma_{100} + r_{10j}$$

where γ_{00j} represents the mean initial status within adolescent j; γ_{000} is the overall mean initial status; γ_{10j} is the mean rate of change within adolescent j; γ_{100} is the overall mean growing rate; and u_{00j} and u_{10j} are Level 3 random error terms (associated with the intercept and slope). As can be seen, the Level 2 slopes and intercepts become the outcomes of the Level 3 model. Level 3 predictors assessed the additional influence of OCP or DMPA experience on time-related changes in condom non-use.

Results

The original sample contained 237 women providing 732 enrollment and visits at three-month intervals over the 27-month follow-up. In order to focus appropriately on the effects of hormonal contraceptive choice, and partner-specific relationship quality and partner-specific coital frequency on change in condom non-use over time, analyses were limited to the 176 women using OCP or DMPA (Level 3 variables), during relationships with 279 sex partners (and thus 275 assessments of partner-specific relationship quality and partner-specific coital frequency; Level 2 variables) with 478 visits. On average, participants contributed 4.2 visits each, with a range from 2 to 10.

Overall, the average level of condom non-use was 4.10 unprotected coital events per partner during any given three-month period. The average number of coital events per partner was 7.57 during any given three-month period. Average relationship quality was 18.5 per partner during any given three-month period. At each visit, DMPA use was more common than that of OCP (Table 1).

Average condom non-use and average coital frequency increased linearly over the 27-month follow-up period (Figure 1). For example, the average number of unprotected coital events per partner was 6.13 at enrollment and 9.54 by the end of the 27-month follow-up period. Average rela-

Table 2
Taxonomy of models—condom nonuse over time

	Parameter[a]	Time only model	Relationship quality model	Coital frequency model	Coital frequency-relationship quality model	DMPA model	OCP model
Intercept	y00	3.64 (.82)	3.52 (.82)	4.14 (.94)	3.78 (.81)	3.83 (.81)	3.63 (.78)
Time	y10	.2 (.09)	.18 (.08)	.13* (.07)	.16 (.06)	.12 (.05)	.2 (.06)
Relationship quality	y01	—	.65 (.17)	—	.44 (.15)	.44 (.15)	.44 (.15)
Coital frequency	y11	—	—	.02 (.00)	.01 (.00)	.01 (.00)	.01 (.00)
DMPA experience	y101	—	—	—	—	.06 (.02)	—
OCP experience	y101	—	—	—	—	—	−.04* (.02)
Pseudo R-square		.07					
		—	.09				
		—	—	.11			
		—	—	—	.13		
		—	—	—	—	.15	.15
Deviance		3761.5	3747.8	3716.8.9	3708.4	3705.5	3711.2
AIC		3715.9	3693.1	3704.9	3701.9	3653.7	3659.6
BIC		3728.3	3699.0	3706.3	3658.8	3656.3	3658.2

Note. Numbers are beta and (standard errors). All beta coefficients are statistically significant at $p < .05$ unless otherwise noted.

[a] See Appendix for guide to symbols.

[b] Final model includes time (Level 1), coital frequency and relationship quality (Level 2) plus contraceptive method experience (Level 3).

* $p = .06$.

tionship quality remained relatively stable during the follow-up period (Figure 2).

Analyses showed that condom non-use increased as a function of time ($\beta = .12$; $p = .03$, Level 1 analysis). A convention of LGC analysis is to report parameter estimates as unstandardized betas [16]. Estimates should be understood in reference to their original metrics: for example, a one-unit increase in time is associated with a .12-unit increase in condom non-use.

Both coital frequency and relationship quality separately resulted in improved model fit compared to the Time Only model. Addition of both coital frequency and relationship quality yielded improved fit over models with only coital frequency or relationship quality (Table 2). The source of
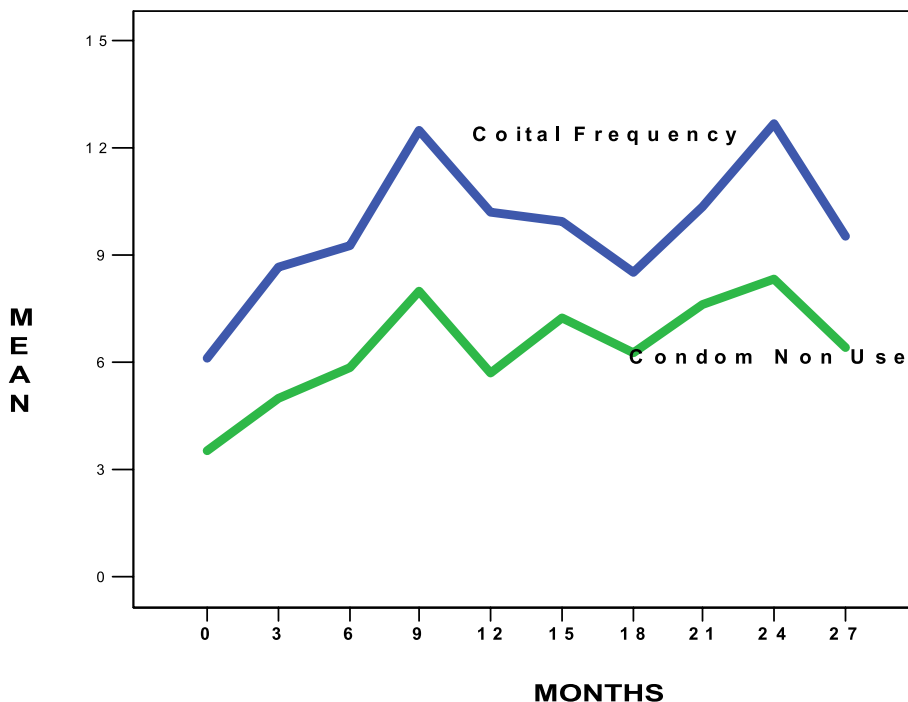

Figure 1. Partner-specific coital frequency and condom non-use over the 27 months.
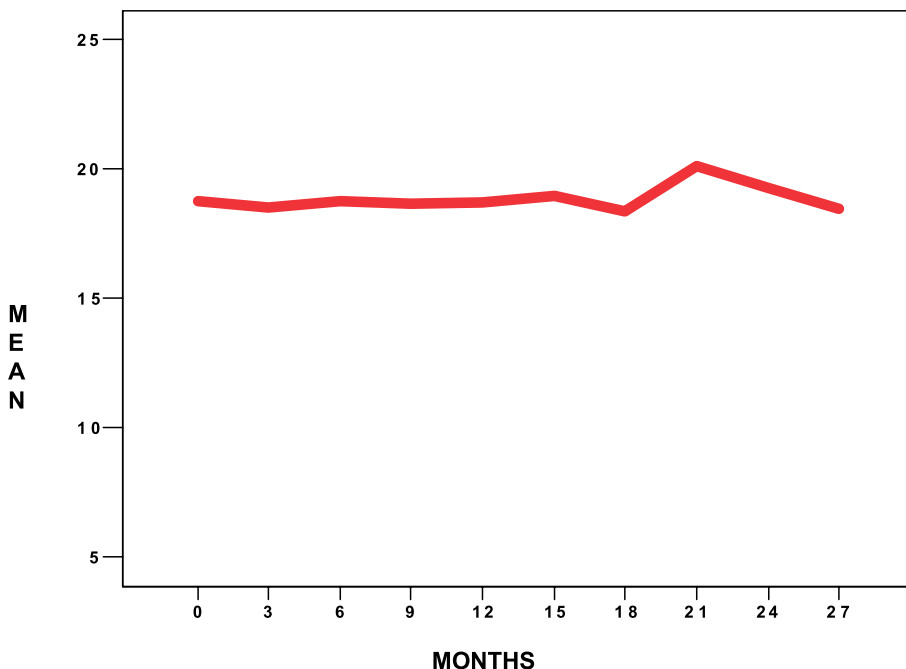
Figure 2. Mean partner-specific relationship quality over 27 months.

influence differed, however. Increased condom non-use over time was a function of increased coital frequency ($\beta = .01$; $p = .00$), while higher levels of relationship quality were associated with increased condom non-use at enrollment ($\beta = .44$; $p = .00$, Level 2 analysis).

Addition of measures of OCP and DMPA experience produced significant increases in model fit. The pseudo-R^2 estimates showed substantial reductions in model variance with the addition of model components (Table 2). The AIC and BIC of the final model decreased (compared to the models containing only coital frequency and relationship quality [Table 2]), indicating improved model fit.

Increased OCP experience (compared to DMPA) was associated with decreased rate of change in condom non-use ($\beta = -.04$; $p = .06$) (Table 2). Increased DMPA experience was associated with increased rate of change in condom non-use ($\beta = .06$; $p < .00$). The contrast in latent growth curves for OCP users versus DMPA users is illustrated in Figure 3. This figure shows a much steeper rate of increase in condom non-use for participants who reported more cumulative experience with DMPA, compared to those with greater OCP cumulative experience.

Discussion

The results of this study clearly demonstrate a temporal increase in condom non-use during a 27-month follow-up. Both relationship characteristics and coital frequency influence the rate of increase in condom non-use, with adolescent women perceiving higher relationship quality and reporting greater coital frequency at greater risk for STI

exposure. Hormonal contraceptive methods are not equivalently associated with the overall temporal decline in condom use: more experienced DMPA users become substantially less likely to use condoms over time, while experienced OCP users maintain relatively stable rates of condom use.

The finding that condom non-use becomes more frequent over time is consistent with other research. For example, condom use declines not only within relationships, but becomes lower with succeeding relationships [9]. In other research, the time required for levels of condom use in new relationships to approximate that of established relationships is about three weeks [10].
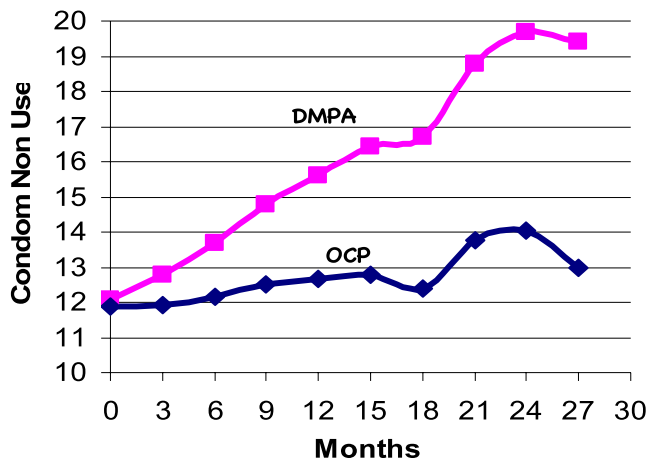

Figure 3. Growth curves of condom non-use for OCP coverage, and DMPA coverage 27 months.

Developmentally, adolescent romantic relationships appear to shift from a primarily self-focus during early adolescence to a substantially couples-perspective during middle and late adolescence [21]. Parental control and supervision is likely stricter for younger than for older adolescents. The less relationship-oriented sexual activity and tighter parental control of early and middle adolescence makes condoms an expedient but reasonably effective form of contraception. From a relationship perspective, an increasing sense of oneself as a member of a couple rather than an individual in a pair means that factors such as trust, intimacy, and relationship maintenance become important functions of sex within relationships [22]. Even if adolescents accurately estimated STI and pregnancy risk in sexual relationships, condom use works against the romantic ideals that are part of many adolescent sexual relationships [23]. From a pragmatic perspective, condom non-use may increase over time simply as a function of interest in and access to effective methods that separate sex from pregnancy and STI prevention [24].

These findings are also consistent with others in that both relationship characteristics and coital frequency are important influences on levels of condom use within a relationship [11,12,19]. One important contribution of the current research is evidence that coital frequency and relationship quality have different effects on levels of condom non-use. Relationship quality appears to affect condom non-use by its influence on initial levels of non-use, so that higher levels of relationship quality were associated with more frequent condom non-use at study entry. Coital frequency, on the other hand, influenced the rate of change of condom non-use over time. This suggests that relationship characteristics present early in a relationship, rather than relationship duration, are important early influences on a couple's condom use behaviors. As shown elsewhere, relationship quality is an important correlate of coital frequency, but coital frequency has the most direct proximal effect on condom non-use [25].

The data also demonstrate important differences in the association of contraceptive method choice and condom non-use, with increased non-use primarily a characteristic of participants with more experience with DMPA. An earlier study found low levels of condom use among users of contraceptive implants [26]. However, that study did not assess condom use among users of other contraceptive methods. Reasons for the differential effect of contraceptive method on condom non-use are not known, although the marked difference in demand characteristics of the methods is a plausible explanation [15]. Differential effects suggest that "dual contraceptive method use" is not simply an issue of a combination of any coitus-independent method with condom use. Rather, clinical and public health efforts to encourage dual method use may need to include evaluation of method choice as well as relationship and sexual behavior factors. Contraceptive patches or vaginal contraceptive rings are coitus-independent but require weekly attention (and do not typically affect menses), future research should address condom non-use among users of these methods.

Limitations

The sample is relatively homogenous in terms of geography (drawn from residents of a single urban area), race (mostly African-American) and socioeconomic status (mostly lower and middle socioeconomic status). Although the sample reasonably resembles the clinical population from which it was assembled, generalization of results should be made with caution. Secondly, a limited number of predictors of condom non-use were examined. Condom use has been linked to a host of socioeconomic, cultural, familial, psychological, and behavioral factors [27]. However, few of these factors have been investigated in the context of complex longitudinal models. We chose to focus on factors likely to have proximal influence on condom use behaviors. Thirdly, a limited number of contraceptive methods were assessed. If other coitus-independent methods become increasingly used with condoms these methods would be of interest. Finally, the resulting growth curves refer to *group-level* change over time in condom non-use. These results cannot be interpreted to represent developmental trajectories of individual participants.

Conclusion

The sometimes competing needs for effective contraception and effective STI prevention represent complex behavioral targets to achieve even for a short period of time. These data demonstrate, however, that condom use, especially, represents a developmental "moving target" subject to change over time and in response to changes in relationships, sexual behaviors and contraceptive choices. Perhaps the most important message to derive from our data is the suggestion that efforts to encourage condom use must be persistent, and must be adjusted to the relational and contraceptive needs of a given time.

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Dual Method Use Among a Sample of First-Year College Women

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Abstract

CONTEXT—Dual method use—using one type of contraceptive to reduce the risk of STDs and another to prevent pregnancy—is effective but understudied. No prior studies have employed an event-level approach to examining characteristics associated with dual method use among college women.

METHODS—In 12 consecutive monthly surveys conducted in 2009–2010, data on 1,843 vaginal intercourse events were collected from 296 first-year college women. Women reported on their use of condoms and hormonal contraceptives during all events. Multilevel regression analysis was used to assess associations between event-, month- and person-level characteristics and hormonal use and dual method use.

RESULTS—Women used hormonal contraceptives during 53% of events and condoms during 63%. Dual method use was reported 28% of the time, and only 14% of participants were consistent users of both methods. The likelihood of dual method use was elevated when sex partners were friends as opposed to romantic partners or ex-boyfriends, and among women who had received an STD diagnosis prior to college (odds ratios, 2.5–2.9); it also increased with level of religiosity (coefficient, 0.8). Dual use was less likely when less reliable methods were used (odds ratio, 0.2) and when women reported more months of hormonal use (0.8), were older (coefficient, –4.7) and had had a greater number of partners before college (–0.3).

CONCLUSIONS—A better understanding of the characteristics associated with dual method use may help in the design of potential intervention efforts.

STDs and unplanned pregnancy affect many young people. In the United States, 20 million new STD diagnoses are made each year,[1] and although teenagers and young adults (15–24-

year-olds) make up only 25% of the sexually active population, they account for 50% of all gonorrhea infections and 75% of all chlamydia infections.[2] In addition, U.S. women aged 18–19 experience a high rate of unplanned pregnancy (162 per 1,000),[3] which exceeds rates in other industrialized nations.[4] These consequences of unprotected sexual behavior are common despite the availability of highly effective contraceptive and preventive methods.

Dual method use involves the use of a contraceptive to reduce pregnancy risk and another method to reduce the risk of STDs. This combined approach is recommended because condom use is the most effective method for preventing the spread of STDs,[5] whereas hormonal contraception is the most effective method for pregnancy prevention.[6]

Despite the efficacy of dual method use as a protective strategy, uptake of this practice remains low; in one review, rates of dual use ranged from 12% among sexually active women aged 21–25 (2006–2008) to 23% among men and women aged 18–26 and in dating relationships (2002–2005).[7] National data indicate that fewer than one-third of sexually active, unmarried women aged 15–19 use condoms consistently,[8] and rates are even lower when hormonal contraceptives are used[9] and in romantic relationships.[10] Increasing dual method use among 15–19-year-old females is a goal of Healthy People 2020.[11] To improve our understanding about dual method use, for this exploratory study, we examined the prevalence, use patterns and correlates of dual use among female college students.

BACKGROUND

Gaps in the Literature

The literature on dual method use is limited in several ways. First, most studies have focused on younger adolescents;[12] accordingly, we have limited information about the prevalence of or characteristics associated with dual method use among adolescents older than 18 and college students. This is surprising, given that college students are likely to be sexually active and to engage in serial monogamy,[13] and thus have multiple sexual partnerships during the college years.

Second, many studies of the correlates of dual method use have investigated a small number of variables.[14–16] However, sexual behavior is influenced by multiple variables, and is associated with individual, dyadic, familial, peer and other sociocultural characteristics.[17] Research that evaluates a wider range of correlates reflecting a more ecological framework is needed to better understand sexual and contraceptive behavior.[18]

Third, most studies have relied on one-time measures involving a long recall period (e.g., the past 3–6 months), which undermines the reliability of the data,[19] and implicit averaging across events, which results in less precise assessment. Such methods do not capture important variability among events, as use of both condoms and hormonal contraceptives can change over time, and use of either method is often inconsistent. Moreover, features related to the sexual event itself (e.g., partner type or substance use) may be associated with dual method use. Event-level studies address these concerns; however, studies limited to single events are also imperfect, because if that event is not representative, it can distort our understanding. Hence, event-level studies that employ multiple events are needed, as they

can provide reliable and precise data that are more representative of a person's sexual experiences.[20]

Potential Correlates of Use

A wide range of sociocultural and behavioral characteristics may be associated with contraceptive use, and these associations have been examined to varying degrees.

•**Relationship type and duration**—Hormonal contraceptive use becomes more frequent, and condom use less frequent, as relationship duration increases,[21–23] and relationship commitment and duration are negatively associated with dual method use.[24,25] Moreover frequent intercourse (common with steady partners) is negatively related to condom use[26] and dual method use.[27] In addition, condom use is more common with casual than with committed partners.[28,29] Notably, few studies have considered the likelihood of dual use with specific types of sexual partners (e.g., acquaintances, friends, ex-boyfriends or new romantic partners). However, studies have suggested that the types of sexual activities engaged in and the emotional reactions to sexual encounters differ across types of casual sexual partners,[30,31] and one study found that condom use was more common with ex-boyfriends, ex-girlfriends and acquaintances than with strangers and friends.[30]

•**Substance use**—Drinking, smoking marijuana and cigarette smoking may be related to dual method use, although results from past research are mixed. Alcohol and marijuana use are thought to interfere with sexual decision making,[32,33] and these behaviors may lead to decreases in condom use[34,35] and dual method use.[14] However, one study of college students found no association between substance use and dual method use.[25] Research has also associated cigarette smoking with higher levels of risky sexual behavior,[36] although smoking in adolescence may be positively associated with consistent condom use in young adulthood.[37]

•**Hormonal contraceptive use**—Research has suggested that as women gain experience with hormonal methods, they may reduce their condom use (and thus dual method use), possibly because they are more confident that their hormonal contraceptive will protect against pregnancy.[26]

•**Sexual history and risk perceptions**—One study suggested that women who have partners they perceive as risky may be more likely than others to use dual methods,[25] while another found that dual use was negatively correlated with perceptions of STD risk.[16] Other research has found that women who have had an STD are more likely than others to use condoms,[38] possibly because they place greater importance on protection. Some studies have found that young people who have had a greater number of sexual partners are more likely than those who have had fewer partners to use dual methods,[39,40] but research has also suggested that condom use declines more rapidly within relationships for those who have had more past partners.[23] An additional element that may relate to risk perception is use of less reliable contraceptive methods. The diaphragm, sponge, fertility awareness and withdrawal are less effective than condoms and hormonal contraceptives for both pregnancy and STD prevention;[6,41] however, women using these methods may believe they are

adequately protected.[42] Most prior studies of dual method use have either not considered these methods or included them in the definition of dual method use despite their lower effectiveness.[12,14,16]

•Parent and peer characteristics—One study found that positive parental attitudes toward condom use and birth control were associated with increased levels of dual method use.[16] Similarly, discussing safer sex with parents has been correlated with dual use;[12,43] however, studies have not investigated the role of communication with peers. Parental connectedness appears to be protective against sexual risk behavior and pregnancy,[44] so we might expect it to be positively associated with dual method use, although no studies have specifically examined this.

•Personality—Impulsivity and sensation-seeking are both related to risky sexual behavior,[45] and one study found that impulsivity was negatively associated with dual use.[46] In contrast, conscientiousness has been found to be positively associated with condom use,[47] but its association with dual method use has not been explored.

•Demographic characteristics—Past research has suggested that the prevalence of dual use is higher among adolescents than among adults,[7,39] and higher among blacks than among whites or Latinas.[15] Religiosity is commonly regarded as protective against sexual activity in general,[48] but studies have found mixed results regarding its association with condom use,[48,49] and the possible correlation between religiosity and dual method use has not been examined. A final demographic correlate is socioeconomic status; one study showed that teenagers from higher status groups were more likely than others to use condoms,[50] and this variable has been assessed in some dual method studies.[16]

The Current Study

This exploratory study addresses two questions: What is the prevalence of dual method use in a sample of first-year college women? And what characteristics are associated with dual use in this sample? We used event-level data from multiple sexual events, and considered a wide variety of event-, month- and person-level characteristics that may be associated with dual method use, many of which have rarely or never been considered previously. Consistent with a behavioral ecological framework,[18] we included proximal variables related to the sex partner and characteristics of the sexual event—often neglected in previous studies—as well as more distal ones such as family and peer characteristics. We also considered two categories of risk behavior—substance use and past sexual experience—which are important elements in an ecological framework.[18]

METHODS

Participants and Procedures

Women came from a pool of 483 first-year students who were attending a private university in upstate New York and who were participating in a yearlong study of health behaviors and relationships. The larger study, conducted between September 2009 and September 2010, explored a variety of health behaviors (e.g., substance use, diet, exercise, sleep), as well as

sexual behavior and psychosocial adjustment.[51–53] The full sample constituted 26% of first-year female students for the fall 2009 semester. The 296 women included in the current study reported at least one episode of vaginal intercourse with a romantic or casual partner during their first year of college.

The university's institutional review board approved all study procedures. Participants were recruited via a mass mailing sent to first-year female students. Campus flyers, word of mouth and the psychology department participant pool bolstered recruitment. Most participants (61%) heard about the study through the mass mailing, 28% signed up through the department pool, and 11% responded to flyers or word of mouth. Interested students attended an orientation session, after which they provided informed consent and completed the initial survey. Subsequently, participants completed monthly online assessments for one year; surveys were completed during the first week of each month, and reports covered the previous month. Participants received $10–20 for each survey, depending on its length.

Measures

• Event-level variables—At each monthly survey, women who said they had had oral or vaginal sex during the past month reported on their most recent encounter involving oral, vaginal or anal sex with both a romantic partner and a casual partner. (A romantic partner was defined as "someone whom you were dating or in a romantic relationship with at the time of the physical intimacy"; a casual partner was "someone whom you were not dating or in a romantic relationship with at the time of the physical intimacy, and there was no mutual expectation of a romantic commitment; some people call these hookups.") Thus, each participant could describe 0–2 encounters per month, or 0–24 total. Only reports of vaginal sex in the preceding month were included in this analysis.

For vaginal intercourse events, participants reported all contraceptive methods they had used. Response options were nothing; male condom; pill, patch or ring; withdrawal ("pulling out"); injectable; female condom; IUD; diaphragm, cervical cap or sponge; fertility awareness (calendar, mucus, basal body temperature); and other. Women were coded as using a condom if they reported male or female condom use. They were coded as using another reliable contraceptive if they had used the pill, patch, ring, injectable or IUD; no women in our sample reported IUD use, so this category is henceforth referred to as "hormonal contraceptive use." Women were coded as using a less reliable method if they had used withdrawal; a diaphragm, cap or sponge; or fertility awareness.[6]

For events with romantic partners, relationship duration was dichotomized into one month or less or longer than a month. The one-month cutoff was chosen because condom use begins to decline within weeks of beginning a new relationship.[10] For events with casual partners, participants were asked to identify their partner; response options were a stranger, an acquaintance, a friend, an ex-boyfriend and other. Answers of "other" were rare (2%) and were coded as missing.

Participants also reported whether they had drunk alcohol or used marijuana before each event.

• Month-level variables—Some variables were assessed on a monthly basis but were not linked directly to the sexual events reported. Because measures were collected over one year, we included the month of data collection in models, ranging from 2 (October 2009) to 13 (September 2010). Participants who were involved in romantic relationships reported their relationship duration in months. Women indicated the number of days in the past month during which they had engaged in binge drinking (consuming four or more drinks on one occasion) or had smoked marijuana. They were also asked whether they had smoked a cigarette during the past month; those who had smoked reported the average number of cigarettes per day. Because of low rates of cigarette smoking, a dummy variable was created indicating whether participants had smoked at least one cigarette a day, on average.

Participants reported the number of times they had had vaginal intercourse with romantic and casual partners during the past month. We created separate counts of monthly intercourse events by type of partner (excluding the event under analysis). Similarly, participants reported the number of romantic and casual partners they had had intercourse with in the past month; these counts also excluded the event under analysis. Finally, we created a variable indicating women's average number of months of hormonal contraceptive use; this included only months after women had enrolled in college.

• Person-level variables—These variables were assessed only once during the year. Several items concerned sexual history. At baseline, participants indicated the number of partners they had had vaginal intercourse with, whether they had ever received an STD diagnosis and whether they had ever been pregnant prior to enrolling. In April 2010, participants answered one item assessing perceived STD risk: "What do you think your chances are of getting an STD, such as gonorrhea or genital herpes?" Responses were rated on a scale from 1 (no chance) to 5 (very high).

Scales were used to assess parental and peer characteristics. In October 2009, participants completed eight items, adapted from a subscale of the Parenting Style Index,[54] indicating parental connectedness (e.g., "I can count on my parents to help me out if I have some kind of problem"). Responses were scored on a scale from 1 (strongly disagree) to 4 (strongly agree) and were averaged to create a total score (Cronbach's alpha, 0.91). In August 2010, participants answered two items about how their parents would feel about their using birth control at this point in their life; responses were rated on a scale from 1 (strongly disapprove) to 5 (strongly approve).[55] Items were averaged for participants reporting on both parents (Cronbach's alpha, 0.75); single items were used for those reporting on only one parent. In March 2010, participants completed items from the Parent-Adolescent Communication Scale[56] indicating how often since starting college they and their parents had discussed five sexual topics (e.g., protecting themselves from pregnancy and how to use condoms); the scale ranged from 0 (never) to 4 (often). These items were averaged to create a total score (Cronbach's alpha, 0.91). Finally, in March 2010, participants indicated how often in the past month they had discussed three sexual topics with peers: having sex, protection against STDs and protection against pregnancy; responses were scored on a scale from 1 (never) to 6 (nearly every day). Items were adapted from a peer alcohol communication assessment[57] and were averaged to create a total score (Cronbach's alpha, 0.82).

Three scales assessed personality. At baseline, impulsivity and sensation-seeking were measured using six items each from subscales of the Impulsiveness-Monotony Avoidance Scale.[58] Participants indicated how well each item (e.g., "I often throw myself too hastily into things" and "I like doing things just for the thrill of it") applied to them, using a Likert scale from 1 (not at all like me) to 4 (very much like me). Scores were averaged to create a total score (Cronbach's alpha, 0.82 for each scale). Finally, in June 2010, participants responded to items from the Ten-Item Personality Inventory[59] indicating how strongly they agreed that various traits represented them; responses were scored on a scale from 1 (strongly disagree) to 7 (strongly agree). Two items represented conscientiousness ("dependable" and "self-disciplined") and were averaged to create a total score (Cronbach's alpha, 0.42).

Several demographic variables were also assessed. A dummy variable was created to indicate whether participants were older than 18 at baseline, and two other variables indicated whether participants identified themselves as white, black or Asian, or as Latina. Socioeconomic status was assessed using a 10-point ladder,[60] on which participants ranked their family relative to other U.S. families. Finally, participants reported the extent to which they considered themselves religious (from "not religious" to "very religious") and their frequency of attending religious services (from "never" to "more than once a week"). These items were averaged, and higher scores on a 0–3 scale indicated greater religiosity (Cronbach's alpha, 0.80).

Analysis

Completion rates for monthly surveys ranged from 82% (in month 11) to 100% (in month 1); on average, participants completed 11.8 months of data collection (standard deviation, 2.2). To maintain the entire sample, we used multiple imputation to replace missing values.[61] Multiple imputation is a method for dealing with missing data that avoids biases associated with the use of only complete cases or with single imputations.[62] We imputed 100 complete data sets using Mplus 7,[63] and all study variables were included in the imputation. Analyses were conducted with all 100 data sets, and parameter estimates were pooled using the imputation algorithms in Mplus.

We used multilevel modeling in Mplus 7 to analyze the data. A total of 1,843 sexual events were reported by 296 participants. Given that hormonal contraceptive use is unlikely to vary between events occurring in the same month, we first explored associations between hormonal use and month-level and person-level characteristics. Next, we examined associations between event-, month- and person-level characteristics and condom use in 977 events reported by 181 women in which hormonal contraceptives were also used. Coefficients for variables that were highly nonsignificant ($Z<1.00$) were constrained to zero to increase model parsimony and stabilize estimates.[64] Odds ratios (from logistic regression analyses at the event and month levels), unstandardized betas (from linear regression analyses at the person level) and 95% confidence intervals are reported throughout.

RESULTS

Sample Characteristics

The majority of vaginal intercourse events occurred with established romantic partners (53%); events with new romantic partners (22%) and friends (15%) were the next most common (Table 1). Participants reported using alcohol prior to 20% of events, and marijuana before 7%. For 30% of intercourse events, women had used a less reliable contraceptive method.

The average duration of romantic relationships was nine months. Binge drinking and marijuana use occurred 2–3 times per month, on average, but cigarette smoking was relatively uncommon. Women reported a monthly average of 5.5 intercourse events with romantic partners and 0.4 events with casual partners; most women did not report other romantic or casual partners. On average, women who used hormonal contraceptives did so for four months during college.

The great majority of participants (96%) were age 18; the mean age was 18.1 (standard deviation, 0.2—not shown). Most women were white (71%); the remainder were black (13%), Asian (8%) or of other race (7%). Overall, 11% were Latina. On average, participants reported being middle- to upper-middle class, and had relatively low levels of religiosity.

Participants perceived themselves to be at relatively low risk of STD infection, despite reporting two sexual partners, on average, prior to college; few women reported a history of either STD diagnosis or pregnancy. On average, women reported a high level of connectedness with their parents, perceived their parents to have neutral or positive attitudes toward birth control, and reported communicating about sex with both their parents and peers relatively infrequently. Finally, women reported moderate levels of impulsivity and sensation-seeking, and a high level of conscientiousness.

Patterns of Contraceptive Use

Across 1,843 sexual intercourse events, women reported using a variety of contraceptive methods (Table 2). Male condoms were used in 63% of events; the pill, patch or ring in 53%; withdrawal in 30%; and no method in 6%. Other methods were used rarely.

Multiple contraceptive methods were used in 45% of events. Condoms and hormonal methods (the combination of primary interest in this study) were used together in 28% of events, condoms and less reliable methods in 13%, and hormonal and less reliable methods in 14%. In 5% of all cases, a condom, a hormonal method and a less reliable method were used in combination.

Of the 296 women who engaged in intercourse over the course of the study, 39% did not report any hormonal contraceptive use, while 34% reported such use during all intercourse events. The remaining 27% reported inconsistent use of hormonal methods across the year; these women either initiated use (13%), stopped use (7%) or reported other patterns of use (6%).

Forty-six percent of women were consistent condom users across all reported events, while 11% never used condoms; the remaining 43% reported inconsistent condom use. Only 14% of women were consistent dual method users; 53% never used dual methods, and the remaining 33% used dual methods inconsistently.

Correlates of Method Use

•Hormonal methods—Our multilevel model (Table 3) showed that women were more likely to use a hormonal contraceptive if they reported more frequent intercourse with romantic partners (odds ratio, 1.1) and perceived that their parents had more positive attitudes toward birth control (coefficient, 1.2). In contrast, women had a reduced likelihood of reporting hormonal use if they were older than 18 (−4.7), black (−4.3) or more religious (−1.0). This model explained 18% of the event-level variance and 25% of the person-level variance.

•Dual methods—Women were more likely to report dual method use when their partner was a friend rather than an established romantic partner (odds ratio, 2.5). In analyses that compared all partner categories (not shown), women were more likely to be dual users when their partner was a friend rather than a new romantic partner (2.5; 95% confidence interval, 1.0–6.1) or an ex-boyfriend (2.8; 95% confidence interval, 1.2–6.6); differences were not found between any other categories.

Women had a reduced likelihood of reporting dual method use if they had used a less reliable contraceptive method (odds ratio, 0.2) or had more months of experience with hormonal methods (0.8). At the person level, women were less likely to report dual use if they were older than 18 (coefficient, −4.7) or had had a greater number of past partners (−0.3). They were more likely to have been dual users if they reported greater religiosity (0.8) or had received an STD diagnosis prior to entering college (2.9). This model explained 29% of the event-level variance and 20% of the person-level variance.

DISCUSSION

Hormonal contraceptives and condoms were used together in only a quarter of intercourse events reported by participants; half of the women said they had never used dual methods, and a third reported inconsistent dual use. The inconsistency of dual method use among our participants indicates the need to examine associated characteristics using event-level, time-varying data rather than cross-sectional data. The prevalence of dual method use in our sample appears to be similar to that in other populations.[7] Given the high rates of STDs and unplanned pregnancy among women aged 18–19,[2,3] and the ubiquity of serial monogamy during the college years,[65] increasing the rates of dual method use among college women should be a goal for health educators and providers.

Our study showed that dual use declined as experience with hormonal contraceptives increased—by 20% with each additional month of use. One previous study[26] addressed the decline in condom use with increasing experience with hormonal contraceptives; however, these researchers noted a decline primarily among injectable users but not among pill users. We found a negative association between hormonal experience and dual method use, even

though the great majority of hormonal users in our study were using the pill, patch or ring. Women who used a less reliable contraceptive in conjunction with a hormonal method were also relatively unlikely to use a condom. Women may feel more confident about pregnancy prevention without a condom as their experience with hormonal methods increases, or if they use withdrawal or natural family planning methods in addition to a hormonal contraceptive. However, these less effective methods do not protect against STD transmission.

Women's number of past sexual partners was inversely related to their reports of dual method use. This finding contrasts with results from other studies, in which young people with more recent partners were more likely to use condoms.[39,40] The reduced likelihood of dual use women with more previous partners may be due to the tendency for condom use to decline more rapidly in each successive sexual relationship.[23] Although relatively few women in our sample had received an STD diagnosis, those who had had an STD were more likely than others to engage in dual method use, consistent with theories that invoke perceived risk as a determinant of health behaviors.[66] Interestingly, however, our measure of STD risk perception was not associated with dual use. Women with past diagnoses may perceive themselves as being at lower risk as a result of their condom use. Future research should employ multiitem measures of risk perceptions.

Religiosity had a complex relationship with contraceptive use in our sample. Although women who were more religious were less likely than others to use hormonal contraceptives, among those who used these methods, religiosity was positively associated with dual method use. The role of religiosity should be further explored in future studies.

Compared with women who were having sex with romantic partners (both short- and long-term), those having sex with friends were more likely to report dual method use. Previous studies have found that dual use is less common with romantic than with casual partners,[24,25] but they did not examine associations between specific partner types and dual method use. Although "hookups" (casual sexual encounters, which often occur with friends[30]) are often framed in a negative light, this finding suggests that some hookup experiences may involve protection against both pregnancy and STDs.

A number of variables investigated in our study, including sensation-seeking, conscientiousness, and parental and peer communication about sex, were not associated with dual method use. Surprisingly, substance use—at either the month or the event level—was not associated with dual use, in contrast to another study's finding that situational alcohol use was negatively related to dual method use among men and women aged 20–23.[14] Future studies might examine gender-specific associations between situational substance use and dual method use, ideally using event-level data.

Limitations and Future Directions

Several limitations of the current study suggest directions for future research. First, our data came from first-year female students at one university; generalizability to other settings and populations is not certain. Future studies should collect data from males and from a range of other institutions. In addition, although use of event-level measures is a major strength, we

cannot determine causal relationships from our data; some variables could be either predictors or outcomes of dual method use. Moreover, a number of our variables were assessed only once; future studies using event-level data should assess some of these variables (such as religiosity, parent and peer characteristics, and risk perceptions) over time, as more precise measurement may strengthen the assessment of their relationship with dual method use. Finally, our study did not assess some proximal variables, such as attitudes and intentions related to dual method use, that have been studied more commonly than event-level features in the past.[16,40] Given the inconsistency of dual method use, future research should consider both event-level characteristics and constructs from ecological and health behavior theories.[67] Ideally, this research should be based on specific theoretical models; our exploratory study suggests some variables that these models should incorporate.

Conclusions

This study identified a number of characteristics that are associated with dual method use, which occurred in only a quarter of reported intercourse events. A better understanding of such characteristics may aid in intervention design; if our results are borne out by more generalizable studies, the implication may be that women need to be counseled on the importance of maintaining use of condoms as their sexual relationships become more serious, as they gain experience with hormonal contraceptives and even when they are also using less reliable methods, such as withdrawal. Our findings demonstrate the importance of considering event-level and time-varying characteristics that may be associated with dual method use, in addition to the person-level characteristics that are more commonly considered. Future research should collect further data related to event-level characteristics to begin to inform potential intervention efforts. Moreover, longitudinal research is needed to identify predictors of dual method use.

Acknowledgments

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TABLE 1

Selected event-, month- and person-level characteristics of vaginal intercourse events among first-year college women attending a private university, New York State, 2009–2010

Characteristic	% or mean
Event level	(*N*=1,843)
Partner type	
Stranger	1
Acquaintance	4
Friend	15
Ex-boyfriend	5
New romantic (1 month)	22
Established romantic (>1 month)	53
Used alcohol before intercourse	20
Used marijuana before intercourse	7
Used less reliable contraceptive[†]	30
Month level	(*N*=1,843)
Month of data collection (range, 2–13)	7.5 (3.5)
Months of romantic relationship (range, 0–53)	9.1 (12.1)
No. of days engaged in binge drinking (range, 0–14)	2.8 (3.4)
No. of days used marijuana (range, 0–21)	2.4 (5.1)
Smoked cigarettes	14
No. of intercourse events[‡]	
With romantic partner (range, 0–31)	5.5 (7.0)
With casual partner (range, 0–7)	0.4 (1.2)
No. of intercourse partners (range, 0–2)[‡]	
Romantic	0.1 (0.3)
Casual	0.1 (0.3)
Months of hormonal contraceptive use (range, 1–12)[§]	4.2 (2.8)
Person level	(*N*=296)
Aged >18	4
Race	
White	71
Black	13
Asian	8
Other	7
Latina ethnicity	11
Family socioeconomic status (range, 1–10)	6.3 (1.6)
Religiosity (range, 0–3)	0.9 (0.7)
No. of intercourse partners before college (range, 0–9)	2.4 (2.4)
Perceived STD risk (range, 1–5)	2.0 (0.9)
Ever had STD diagnosis before college	3

Characteristic	% or mean
Ever pregnant before college	2
Parental connectedness (range, 1–4)	3.4 (0.5)
Parental attitude toward birth control (range, 1–5)	3.5 (1.1)
Parental communication about sex (range, 0–4)	1.7 (0.7)
Peer communication about sex (range, 1–6)	2.5 (1.1)
Impulsivity (range, 1–4)	2.2 (0.6)
Sensation-seeking (range, 1–4)	2.9 (0.6)
Conscientiousness (range, 1–7)	5.2 (1.1)

[†] Withdrawal, diaphragm, cervical cap, sponge or fertility awareness.

[‡] Excludes the current event or partner.

[§] Includes only women who reported use (181 women across 977 months).

Notes: Data for which no ranges are shown are percentages. Figures in parentheses are standard deviations.

TABLE 2

Percentage of vaginal intercourse events reported by first-year college women, by contraceptive method used

Method	%
Condom	**63**
Male	63
Female	0.1
Hormonal method	**53**
Pill/patch/ring	53
Injectable	0.3
IUD	0%
Less reliable method	**30**
Withdrawal	30
Fertility awareness	2
Diaphragm	0.3
No method	**6**
Multiple methods	**45**
Condom plus hormonal method	28
Condom plus less reliable method	13
Hormonal plus less reliable method	14
2 methods	45
3 methods	5

TABLE 3

Odds ratios from logistic regression analyses assessing associations between event-level and month-level characteristics of first-year college women's vaginal intercourse events and hormonal contraceptive use or dual method use, and unstandardized coefficients from linear regression analyses assessing associations between person-level characteristics and such use

Characteristic	Hormonal use	Dual use
Event level		
Partner type		
Stranger	na	‡
Acquaintance	na	‡
Friend	na	2.47 (1.001–6.11)[*]
Ex-boyfriend	na	0.42 (0.09–1.88)
New romantic	na	‡
Established romantic (ref)	Na	1.00
Used alcohol before intercourse	na	1.68 (0.81–3.50)
Used marijuana before intercourse	na	‡
Used less reliable contraceptive	na	0.24 (0.11–0.52)[***]
Month level		
Month of data collection	1.10 (0.99–1.21)[†]	1.11 (0.97–1.28)
Months of romantic relationship	‡	na
No. of days engaged in binge drinking	‡	1.05 (0.95–1.15)
No. of days used marijuana	1.06 (0.96–1.17)	‡
Smoked cigarettes	0.58 (0.25–1.36)	‡
No. of intercourse events		
With romantic partner	1.11 (1.05–1.17)[***]	0.97 (0.93–1.01)
With casual partner	‡	‡
No. of intercourse partners		
Romantic	‡	2.65 (0.96–7.32)[†]
Casual	‡	‡
Months of hormonal contraceptive use	na	0.80 (0.66–0.96)[*]
Person level		
Age >18	−4.71 (−8.72 to −0.69)[*]	−4.66 (−8.76 to −0.55)[*]
Race		
White (ref)	1.00	1.00
Black	−4.25 (−6.60 to −1.90)[***]	‡
Asian	‡	1.59 (−0.21 to 3.40)[†]
Latina ethnicity	‡	‡
Family socioeconomic status	0.33 (−0.11 to 0.77)	‡
Religiosity	−0.96 (−1.88 to −0.04)[*]	0.75 (0.01–1.49)[*]
No. of intercourse partners before college	‡	−0.34 (−0.59 to −0.08)[**]

Characteristic	Hormonal use	Dual use
Perceived STD risk	−0.47 (−1.34 to 0.40)	‡
Ever had STD diagnosis before college	1.97 (−0.88 to 4.82)	2.88 (1.17–4.59)***
Ever pregnant before college	‡	‡
Parental connectedness	‡	−0.92 (−1.96 to 0.12)†
Parental attitude toward birth control	1.16 (0.46–1.86)***	0.47 (−0.07 to 1.02)†
Parental communication about sex	‡	‡
Peer communication about sex	0.35 (−0.28 to 0.98)	†
Impulsivity	−1.09 (−2.26 to 0.09)†	−0.71 (−1.45 to 0.03)†
Sensation-seeking	‡	‡
Conscientiousness	0.36 (−0.28 to 1.00)	0.31 (−0.17 to 0.79)
R^2 within	0.18 (0.03–0.32)*	0.29 (0.15–0.43)***
R^2 between	0.25 (0.15–0.35)***	0.20 (0.07–0.34)**

*
p<.05.

**
p<.01.

***
p<.001.

†p<.10.

‡Measure was constrained to 0 in the model.

Notes: Figures in parentheses are 95% confidence intervals. na=not applicable, because measure was not included in the model. ref=reference group.