The Intrauterine Device in Women of Childbearing Age Has A Greater Long-Term Cost-Benefit than Oral Contraception Pills

Laura Rogers
Pacific University

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Abstract
Unplanned pregnancy remains a major problem in the United States, despite the widespread usage of contraception. Improper and inconsistent usage of short acting reversible contraception contributes to the unplanned pregnancy epidemic. Hormonal and copper intrauterine devices are safe and cost-effective alternatives, but usage in the United States remains low.

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Annjanette Sommers, PA-C, MS

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The Intrauterine Device in Women of Childbearing Age Has A Greater Long-Term Cost-Benefit than Oral Contraception Pills

Laura Rogers

A Clinical Graduate Project Submitted to the Faculty of the School of Physician Assistant Studies

Pacific University

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Faculty Advisor: Annjanette Sommers, PA-C, MS

Clinical Graduate Project Coordinator: Annjanette Sommers, PA-C, MS
Biography
Laura Rogers is a transplant to the West Coast from Washington, DC. She graduated from William and Mary in 2009 with a degree in Biological Anthropology. Laura taught English abroad in Morocco before settling into a medical profession. Her interests include women’s health and orthopedics. She looks forward to starting her career with Providence Health & Services in Portland, OR, after graduation.
Abstract

Background: Unplanned pregnancy remains a major problem in the United States, despite the widespread usage of contraception. Improper and inconsistent usage of short acting reversible contraception contributes to the unplanned pregnancy epidemic. Hormonal and copper intrauterine devices are safe and effective alternatives, but usage in the Unites States remains low.

Methods: An extensive search of MEDLINE-Ovid, CINAHL, and Web of Science was conducted. Keyword terms included: long-acting reversible contraception, contraception, cost effectiveness, and levonorgestrel-releasing intrauterine system. The studies were limited to the English language and those done on humans. Only publications from the last fifteen years were considered. The articles were further limited to studies done in the United States. References of articles were reviewed for further sources.

Results: A total of 47 articles were reviewed and three met inclusion criteria. The first two studies were economic analyses of the use of hormonal IUDs. The third study is a retrospective cohort which included an economic analysis. Two of the studies were funded in part by Bayer, a drug company that has a vested interest in IUDs being cost-effective. The quality of the data remains high.

Conclusion: The hormonal and copper intrauterine devices are safer, more cost effective alternatives to oral contraceptive pills. They require a one-time insertion and last for several years. They allow the user privacy and peace of mind, while approaching effectiveness levels of sterilization.

Keywords: long-acting reversible contraception, contraception, cost effectiveness, and levonorgestrel-releasing intrauterine system (LNG-IUS).
Acknowledgements

To my Lake Braddock and W&M crew-thank you for being there when I need it. To new adventures!

To my parents: Thank you for all the support and positive energy. We got through it together.
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List of Abbreviations

IUD.................................................................Intrauterine Device
UP.............................................................................Unplanned Pregnancy
OCP........................................................................Oral Contraceptive Pills
LNG-IUS.........................................................Levonorgestrel Intrauterine System
SARC...............................................................Short Acting Reversible Contraception
LARC..............................................................Long Acting Reversible Contraception
The Intrauterine Device in Women of Childbearing Age Has A Greater Long-Term Cost-Benefit than Oral Contraception Pills

BACKGROUND

The CDC lists family planning as one of the top ten public health triumphs of the 20th century[^1]. Female contraception allows women to control the timing of pregnancy and family size, while directly impacting their opportunities in education, workforce participation, and income stability. Reversible methods of contraception include hormonal short acting reversible contraception (SARC), barrier methods, withdrawal, and long-acting reversible contraception (LARC). SARC methods remain the most popular, with 55% of contraceptive users electing for oral contraception pills, a patch, a vaginal ring, or injections (Table 1)[^2]. The oral contraceptive pill (OCP) is the most widely used method, even though improper or inconsistent use contributes to a high rate of failure. The OCP fails less than 1% of the time when used directly as prescribed, while typical inconsistent and incorrect usage results in contraceptive failure 9% (Table 2)[^2]. Thus despite the wide varieties of contraceptive options on the market, over fifty percent of pregnancies in the United States are unplanned. This results in 3.4 million unintended pregnancies per year, 60% of which ended in live birth[^3].

In contrast, LARC has the same effectiveness with typical and perfect use[^2]. LARC methods include the copper intrauterine device (Paragard), hormonal intrauterine devices (levonorgestrel-releasing Mirena, Skyla, and Liletta), and hormonal implants (etonogestrel-releasing Implanon). These safe methods are not user dependent, have similar effectiveness to permanent sterilization, and are associated with rapid return to fertility on discontinuation. The IUD is the most popular of these options, but only 10% of contraceptive-using American women currently opt for an IUD[^2].
This percentage is growing but remains low due to high initial cost, provider and patient education, and provider practice patterns. Heavy resistance to intrauterine devices (IUDs) stems from public and health care provider fear. The IUD was introduced to the US in the 1960s. By the 1970s several different IUDs were on the market, all of them unregulated by the FDA. The Dalkon Shield had a design flaw that introduced bacteria into the sterile uterine environment. This design flaw caused serious complications including pelvic inflammatory disease, sterility, sepsis, and death. Early studies on IUDs did not differentiate between the Dalkon Shield and other IUDs. The Dalkon Shield was voluntarily pulled from the market and IUD usage in the United States plummeted. IUDs remained popular overseas and have proved to be a safe contraceptive option for women.

The hormonal IUD Mirena was announced to the United States in 2000, nineteen years after being introduced and approved for European markets. Usage remains low but has tripled in the US since 2002. As the popularity of Mirena grew, so did the price. Bayer increased the per unit price in March 2010 from $470 to $703. Out of pocket cost for IUD insertion for women with health insurance routinely was $800-1200, making it an unaffordable option for the majority of women. Reimbursement for providers from health insurance companies remained an issue and the price jump made it infeasible to stock in low income clinics. Bayer had discovered in addition to preventing pregnancy, the hormonal IUD was found to reduce endometrial and cervical cancer, reduce menorrhagia and provide an alternative treatment for hysterectomies.

Despite this, misinformation about LARC remained among health care providers. A 2008 survey of health care providers found 40% did not offer LARC to patients and less than 50% believed nulliparous women were appropriate candidates for IUDs, despite literature proving otherwise. The American College of Obstetricians and Gynecologists endorses IUD use in
adolescents regardless of parity. In October 2014 the American Academy of Pediatrics amended their reports and recommended LARC as the first line contraception option in adolescents. Pediatricians and family practice providers report a lack of training opportunities as a barrier in implementing this recommendation. Adolescents are some of the most at risk populations for unintended pregnancies, accounting for over six hundred thousand live births per year. Unintended pregnancy in women is associated with delayed prenatal care, maternal depression, low birth weights, poor infant and maternal outcomes, and low rates of breastfeeding. Adolescent women could benefit from a “fit and forget” method of contraception is discreet and lasts for years. With the Affordable Care Act executive mandate ordering insurance companies to pay for all methods of contraception, interest in IUDs is rising. This suggests cost was a prohibiting factor in women’s decision to use IUDs. Since an IUD lasts for 3-10 years depending on the device, the initial acquisition and insertion cost could be compared to the cost of unintended pregnancies. The IUD has the potential to be more cost effective than OCP.

METHODS

An extensive search of MEDLINE-Ovid, CINAHL, and Web of Science was conducted. Keyword terms included: long-acting reversible contraception, contraception, cost effectiveness, and levonorgestrel-releasing intrauterine system (LNG-IUS). The studies were limited to the English language and those done on humans. Only publications from the last fifteen years were considered. The articles were further limited to studies done in the United States. References of articles were reviewed for further sources.

RESULTS
A total of 47 articles were reviewed and three met inclusion criteria. The first two studies\textsuperscript{12,13} were economic analyses of the use of hormonal IUDs. The third study\textsuperscript{14} is a retrospective cohort which included an economic analysis.

**Trussell et al (2013)**

This economic model study\textsuperscript{12} evaluated the cost of unintended pregnancy (UP) and long acting reversible contraception’s potential to reduce health care costs associated with that UP. The study estimated the cost of UP that result from imperfect contraceptive use. The contraceptive adherence patterns and rates of UP in the United States were pulled from other databases.\textsuperscript{12}

The potential savings from widespread IUD use cannot be understated. “Total costs to the US taxpayers from UP have been estimated to range from $9.6-12.5 billion a year, whilst annual direct medical costs have been estimated to be $5 billion. These costs are theoretically avoidable.”\textsuperscript{12} Half of UP in the United States occur in women who report using contraception\textsuperscript{3}, and the contraceptive failure occurs from imperfect adherence. IUD does not rely on perfect user compliance, as the device lasts for years after the initial insertion. Trussell et al (2013) compared the cost of UP due to imperfect adherence and the potential savings from switching to IUDs. The authors created an economic model that took into account the annual number of UP and their cost, the cost and use of contraception in the US, the number of UP associated with imperfect contraceptive use, and the cost-effectiveness of increased usage of IUDs.\textsuperscript{12}

The cost of unintended pregnancy was factored in from the Medicare Fee Schedule and multiplied by the number of annual UP. Contraceptive cost included the product cost and the associated fees with the provider visit. Product costs were obtained from IMS MIDAS, the Medi-Span Master Drug Database, and consultations fees were taken from Medicare Fee Schedule\textsuperscript{12}. \textsuperscript{12}
The authors created three scenarios that looked at 10% of women ages 20-29 who were switched from OCP to IUDs, 10% of women aged 20-29 using SARC switched to IUDs, and 10% of women aged 20-39 switched to SARC or no method to IUDs. The age range of 20-29 was chosen because 53% of UPs in the United States are in this age group.\textsuperscript{12}

All three groups achieve cost neutrality within two years. The greatest savings occurred when women using no method or a SARC switched to an IUD. Limitations include only factoring in a first year failure rate for contraceptive methods. The cost of live birth may be underestimated as all prenatal costs were omitted.\textsuperscript{12}

\textbf{Trussell et al (2014)}

This is a state transition model study\textsuperscript{13} looking to prove the cost effectiveness of Skyla over SARC methods. The LNG-IUS 13.5mg (Skyla) is a levonorgestrel intrauterine device approved for three years of use. It is smaller than Mirena, the other levonorgestrel intrauterine device on the market and was designed for nulliparous women. Skyla was compared to SARC methods in a cohort of women 20-29 years. This age group in the United States currently uses OCP more and IUDs less than any other group.\textsuperscript{13}

From an insurance company perspective, the LNG-IUS 13.5mg is a more cost effective option than OCP, when the costs of unintended pregnancy and cost of OCP is taken into account.\textsuperscript{13} The LNG-IUS 13.5mg is approved for three years of use in nulliparous and parous women. The study considered the cost of the drug in question, provider compensation for consultation and insertion, and cost of method failure. The costs were pulled from Medi-Span Master Drug Database, the wholesale acquisition price, the Healthcare Cost and Utilization
Project data, and the 2012 Medicare Reimbursement Fee Schedule. Method failure was measured in live birth, induced abortion, miscarriage, or ectopic pregnancy.

The effectiveness of each method was measured by the average number of contraceptive failures over a three year time period. “Compared to the SARC comparator, LNG-IUS 13.5mg was more effective (64 UP vs 276 UP) and less costly ($1,283,479 USD vs. $1,862,633 USD) in a starting cohort of 1000 women aged 20 to 29 years in each arm, over the three year time horizon.” The results were most sensitive to the probability of failure of OCP, the cost of live births, and the continuation rate of the IUD. This analysis has limitations as the cost of adverse drug reactions or IUD complications were not included in the study. The cost of UP was derived from the Medicare billing schedule, which is lower than private insurers. This study probably underestimated the total cost of UP. The failure rates with “typical use” were applied to all three years in the prospective study and the authors admit failure rates would likely be lower after the first year as uncompliant users would fail early and be removed from the study.

**Rodgrìuez et al**

This retrospective cohort study examined the cost effectiveness of offering postpartum IUD insertion to recent US immigrants with Emergency Medicaid insurance. Undocumented and legal immigrants who have been in the United States for less than five years are only eligible for health insurance with Emergency Medicaid (EM). EM does not cover the cost of prenatal care or contraception. The “lack of health insurance is associated with multiple obstetrical and neonatal outcomes that are detrimental to the health of the woman and child, and expensive for the hospital, society, and the state.” The authors created two models for their cost benefit scenario: hospital provision of IUDs postpartum and state funding of IUDS postpartum. The
costs and benefits were measured by comparing the costs of pregnancies averted over the costs of IUD purchase and insertion.

The cohort was designed by searching the OHSU database for women with EM insurance who had delivered babies at OHSU during 2002. The next four years of hospital data on these women was included in the cohort, determine by “pregnancy rates, pregnancy outcomes, pregnancy costs, and net revenue by procedure type.” The authors estimated the number of pregnancies averted by factoring the IUD failure rate, continuation, and expulsion. The IUDs were placed immediately postpartum, which is a known risk factor for IUD expulsion. This was considered when estimating the number of pregnancies averted. The IUD was offered as a reversible form of contraception instead of sterilization.

Delivery procedure and contraceptive costs were compared. Possible pregnancy outcomes included were cesarean delivery, vaginal delivery, vaginal delivery with sterilization, ectopic pregnancy, spontaneous abortion, and threatened abortion. The costs were estimated for the state by the amount paid to the hospital for each diagnosis, while the cost for the hospital included the charges minus the revenue for the state. IUD costs included the price of the device, insertion time, and removal. The outcomes were measured from hospital records. Cost savings differed depending on the state or hospital model. The hospital program had a benefit ratio of 0.30, losing $0.70 dollars per dollar spent…” program costs for IUS, insertion, and removal are estimated for 1000 women at $328,000.” Newborn care generates positive revenue for the hospital, while providing IUDs loses the hospital money since they are not being reimbursed by EM. In comparison, the state funded program “would save $2.94 in costs for repeated obstetrical care for every state dollar spent on an IUD program.” Rodriguez et al
projected that state would spend $2.1 million dollars covering the costs of UP in the following four years, while the IUD program could cut that number in half.

**DISCUSSION**

When taking into account the cost from unintended pregnancy, IUDS are more cost effective than OCP. IUDs prevent a higher number of unintended pregnancies and produce net-cost savings. This is driven by the significantly lower failure rates of IUDs, which are also not dependent on user compliance. This makes them suitable for women with irregular access to healthcare or irregular routines. While IUDS methods are highly effective in preventing unintended pregnancies, they do not provide protection against sexually transmitted infections (STIs). None of these studies made any inferences or hypothesis as to costs of STI infection with increased IUD use. Further studies must be done to see if there is any correlation.

Discontinuation is the key determinant to the cost effectiveness of IUDs. Reasons for discontinuation include changes in bleeding patterns, headache, acne, weight gain, expulsion, and pregnancy intention. Further investigation needs to be made on pain control during IUD insertion. IUD insertion is notoriously more difficult on insertion for nulliparous women, and could prove an obstacle for widespread IUD use. Existing literature proves that prophylaxis ibuprofen, acetaminophen, or misoprostol do not help with IUD insertion pain. The majority of women experience a discomfort similar to menstrual cramps on insertion, but a small subset of 17% experience significant pain that needs to be subsequently managed. Studies on the use of lidocaine gel and spray are currently conflicting and inconclusive. Further study is warranted.

The hypothetical models of the previously discussed articles are supported by a recent ecological study in Colorado (CO). In 2009, twenty eight Title X agencies in CO received
funding to support the provision of LARC to patients visiting these clinics. These clinics served 
95% of CO’s low income population and were able to provide LARC at no cost or a sliding 
scale. In the next three years, the number of high risk births, abortions, and WIC caseload 
plummeted\(^1\). The expansion of the Affordable Care Act and contraceptive mandate has the 
potential to replicate the success of the Colorado clinics.

**CONCLUSION**

The hormonal and copper IUDs are more cost effective than OCPs. The higher initial cost 
acquiring and inserting the devices is offset by several years of preventing pregnancy. The 
method failure rates approach sterilization, while remaining completely reversible\(^2\). The far 
reaching implications are staggering. $5 billion dollars is the estimated medical cost of UP in the 
United States every year\(^2\). IUDs are the safe and cost effective answer to avoiding unintended 
pregnancies.
References


Table 1:

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<th>Percentage of Contraceptive Users</th>
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Table 2

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<td>IUD-Copper T</td>
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