

A COMPARATIVE ANALYSIS OF REGULATED EMERGENCY CONTRACEPTION VS.
DEREGULATED EMERGENCY CONTRACEPTION

A Research Project by

Alicia Nguyen

Bachelor of Arts, Wichita State University, 2005

Submitted to the Department of Physician Assistant
and the faculty of the Graduate School of
Wichita State University
in partial fulfillment of
the requirements for the degree of
Master of Physician Assistant

May 2007

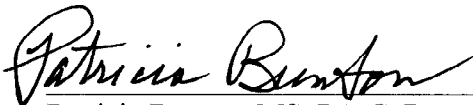
Wichita State University
College of Health Professions
Department of Physician Assistant

We hereby recommend that the research project prepared under our supervision by Alicia Nguyen entitled A comparative analysis of regulated emergency contraception vs. deregulated emergency contraception be accepted as partial fulfillment for the degree of Master of Physician Assistant.

Approved:



Richard D. Muma, PhD, MPH, PA-C, Chair and Associate Professor
Department of Physician Assistant



Patricia Bunton, MS, PA-C, Research Advisor
Department of Physician Assistant

6/6/07

Date

Dedication

To my mom, brother and my dear friends

ACKNOWLEDGEMENTS

I would like to thank my advisor, Patricia Bunton for her support and advice these past two years of Physician Assistant school. I would also like to extend my gratitude to another member of my committee, Richard Muma, for his helpful comments and suggestions on all stages of this project.

ABSTRACT

Introduction: With the introduction of emergency contraception, the likelihood of an unintended pregnancy can be reduced by up to 70% to 80%; however, limited access to EC, poor knowledge of its mechanism of action, therapeutic uses and adverse effects and lack of public awareness of its existence have weakened its potential benefits. Numerous studies have been conducted to determine if advanced provision of EC or OTC EC is more effective than prescription-only EC in minimizing the risks of unintended pregnancy. Methodology: An evidence-based systematic review of the literature was done using Medline, FirstSearch, and CSA databases from 1998 to the present. The MeSH terms utilized in the search were emergency contraception/EC; Plan B; OTC/over the counter; deregulation/regulation; prescription; levonorgestrel. Articles were chosen based on the criteria that they were peer-reviewed, were randomized controlled trials, and that the information in the articles answered the research question. Results: Twenty-six articles met the criteria and were selected for review. The literature demonstrates that with accurate, adequate education there is little abuse potential with advanced provision of EC or OTC EC. The literature has also shown no evidence of increased frequency of unprotected sex or increased incidence of sexually transmitted diseases with unrestricted access. Conclusion: Increased access to EC through the establishment of OTC status or advanced provision results in a lower occurrence of unintended pregnancies than prescription-only EC.

TABLE OF CONTENTS

Chapter	Page
ABSTRACT	v
TABLE OF CONTENTS	vi
1. INTRODUCTION	1
2. METHODOLOGY	4
3. LITERATURE REVIEW	5
4. DISCUSSION	
Evidence in the Literature	11
Weaknesses in the Literature	13
Gaps in the Literature	14
Validity of the Review	15
Weaknesses of the Review	15
5. CONCLUSION	16
REFERENCES	17
APPENDICES	
A. Included articles	20
B. Excluded articles	32
VITA	33

CHAPTER ONE

INTRODUCTION

Every year over 800,000 teen pregnancies occur in the United States (US) and approximately 85% of these pregnancies are unintended ¹. The United States holds the highest rate for unplanned teen pregnancies amongst all developed countries in the world – quadrupling the rate of Germany, septupling the rate of the Netherlands and nonupling the rate of Japan ². The most recent data available in a 1999 study showed that approximately 56.5% of teenage pregnancies resulted in a live birth, 28.5% resulted in an induced abortion and 15% resulted in a miscarriage or stillbirth ³.

Although birth rates have declined in years past, teen pregnancy remains a growing concern in the United States. It has affected society on so many levels that it has become a public health matter and with such startling figures for unintended pregnancy rates, it is apparent that abstinence and the continuation of utilizing contraceptives are vital in the reduction of these numbers. There are a few points of concern in regards to contraceptives, such as increasing their usage, provision of adequate knowledge and/or education for appropriate utilization and their level of accessibility. Amongst all methods of contraceptives, emergency contraception (EC) has experienced the most difficulty in all three areas.

The American Academy of Pediatrics defines emergency contraception as “hormonal medications used within 72 to 120 hours after unprotected or underprotected coitus for the prevention of unintended pregnancy” ³. Forms of emergency contraception would include the copper intrauterine device (IUD) and even the Yuzpe regimen which involves high doses of “off-label” combination contraceptives. There were two FDA (Food and Drug Administration)-approved medications for emergency contraception in the United States but shortly after Plan B

was approved on the market, Preven was sold to a different manufacturer and then it was no longer being manufactured⁴. Preven was approved in 1998 for the use of emergency contraception and it included a combination of estrogen (ethinyl estradiol) and progestin (levonorgestrel) – comparable to the same hormones that are found in combination oral contraceptives³. The only product remaining on the US market that is packaged exclusively for emergency contraception and is FDA-approved is Plan B (levonorgestrel), a progestin-only formulation that was approved in 1998⁴. Of the various forms of emergency contraceptives available, extensive research through randomized, clinically-controlled trials have shown that the levonorgestrel formulation has greater efficacy and fewer adverse effects than the combination hormone methods Preven and the Yuzpe regimen²⁻⁵.

Late last year, the FDA finalized a long, ongoing battle with the deregulation of Plan B. In the late months of last year, Plan B was made available “behind-the-counter”. Customers wanting to purchase Plan B would have to request the product from a pharmacist who is licensed to sell it and customers must also present a government-issued identification card that proves that they are above 18 years of age; customers below 18 years of age must have a written prescription from a doctor in order to make the purchase⁶. Since Plan B is deregulated only for “behind-the-counter” status, patients may find themselves in a dilemma if they are minors seeking Plan B on a weekend and/or if the emergency department does not dispense emergency contraception.

Being the only approved emergency contraception on the market, Plan B has faced a vast array of impediments ranging from limited availability to unawareness of its existence. One study that was conducted on inner-city teenagers showed that of the 71% who were sexually active, only 30% had heard of emergency contraception³. Other contributing factors responsible for the lack of emergency contraception usage are inadequate understanding of its mechanism of

action, concerns regarding its adverse effects, assumptions that unrestricted access to emergency contraception usage would lead to an increase in the frequency of unprotected intercourse and sexually transmitted diseases (STDs) and that it would compromise routine use of contraceptives.

Emergency contraception has the strong potential to significantly reduce rates for unintended pregnancies but its capability has been dramatically blunted through numerous barriers. Deregulating emergency contraception would increase access, decrease rates of unintended pregnancies and lead to a greater public awareness of emergency contraception ². Methods that would constitute as deregulation or increased access of EC would include direct supply by pharmacies or emergency departments, distribution of advanced provisions by health professionals and dispensing of EC over the counter.

CHAPTER TWO

METHODOLOGY

The design of this study was a systemic review of evidence-based medicine. The objective was to analyze the benefits, risks and controversies surrounding regulated emergency contraception versus deregulated emergency contraception and to determine if one is more beneficial in minimizing the risks for unplanned pregnancies. This study was conducted using CSA and FirstSearch to explore the Medline databases which included articles from 1998 to the present.

Articles were chosen for review based on whether they were peer-reviewed, if they were randomized controlled trials and relevance of the data to the purpose of this study. For example, the inclusion criteria requirement was that each article was to be retrospective, a randomized controlled trial, cohort, actual use study or a literature review. Each article that met one of the above requirements was then extracted and examined and selection was based upon how well the data could be extrapolated to the study question. The following key terms were used: emergency contraception, EC, Plan B, levonorgestrel, advanced provision, OTC, over the counter, deregulation, regulation, prescription.

CHAPTER THREE

LITERATURE REVIEW

Emergency contraception began in the 1960s when a Dutch physician first provided high doses of estrogen to a thirteen year old girl who had been the victim of a rape ⁷. This method of pregnancy prevention became a growing trend until the 1970's when a Canadian physician, Dr. Albert Yuzpe, developed a combination estrogen-progestin regimen that is now known as the Yuzpe regimen ⁷. Since then, emergency contraception has been used in several situations, such as a contraceptive failure, a rape situation that did not involve protection or an unplanned sexual intercourse without protection.

Levonorgestrel or "Plan B" is a two-pill formulation that follows a US FDA-approved regimen which states that the first dose is to be taken within 72 hours of unprotected sex for optimal efficacy, followed by a second dose to be taken exactly 12 hours later ⁸. Although emergency contraception in general is effective up to 120 hours after sexual intercourse, the efficacy greatly diminishes as the window of time expands from the time of intercourse to the intake of the first dose of emergency contraception ¹.

Since the efficacy of emergency contraception is time-sensitive, it is apparent that increased access is crucial and essential to achieving optimal EC efficacy to prevent unintended pregnancies – up to 89%, according to one study ³. Of particular relevance to the efficacy of EC in preventing unintended pregnancies, one study examined the effect that increased EC access had on pregnancy rates. This study found that although the increased access (treatment) group was more likely to use EC and was likely to use it earlier in comparison to the clinic-access (control) group, pregnancy rates in the treatment group were higher than the control group and the pregnancy rates were not similar to findings in the literature ⁹. One particular study found

that of the 36 women who were given advanced supplies at home, 74% did not use EC because they did not think the chances of getting pregnant were very high ¹⁰.

A review of the literature demonstrates that in studies that evaluated differences between those with increased EC access (treatment group) and those with clinic access only (control group), control groups had lower rates of EC usage, a longer time span from unprotected intercourse and the first dose of EC and higher pregnancy rates ^{1, 11-16}. One study examined patterns of EC use between advanced provision and information-only groups and it did find that although advanced provision of EC did not increase risky sexual behavior, the treatment group had a slightly higher pregnancy rate than the control group ¹⁷; other than this project, no studies in the literature could be found to indicate that restricted EC access is more beneficial or less harmful than unrestricted EC access.

One of the most efficient ways of increasing access to emergency contraception is through advanced provisions by a health care provider. This method of availability, however, has raised concerns on safety and usage, possible abandonment of routine contraceptive use, increased incidence of risky sexual behavior and/or sexually transmitted diseases.

Regarding the issue of safety, all but four studies ^{12, 18-20} showed that most women of various levels of education and income, who acquired emergency contraception through increased access had very good labeling comprehension, knowledge of adverse effects and understanding of EC use ^{8, 9, 11, 16, 21, 22}. An “actual use” study was executed in five pharmacies near Seattle, Washington between 2001 and 2002 to assess the impact that over the counter EC would have on use, pregnancy and adverse effects ⁸. The study concluded that female participants of various levels of education and income were able to use EC appropriately and tolerated the adverse effects well – both without the supervision or counseling of a physician ⁸.

The majority of patients who used EC indicated that they either used it due to contraceptive failure or absence of contraception use during coitus; these were the same reasons patients gave upon their admission visit on why they would want to receive emergency contraception ⁸.

Opponents of advanced provision to emergency contraception have also argued that increased access would tempt patients to abandon their routine contraceptives and rely on emergency contraception as their main form of contraception; the literature has not shown this to be true. Several authors have reported that advanced provision has not negatively affected use of routine contraception but in some cases have led to patients switching to more reliable forms of contraceptives ^{1, 9-14, 16, 20, 23, 24}. Of all studies that addressed this issue, only one study indicated that advanced provision of EC led to decreased usage ²⁵. This study assessed women requesting EC in a clinic in order to evaluate the short and long term effects that EC had on unintended pregnancies and frequency of chlamydia infections ²⁵. Ten of the 134 women who requested EC became pregnant and although all 10 had received a prescription for oral contraceptives, some started and stopped it secondary to adverse effects; others never started their oral contraceptives at all ²⁵.

Advanced provision of EC has also raised concerns of a possible increase in risky sexual behavior and/or sexually transmitted diseases. Though it has been previously stated that increased availability of emergency contraception does not negatively affect routine contraceptives, the literature has conflicting information on risky sexual behavior. Two studies found that groups that were given advanced provisions of emergency contraception had higher pregnancy rates than the control groups ^{1, 9}. One randomized, controlled trial of Plan B was conducted to assess the effect of increased access amongst young adolescents. This trial indicated that adolescents less than 16 years of age carried the highest percentage in STD

acquisition and that across the board for all age groups, clinic and pharmacy access had the highest rates for incidence of STDs⁹. On the contrary, other studies in the literature have demonstrated that increased access to emergency contraception has not led to an increase in risky sexual behavior^{11, 13, 14, 16, 20}.

Another means of increasing EC access is through establishment of EC behind-the-counter, through a pharmacy. Several states in the US have even permitted pharmacists to write scripts for emergency contraception³. Despite this sanction, pharmacies throughout the United States have not shown promising numbers when it comes to emergency contraception availability. A survey conducted in 2002 in pharmacies in New York, New York showed that only half of the pharmacies dispensed emergency contraception³. Another study conducted in 2001 in pharmacies in Indiana indicated that for those who were seeking emergency contraception, less than half were not able to obtain EC because the pharmacy did not have it available³. Reasons that were given for this inaccessibility were personal and/or religious beliefs and lack of trained personnel licensed to dispense emergency contraception³.

Another way that patients can acquire emergency contraception behind the counter is through pharmacies that do not require a prescription. Allowing patients accessibility of EC without a prescription allows an individual to privately acquire it at their own convenience and would cut down on health care costs and potentially save money for those who live too far from a location that offers it⁴. Currently, only 7 states have allowed nonprescription pharmacy access of EC². A population-based cohort study that was conducted between 1996-2002 allowed pharmacists, who received standardized training for this occasion, to dispense emergency contraception without a prescription from a doctor²⁶. Results showed an increase in EC usage amongst all age groups and 98.2% of those who obtained EC did so within 72 hours of

unprotected sexual intercourse²⁶. Another similar study demonstrated that all patients obtained emergency contraception within 72 hours, most (65%) obtained their EC directly from a pharmacist and that the majority of them (29%) obtained EC on a Sunday²¹. Two randomized controlled trials have demonstrated that even though pharmacy access does allow timely EC access and that it does not lead to abandonment of routine contraceptives, the pharmacy access groups and clinic access groups had almost identical rates of EC use^{9, 14}.

Patients who experience difficulty in acquiring EC from the clinic or pharmacy may find themselves resorting to the emergency room; a Mawhinney and Dornan study observed that requests for EC increased significantly when it was past the open hours of local pharmacies⁴. “The commonest reasons for requiring EC were condom breakage and getting carried away, which is consistent with previous research”²⁷. The literature, however, has not shown that emergency departments are a reliable route for acquiring EC^{4, 28}. In 2002, 597 United States Catholic and non-Catholic emergency departments were surveyed by trained female interviewers in order to assess if there was a difference in the availability of emergency contraception²⁸. The female interviewers posed as female patients who had unprotected sexual intercourse on a Thursday evening and were seeking EC past clinic hours²⁸. The results showed that even in cases of sexual assault, 42% of non-Catholic and 55% of Catholic hospitals still did not dispense emergency contraception²⁸. Of the hospitals who gave valid referrals, only 20.3% of non-catholic and 35.5% of Catholic hospital referrals led to a successful outcome²⁸.

Although Plan B is not approved for over the counter status, it appears to be another route to fast, easy access to EC. In order for a drug to achieve over the counter status, the FDA usually requires that the drug undergo two trials; one trial would test for its labeling comprehension and another trial would be an “actual-use study”²⁹. These two trials are not

actually required by law and in the case of a medical and/or public concern, this process could be bypassed and a drug could achieve immediate over the counter status²⁹.

Studies have been executed to evaluate the effects of bringing EC over the counter. One randomized cohort study concluded that participants agreed nonprescription EC would help cut down on time and cost, that nonprescription access to EC actually encouraged patients to use their regular method of contraceptive more responsibly²⁴. Although these studies assert that patients have adequate labeling comprehension without physician supervision, a review of the literature has found a lack of evaluation on the incidence of sexually transmitted diseases. Of the studies that evaluated accessibility of EC OTC, none were found to assess its effects on incidence of STDs.

CHAPTER FOUR

DISCUSSION

Evidence in the Literature

All but four studies^{12, 18-20}, concerning EC comprehension have shown that the majority of patients used it correctly, had a good understanding of the mechanism of action, the therapeutic uses and/or adverse effects of emergency contraception^{8, 9, 11, 16, 21-24}. The sample populations included all age groups, minorities with poor English-speaking skills and/or those with low income or poor education.

Deregulating emergency contraception has raised concern of possible abandonment of routine contraception but only one study has shown that increased access to EC will negatively affect routine use of regular contraception²⁵. Arguments regarding risky sexual behavior and sexually transmitted diseases with increased availability of EC have also been addressed. A review of the literature has shown conflicting evidence. Two studies have shown that although the sample populations with increased access to EC were more likely to use it and within an earlier time frame than the control group, the treatment group still had higher rates of unprotected sex at follow-up^{1, 9}; other studies from the literature indicate that there is no associated risky behavior or increased incidence of STDs with increased EC availability^{11, 13, 14, 16, 20}.

Despite improved access and an increase in EC usage, EC is still underused. Four studies indicated pregnancy rates in treatment groups were rather high despite increased availability of emergency contraception^{10, 12, 16, 17}.

No literature was found that indicated that restricted access to emergency contraception was more beneficial or efficient than unrestricted access. This literature review confirms the

findings of other studies – that the deregulation of emergency contraception leads to increased usage, promotes timely access, does not compromise routine use of contraceptives and is safe enough to be dispensed over the counter or in advanced provisions.

The literature has stated that up to 89% of unintended pregnancies³ can be prevented through appropriate and timely use of emergency contraception; deregulating emergency contraception allows a patient to acquire and use emergency contraception in a fitting window of time. The literature has established that advanced provision groups were able to access EC in a timely manner and were more likely to use EC than control groups but pregnancy rates in treatment groups were not as low as the literature has claimed; a closer look into this dilemma revealed that treatment groups were not always using EC when it was indicated. Multiple studies across the board have demonstrated that the most common reason women did not use emergency contraception when they should have was because they did not realize the risk of a possible pregnancy. “...not to say that EC will not prevent pregnancy for some women...it may not make much difference to public health. Emergency contraception is useful as a backup for women who have had unprotected sex or a contraceptive mishap, but most women, most of the time will fail to recognize the need to use it”¹⁵ Women need to be better educated about the reproductive cycle and more informed about pregnancy risks.

Open access to emergency contraception can be established through various ways. This evidenced-based study found that advanced provision of emergency contraception is the most efficient route for acquirement of EC. Various authors have reported increased EC use, usage of more reliable forms of contraceptives and no increased incidence of risky sexual behavior with advanced provisions of emergency contraception.

Nonprescription pharmacy access would prove to be another effective route to improve

EC utilization; however, EC must be distributed by a licensed pharmacist who has received special training to appropriately inform patients about emergency contraception and sexually transmitted diseases. When patients could not acquire EC from a pharmacy, it was often because the pharmacy lacked the trained personnel who could carry out this task.

Emergency departments are alternatives to acquiring EC when it is beyond clinic or pharmacy hours. A study that surveyed all non-Catholic and Catholic hospitals in the United States discovered though, that less than half of both Catholic and non-Catholic were dispensing EC – even in cases of sexual assault²⁸. Referrals were given from hospitals who did not dispense EC but only about a quarter to a third of them resulted in successfully acquiring emergency contraception²⁸. Further studies need to be done to evaluate why hospitals are reluctant to distribute emergency contraception to women who are requesting for them, especially in situations where the woman has been sexually assaulted.

Another method of improving EC utilization is through access over the counter. The literature has limited information on trials that evaluated emergency contraception “over the counter” but it has demonstrated that women of various backgrounds have been shown to use emergency contraception safely and appropriately when EC was provided OTC. Incidence of adverse effects and pregnancy rates was relatively low but rates of sexually transmitted diseases have not yet been evaluated. Future comparison studies on increased access to emergency contraception need to include over the counter access along with pharmacy access and advanced to evaluate patient behavior when they are faced with various, deregulated routes of EC access.

Weaknesses in the Literature

One major area of weakness found in the literature is the inconsistency of the characteristics of the participants. Not all studies consistently integrated characteristics like age,

race, level of income, level of education, history of contraceptive use and past sexual history into their selection process; not doing so does affect the outcome of these trials and it makes it difficult to understand the logic behind the decisions that the participants make. This inconsistency in the research participants may contribute to the literature generally advocating contraceptive use and deregulation of emergency contraception, yet it also shows that deregulated emergency contraception is associated with an increase in the incidence of sexually transmitted diseases.

A second area of weakness that was found in the literature is the limited amount of randomized trials on the deregulation of emergency contraception through over the counter status. There is also limited information on the incidence of sexually transmitted diseases with this route of deregulation. Further studies need to be done to see whether or not over the counter emergency contraception has a negative effect on the incidence of sexually transmitted diseases.

Gaps in the Literature

The literature provides sufficient information on both regulated and deregulated emergency contraception and how the route of accessibility affects usage, pregnancy and incidence of sexually transmitted diseases and so on and so forth. There is, however, an area that is obviously not addressed sufficiently in the literature; there are insufficient studies that evaluate emergency contraception over the counter and the effect it has on the incidence of usage, pregnancy, contraceptive use and sexually transmitted diseases. Most studies that are in the literature mostly evaluate emergency contraception through advanced provision and/or behind the counter.

Validity of the Review

The references that were chosen for this project were selected in a systematic manner. CSA and FirstSearch were used to explore the Medline database and specific keywords, which were previously mentioned; these keywords were chosen based accordingly on how well they related to the research question. Strict inclusion and exclusion criteria were established prior to the selection process and articles were then extracted and examined and selection was based on how well the data could be extrapolated to the research question.

Upon evaluation for accuracy of the research that was selected, the studies were then assigned to a level of evidence. A review of the various levels of evidence indicates that 52.2% were level one, 43.5% were level two and 4.3% were level three. Based upon the evaluation of these levels and of the literature, an overall grade of evidence is B.

Weaknesses in the Review

As with any project, an evaluation of its weaknesses is necessary in order to better any future projects. Upon a closer look, the study could have been improved if the databases used were expanded beyond the realm of just Medline, CSA and FirstSearch; doing so could have yielded more results and may even change the results of this study. Another area of weakness that has been brought to attention after a careful evaluation is that this study could have been focused on a more specific area of emergency contraception rather than just addressing deregulated and regulated emergency contraception. Addressing a more narrowed topic of emergency contraception would allow a deeper assessment rather than a loose evaluation on a more generalized topic.

CHAPTER FIVE

CONCLUSION

Increased accessibility to emergency contraception leads to increased usage, promotes timely access, does not compromise routine use of contraceptives and is safe enough to be dispensed over the counter or in advanced provisions; thus, deregulated EC access makes it more beneficial and efficient than restricted accessibility. There is no evidence in the literature that indicates that restricted access is more advantageous.

Of all deregulated methods of emergency contraception, advanced provision of emergency contraception proves to be the best route to EC access with minimal effects. Women with advanced provisions are able to access EC in a more timely manner, are more likely to use it, are able to tolerate adverse effects well without physician counseling and they are more likely to continue their routine contraceptive and/or switch to a more reliable method. Despite advanced provision of emergency contraception though, not all women were using EC when it was indicated because they failed to realize the risk of a pregnancy occurring.

Emergency contraception does need increased access and it can be accomplished but increasing access will be insignificant if women are not utilizing it. Women need to be better educated on reproductive knowledge so that they can realize the risk of a pregnancy with each incident of unprotected sexual intercourse; with this, women will fully understand the need and importance of EC availability and usage.

REFERENCES

1. Belzer M, Sanchez K, Olson J, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. *Journal of Pediatric and Adolescent Gynecology*. 2005 Oct; 18(5): 347-354.
2. Quigley, T. F. 2005;1-10. Emergency contraception: practical, political and ethical considerations. Paper read at Kansas Academy of Physician Assistants Annual CME Conference, at Topeka, KS.
3. Adolescence Co. Emergency contraception. *Pediatrics*. 2005 Oct; 116(4): 1038-1047.
4. Ranney ML, Gee EM, Merchant RC. Nonprescription availability of emergency contraception in the United States: current status, controversies, and impact on emergency medicine practice. *Annals of Emergency Medicine*. 2006 May; 47(5): 461-471.
5. Gemzell-Danielsson K, Marions L. Mechanisms of action of mifepristone and levonorgestrel when used for emergency contraception. *Human Reproduction Update*. 2004 Jul-Aug; 10(4): 341-348.
6. Tanne JH. FDA finally approves Plan B--but with restrictions. *BMJ*. Clinical research ed. 2006 Sep 2; 333(7566): 461.
7. Boonstra H. Emergency Contraception: The Need to Increase Public Awareness. *The Guttmacher Report on Public Policy*. October 2002;5(4): 3-6.
8. Raymond EG, Chen PL, Dalebout SM. "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner. *Obstetrics and Gynecology*. 2003 Jul; 102(1): 17-23.
9. Harper CC, Cheong M, Rocca CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstetrics and Gynecology*. 2005 Sep; 106(3): 483-491.
10. Glasier A, Fairhurst K, Wyke S, et al. Advanced provision of emergency contraception does not reduce abortion rates. *Contraception*. 2004 May; 69(5): 361-366.
11. Gardner JS, Fuller TS, Hutchings J. The effects of self-administering emergency contraception. *The New England Journal of Medicine*. 1998 Nov 5; 339(1): 1-4.
12. Jackson RA, Schwarz EB, Freedman L, Darney P. Advance supply of emergency contraception. effect on use and usual contraception--a randomized trial. *Obstetrics and Gynecology*. 2003 Jul; 102(1): 8-16.

13. Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric and Adolescent Gynecology*. 2004 Apr; 17(2): 87-96.
14. Raine TR, Harper CC, Rocca CH, et al. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. *JAMA*. 2005 Jan 5; 293(1): 54-62.
15. Hu X, Cheng L, Hua X, Glasier A. Advanced provision of emergency contraception to postnatal women in China makes no difference in abortion rates: a randomized controlled trial. *Contraception*. Aug 2005;72(2):111-116.
16. Lo SS, Fan SY, Ho PC, Glasier AF. Effect of advanced provision of emergency contraception on women's contraceptive behaviour: a randomized controlled trial. *Human Reproduction*. 2004;19(10): 2404-2410.
17. Walsh TL, Frezieres RG. Patterns of emergency contraception use by age and ethnicity from a randomized trial comparing advance provision and information only. *Contraception*. 2006 Aug; 74(2): 110-117.
18. Jackson R, Schwarz EB, Freedman L, Darney P. Knowledge and willingness to use emergency contraception among low-income post-partum women. *Contraception*. 2000 Jun; 61(6): 351-357.
19. Goulard H, Moreau C, Gilbert F, Job-Spira N, Bajos N. Contraceptive failures and determinants of emergency contraception use. *Contraception*. 2006 Sep; 74(3): 208-213.
20. Walker DM, Torres P, Gutierrez JP, Flemming K, Bertozzi SM. Emergency contraception use is correlated with increased condom use among adolescents: results from Mexico. *The Journal of Adolescent Health*, 2004 Oct; 35(4): 239-334.
21. Killick SR, Irving G. A national study examining the effect of making emergency hormonal contraception available without prescription. *Human Reproduction*. 2004;19(3): 553-557.
22. Raymond EG, Dalebout SM, Camp SI. Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product. *Obstetrics and Gynecology*. 2002 Aug; 100(2): 342-349.
23. Ellertson C, Ambardekar S, Hedley A, Coyaji K, Trussell J, Blanchard K. Emergency contraception: randomized comparison of advance provision and information only. *Obstetrics and Gynecology*. 2001 Oct; 98(4): 570-575.
24. Gainer E, Blum J, Toverud EL, et al. Bringing emergency contraception over the counter: experiences of nonprescription users in France, Norway, Sweden and Portugal. *Contraception*. 2003 Aug; 68(2): 117-124.

25. Falk G, Falk L, Hanson U, Milsom I. Young women requesting emergency contraception are, despite contraceptive counseling, a high risk group for new unintended pregnancies. *Contraception*. 2001 Jul; 64(1): 23-27.
26. Soon JA, Levine M, Osmond BL, Ensom MH, Fielding DW. Effects of making emergency contraception available without a physician's prescription: a population-based study. *Canadian Medical Association journal = journal de l'Association medicale canadienne*. 2005 Mar 29; 172(7): 878-883.
27. Fox J, Weerasinghe D, Marks C, Mindel A. Emergency contraception: who are the users? *International Journal of STD & AIDS*. 2004 May; 15(5): 309-313.
28. Harrison T. Availability of emergency contraception: a survey of hospital emergency department staff. *Ann Emerg Med*. Aug 2005;46(2):105-110.
29. Grimes DA. Switching emergency contraception to over-the-counter status. *The New England Journal of Medicine*. 2002 Sep 12; 347(11): 846-849.

Appendix A: Included Articles							
Author	Study Year	Title of Article	Research Addresses	Methodological Design	Type of Study	Findings / Results	Level of Evidence
Cheng et al	2005	Advanced Provision of Emergency Contraception to Postnatal Women in China Makes No Difference in Abortion Rates: A Randomized Controlled Trial	The effect of advanced provision of EC on abortion rates	<p>2,000 recruited from postnatal wards in Shanghai.</p> <p>All given info about contraception & advised that mifepristone 10 mg could be used as EC up to 5 days s/p unprotected sex. All were also given a packet of 10 condoms.</p> <p>Randomized into 2 groups using a computer-generated randomization list.</p> <p>Intervention group got 3 courses of mifepristone 10 mg with instructions for use as EC. Control group had to be seen by doctor for tx.</p>	Randomized, control study.	80% of both groups have known about EC but less than 13% in both groups had ever used it. Intervention group (IG) 2x likely to use EC more than once compared with control group (CG) End of year one: 38 in IG & 32 in CG had conceived. 3 ectopic pregnancies. 67 pregnancies were aborted. Incidence of unintended pregnancies s/p 1 year of childbirth in China: 11%. Rates for IG & CG respectively: 3.8%, 3.2%. Only 8 used EC during the cycle in which they conceived, all from IG. 6 used mifepristone, 2 levonorgestrel. 95% of those who didn't use it didn't think they'd get pregnant.	Level 1a
Gemzell-Danielsson, et al	2004	Mechanisms of Action of Mifepristone and Levonorgestrel When Used for Emergency Contraception	The available data on the effects of mifepristone & levonorgestrel on female productive functions relevant to the emergency use of the compounds	This review summarized available data on the effects of mifepristone & levonorgestrel on female productive functions relevant to the emergency use of the compounds.	Systematic review	Contraceptive effects of both levonorgestrel & mifepristone, when used in single low doses for EC, involve either blockade or delay of ovulation, due to either prevention or delay of luteinizing hormone surge, rather than to inhibition of implantation. Pregnancy rates didn't differ b/t mifepristone & levonorgestrel tx in divided or single doses when taken within 5 days of unprotected sex. Though mifepristone is slightly more efficacious in preventing pregnancy, it more likely to postpone ovulation; which put sexually active women aren't using contraception at higher risk for pregnancy.	Level 1a

Gee et al	2006	Nonprescription Availability of Emergency Contraception in the United States: Current Status, Controversies & Impact on Emergency Medicine Practice	The history, efficacy & safety of EC; it also reviews its nonprescription availability of EC in the US, its current status, controversies & its impact on emergency medicine practice	This study was performed using MEDLINE search using MeSH terms “emergency contraception” “post-coital contraception”, ”morning-after pill”, “accident & emergency department”, “casualty department”. Journal articles that were pertinent to the study question were hand searched from references.	Systematic review	Background on emergency contraception Rx EC availability in the US Current over-the-counter EC availability Over-the-counter availability of EC: Pros Over-the-counter availability of EC: Cons Emergency medicine EC studies & potential impact on emergency medicine practice This article recognizes that further studies would be helpful in examining the impact of OTC EC on emergency medicine practice.	Level 1a
Frezieres et al	2006	Patterns of Emergency Contraception Usage By Age and Ethnicity From a Randomized Trial Comparing Advance Provision and Information Only	The impact of the advance provision of EC among family planning clients at 31 clinics in California	9000 pts 15-45 y/o at various community clinics throughout Cali enrolled b/t 10/03 & 10/04. All received study packets. Computer-generated randomization was used to assign participants to tx groups. Half of study packets contained Plan B and the other half only contained EC info & how to obtain it if needed. F/u group was composed of equal numbers of Hispanics, Whites, Asian & African-Americans from 3 age groups: <19 y/o; 19-24 y/o; >24 y/o A randomization SAS program was used to randomly select for phone interview participants who were > 18 y/o.	Randomized controlled Study	Risk event prevalence ↓ with age. Tx group 7% more likely to use EC than those who got EC info only. 11% more of tx group were pregnant compared to info only group. No sig differences in both groups re: reasons for taking EC, side fx, or pregnancy. > 24 y/o were more likely to cite not knowing where to get EC or not know how to use it than younger age groups. Advanced provision ↑ EC use but doesn't ↑ risk-taking behavior. No significant ↓ in unintended pregnancies amongst tx group – may be due to low frequency of EC use compared to high incidence of high-risk events; incorrect method use.	Level 1a

Baird et al	1998	The Effects of Self-Administering Emergency Contraception	How women might behave if emergency contraception were more readily available and the effect that such availability might have on the number of unintended pregnancies.	Randomized, clinically-controlled trial. Women ages 16-44 y/o attending a family-planning clinic & large hospital in Edinburgh, Scotland. Tx group = Given replaceable supply of hormonal EC to take home. Control group = Obtained EC by visiting a doctor. Women whose birthdays fell on even-numbered were assigned to "tx group". Odd-numbered days = "control group"	Randomized, clinically-controlled trial	Tx group more likely to use EC on only 1 occasion than the control group. 91 notification forms returned & only 1 woman used EC incorrectly – lost instruction sheet & didn't take the 2 nd dose. 12 pregnancies during a cycle in which EC had been used – in compliance with 3% failure rate reported in routine clinical practice. 28 of 549 women pregnant (5% rate) in tx group. 33 of 522 women pregnant (6%) in control group. 89% of tx group didn't change their use of other methods of contraception with EC use. 79% tx & 61% control thought EC should be available without Rx.	Level 1b
Belzer et al	2005	Advance Supply of Emergency Contraception: A Randomized Trial in Adolescent Mothers	Whether the advanced provision of emergency contraception to parenting youth would increase emergency contraception utilization and whether AEC would impact the rates of unprotected sex and contraception use.	160 teens 13-20 y/o who were parenting & receiving case management services in a large metropolitan area were recruited. Exclusion criteria: Attempting to get pregnant or on IUD/Norplant Most Hispanic, lived in urban areas. AEC group & tx group chosen by random selection via computer-generated random number table. AEC group (78/160): given 1 pack of Plan B & to call if lost it or needed more. Control group (82/160): Only given EC info & how to access it.	Randomized controlled trial	At baseline, control group more likely to be sexually active AND have unprotected sex past 6 mo than AEC group. At 12 mo, AEC group more likely to have unprotected sex past 6 mo > control. AEC group less sexually active at baseline, 6 mo but at 12 mo, ↑ 38%. Control group the same but ↑ 48% AEC ↑ condom use each at each f/u. OCP ↑ until 12 mo..↓ 9%. Control group ↓ use in condom & OCP. At 6 mo, % of AEC group not using any method ↓ from 26% to 14%. But at 12 mo, ↑ from 14% to 35%...which is why pregnancy rate ↑ from 4 to 6 people in AEC group. Control group pregnancy rate ↓ from 10 to 3 people at 6 and 12 mo. From baseline to 12 mo in AEC group, ↑ in those who switched to more effective method from 16% to 31%. Control group ↓ from 18% to 16%. Advanced supply of EC ↑ its use.	Level 1b

Darney et al	2003	Advance Supply of Emergency Contraception: Effect on Use and Usual Contraception – a Randomized Trial	Whether advance provision of emergency contraception increases its use and/or adversely affects usual contraceptive practices	<p>370 postpartum women at a public inner-city hospital Sept 1998 – March 1999. Eligible if have had a live birth, spoke English/Spanish & would be available for f/u in 1 year. EC group (184) got standard 5 min educational session, supply of EC pills with verbal & written instructions, educational pamph. & how to get more EC pills if needed</p> <p>Control group (186) got routine contra. counseling by their medical provider but it didn't include discussion of EC</p>	Randomized, controlled clinical trial	<p>Majority of subjects were Latina (72%) & most were married/living as married (73%) At baseline, 3% from each group had used EC in past. At 6 mo f/u, EC group more likely to use it at least once in comparison to control group (10% vs 3%) There were 16 unplanned pregnancies in control group vs. 11 in EC group Noticeable improvement in contra. use during f/u in both groups (EC: 35% -> 85%; Control: 37% -> 83%) 75% of subjects changed birth control method; over ½ in each group switched to more effective method At f/u, both groups were more willing to use EC in future (EC: 64%-71) (Con: 65-73)</p>	Level 1b
Gold et al	2004	The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors	Whether adolescents given advance EC have higher sexual and contraceptive risk-taking behaviors compared to those obtaining it on an as needed basis.	<p>301 mainly minority low-income sexually active adolescent females between the ages of 15-20 who did not use long acting contraception.</p> <p>Participants were ÷ into 3 groups: 15-16, 17-18, and 19-20. Were randomly placed into control and experimental group by color of condom chosen</p>	Randomized, controlled trial	<p>Providing advanced EC to adolescents is not associated with more unprotected intercourse or less condom or hormonal contraception use. Comparing 1 & 6 mo f/u, AEC group reported ↑ condom use while control group (as needed basis group) reported ↓ use. Across entire study, 26 in AEC group used EC 38x compared to 20 in control group who used EC 24x. < 15% of AEC subjects returned to get additional courses of EC. AEC group started their EC course sooner & reported fewer #s of pregnancies than the control group</p>	Level 1b

Darney et al	2005	Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs	The effect of direct access to EC through pharmacies & advance provision on reproductive health outcomes	1950 women ages 15 – 24 who attend 4 Cali clinics providing family planning services, who weren't desiring pregnancy, or who weren't using long-term hormonal contraception or requesting EC. Computer-generated randomization sequence used to assign subjects to 1 of 3 tx groups: pharm access, advance provision, or clinic access (control). Women were required to live in the San Fran area to be available for a f/u visit 6 mo after enrollment. Participants were tested & screened for pregnancy & STI's & were treated accordingly	Randomized, single-blind, controlled trial	No sig differences in freq. of unprotected sex, frequency of condom use, or patterns of p.o contraceptive use by study groups. 7.7% became pregnant & 12% acquired STI during study. Clinic group highest % for pregnancy rate. Clinic & pharmacy groups almost tied for highest % in STIs. Pharmacy group highest rate for unprotected sex "every time" Pregnancy rates ↑ as unprotect sex rates ↑. Pharmacy access didn't appear to have any more use than clinic access Advanced group 2x as likely to use EC than women in clinic group. Women with pharm/advanced provision access weren't more likely to abandon contraception or switch to less effective methods.	Level 1b
Cheong et al	2005	The Effect of Increased Access to Emergency Contraception Among Young Adolescents	To analyze data on young adolescents with increased access to emergency contraception	Women who had unprotected sex in the past 3 days were ineligible. Participants randomized into 1 of 3 study groups: pharm access , advanced provision, clinic access *control* All tested for HSV, pregs & chlamydia completed survey, demographics, etc. AP group got packets of Plan B. Clinic access group got a card telling them to go to clinic if needed AC. And then trained pharmacists dispensed EC to participants for free and also gave info on STIs & contraception. At 6 mo f/u, re-tested for HSV, pregs, chlamydia.	Randomized, clinically-controlled trial	EC use: Highest in AP group, in <16 y/o age group. Clinic access least likely esp in < 16 y/o. 20-24 y/o had lowest levels of EC use. 36% of all teens used EC with highest amount in advanced provision group more than other 2 groups. Unprotected sex: Most in advanced group in the < 16 y/o. The same age group in clinic group least likely to have unprotected sex. Condom use: Most consistent in < 16 y/o in AP group. STI acquisition: No variation by age for risk behavior or multiple sex partners but clinic access group had lowest rates for STI acquisition. Pharm access group had lowest pregnancy rates. Teens had highest preg rates (esp AP group). Majority of all age groups (>94%) used EC correctly	Level 1b

Bertozzi et al	2004	Emergency Contraception Use is Correlated With Increased Condom Use Among Adolescents, Results from Mexico	Assesses Mexican teenagers' knowledge of, attitudes toward, and experience with EC and condoms before a randomized controlled educational intervention.	Baseline data from a cluster-randomized controlled trial designed to assess the impact of HIV/STI prevention ed intervention curriculum on condom use, STIs & pregs amongst first-year high school students in Morelos, Mexico was used. Sample included 40 high schools, first-year high school students (~ to sophomore year)	Cluster-randomized controlled trial	Avg age for first sex was 15 for girls and 14.5 years for boys. 39% of both had used a condom in their 1 st sex. > 50% expressed willingness to use EC in future. Among sexually active, 16.4% had tried to get EC & almost all had used it. Correct knowledge of EC was positively correlated with knowledge about how to use a condom. For both girls & boys, h/o EC use was strongly correlated with condom use at last time of sex. No ↑ in risky sexual behavior assc with EC use but rather EC use is assc with HIGHER levels of safer behavior. EC promotion, access & use don't ↑ unsafe sex.	Level 1b
Fan et al	2004	Effect of Advanced Provision of Emergency Contraception on Women's Contraceptive Behaviour: A Randomized Controlled Trial	To evaluate how women behave if given a supply of EC to keep at home, whether they use it correctly and whether there are differences in the way young women behave compared with older women.	280 unmarried women < 26 y/o from Youth Health Care Center & 750 married women ≥26 y/o from Birth Control Clinic b/t 9/1/01 & 2/28/02. Subjects were randomized in blocks of 10 using computer-generated randomization list. Control group (CG) instructed to attend clinic for EC whenever needed. Intervention group (IG) given 3 courses of EC to keep @ home. Were verbally & in writing instructed on how to take EC properly. If all 3 courses used, go to Dr. for counseling re: regular contraceptive use & 3 more courses given if appropriate. No more given after that.	Randomized, controlled trial	Twice as many women in IG used at least 1 course of EC compared with CG. Also, young women were more likely to use EC than older women. Both groups claimed to be using contraception more consistently during the study when compared to prior to study. #1 reason for using EC was unprotected sex; CG = 51% and IG = 71%/ All but one woman used EC within 72 hours; IG group used EC significantly sooner than CG. Pregnancy rate was similar in both groups. - 9 pregnancies in 9 peeps in CG (none used EC in conception cycle); 4 thought pregnancy was low risk; 4 thought contraceptive use was safe. - 8 in 7 peeps in IG: 4, 2..in those respective reasons listed above. Easier access to EC doesn't appear to lead to repeated use, or affect their use	Level 1b

Chen et al	2003	“Actual Use” Study of Emergency Contraceptive Pills Provided in a Simulated Over-the-Counter Manner	To evaluate use of an EC pill product dispensed under simulated OTC conditions. Also to assess repeat use, pregnancy and adverse effects.	Women who requested ECP were asked to look at a modified EC package intended for OTC use. Package of EC given to those who met the study criteria & said that they wanted to try one of these packages. Subjects read the package label if the product was appropriate for her; no unsolicited counseling/instruction given to subjects other than that on the package itself; most paid for the product. Were then contacted 1 and 4 weeks later. & were asked about their use of the product, side effects and pregnancy	Actual use study	585 got EC at first screening (Median age: 21). 540 reported that they actually used the package. Most of the participants used the product correctly and safely. Main reasons for product use were b/c a condom broke/no contra. had been used. Incidence of incorrect EC use was 28% (strict guidelines...no variation allowed here!) < 2% became pregs. 46% reported a side effect but none were serious. Overall, women don’t need provider intervention to use EC safely & effectively.	Level 2a
Aneblom et al	2003	Bringing Emergency Contraception over the Counter: Experiences of Nonprescription Users in France, Norway, Sweden and Portugal.	To learn about women’s experience with nonprescription ECP.	Focus group open discussion with women who had obtained or used EC without a medical prescription in large urban centers in France, Norway, Portugal and Sweden. 4 – 5 focus groups in each country led by a study team. Each open discussion lasted 60 – 90 minutes. Informed consent signed by each participant. Each group covered 3 main topic areas, and then filled out a written questionnaire	Randomized cohort study	All participants said they knew of ECP but actual knowledge of how to use it was limited. Women in each country had questions about the relationship between EC and abortion. Knowledge of the time window in which to take EC varied by location. Nearly all participants said that they read the insert in the package even after consultation from a medical provider. Some feel that pharm access isn’t private and therefore can’t engage in discussion Many said the insert was straightforward and understandable.	Level 2b

Ensom et al	2005	Effects of Making Emergency Contraception Available Without a Physician's Prescription: A Population-Based Study	Whether changes in EC use after public health policy initiative in Dec. 2000 in British Columbia that allowed pharmacists to provide ECs without a Rx.	<p>Data were obtained from 2 linkable administrative databases maintained by BC Ministry of Health Services, PharmaNet & Medical Services Plan</p> <p>Information was provided on pt background info, date of rx filled, quantity, strength, dosage form, brand name of drug, etc</p> <p>Pharmacists to provide EC received standardized 4-hour EC training program</p> <p>During 2001-2002, any women who met criteria for EC completed 10-15 minute pharmacist-pt interview & tx consent form.</p>	Population-based cohort study	Frequency of EC usage highest in 20-24 age group & there was an ↑ in EC usage amongst all age groups post-policy. 56.2% used EC due to birth control failure. 55.7% of pharmacy-provided ECs were obtained within 24 hours of unprotected sex. 86.8% & 98.2% received ECs within 48 & 72 hours of unprotected sex respectively. 40% of women chose Yuzpe regimen from pharmacists despite being told that it's possibly less effective than levonorgestrel & more likely to cause side fx. Lowest cost of Yuzpe regimen could be partly responsible for this. Only 1% requested ECs for future use. Since women with ECs at home can use them asap, ↑ EC access may be warranted	Level 2b
Fairhust et al	2004	Advanced Provision of Emergency Contraception Does Not Reduce Abortion Rates	Whether offering advanced supplies of EC to large numbers of women influenced abortion rates.	Women 16-29 y/o in Lothian offered 5 courses of Schering PC4 to keep @ home. 10 participating general practices were randomly chosen & were mailed ?s (how many had been offered & accepted EC & whether & how they had used it) Annual abortion & birth rates from '98-'01 were compared b/t Lothian & 3 other large Scottish Health Board areas.	Cohort study	<p>6 mo s/p study, clear that very few women actively requested advanced supplies of EC so centers were asked to offer supplies rather than waiting for women to ask. 116 of GP practice & 60 of FP gave away at least 1 packet of E to someone else. Of 647 women from both GP & FP surveys (361, 286), only 36 (5.5%) reported occurrence of unintended pregnancy. Only 8 of 36 used EC to prevent the pregnancy.</p> <p>No significant differences in total abortion rates when 1998 or 1999 were compared with 2000 or 2001. Intervention didn't seem to ↓ abortion rates by ½. Advanced provision supplies of EC ↑ its usage.</p>	Level 2b

Bajos et al	2006	Contraceptive Failures and Determinants of Emergency Contraception Use	The effects of ECP use in a representative sample of women at risk for unintended pregnancy.	<p>Sample included 2863 women aged 18-44 randomly selected fro telephone directory in 2000</p> <p>First phone interview was in 2000 and then every year after that for total of 4 years.</p> <p>Total of 2174 women were analyzed b/t 2000 & 2001.</p> <p>The questionnaire asked about sociodemographics, reproductive & contraceptive hx, ECP & knowledge of its use.</p>	Prospective cohort study	<p>EC use was highest in those with no method (42%) and those on the pill (37.5%) b/t 00-01. ECP use was more prominent amongst younger women (18-24), sociodemographics showed no relation to ECP use. ECP knowledge was poorest amongst those with no diploma for education, those >25 y/o and women in stable relationships. Those using condoms (25.5%) and pill (10.4%) had highest rates. Those who changed contraceptive methods several times during the year & those who engaged in sex prior to 2001 were most likely to use EC. Hx of STD or gynecological f/u wasn't assc with ECP use in 2001. % of EC users was correlated with frequency of sex in year prior to interview.</p>	Level 2b
Fox et al	2004	Emergency Contraception: Who are the Users?	The demographic and sexual characteristics of clients attending a sexual heath clinic for EC.	<p>Info all women attending PHC who received EC b/t 01/99-07/02 was derived from clinic database. Controls were women attending for reasons other than EC during the same study period, matched for year of attendance and age. 10% of cases and controls were reselected using a computer generated random selection program and the data recollected as a form of quality assurance.</p>	Cohort study	<p>99% of those who had unprotected sex and sought EC attended the clinic within 72 hours of unprotected intercourse. 70% between 0 & 24 hours, 25% between 24 & 48 hours & 4% b/t 49-72 hours. 47% requested EC due to contraception failure. 51% requested EC due to NO contraception. 2 new infections (HPV & chlamydia) were diagnosed. Women and students with a regular male partner more likely to require EC. Most common reasons for requiring EC were condom breakage & getting carried away...this is consistent with other research.</p>	Level 2b

Camp et al	2002	Comprehension of a Prototype Over-the-Counter Level for an Emergency Contraception Pill Product	Comprehension of a prototype over-the-counter package label for an emergency contraceptive pill product	Subjects selected b/t 06/18/01 - 07/12/01 @ malls & family planning clinics in/near 8 large US cities. Criteria: 12-50 y/o females, able to read English well enough to read an OTC product label (literacy test given), no health care/marketing background, no hx of participation in this study. Recruiters encouraged to exceed quotes for subgroups of minority women & women at high risk for poor comprehension	Prospective cohort study	19 of the 30 ?s about the package answered acceptably by at least 85%. Median # of ?s answered acceptably was 27 and only 42 (6.4%) gave acceptable answers to all ?s. Women of lower literacy significantly less likely to understand almost all objectives than more literate women. 8/11 objectives understood > 80% of low literacy women. > 93% of subjects understood 3 imp. objectives: product is for prevention of pregnancy, doesn't prevent AIDS/STDs, shouldn't be used by pregnant women. 97% understood EC to be taken w/in 72 hrs or asap s/p sex.	Level 2c
Falk et al	2001	Young Women Requesting Emergency Contraception are, Despite Contraceptive Counseling, a High Risk Group for New Unintended Pregnancies	The short and long term risk of unintended pregnancy and to determine the frequency of chlamydia infections in women receiving EC.	134 women visited youth clinic in city of Örebro requesting EC. A f/u was for additional counseling offered 3 weeks after first visit. Women were requested to complete a questionnaire at primary & secondary visits. Efficacy of EC & counseling provided was assessed in both short & long term (12 mo) re: occurrence of pregnancies.	Outcome research study	Most common reasons given for need of EC were unprotected sex (53%), ruptured condom (30%), missed pill (11%) and other (5%). 73% of the 134 women returned w/in 3 weeks of initial visit. Preggs & chlamydia tests were negative for all. During year following tx, 10 unintended preggs were recorded among the 134. 7 of these 10 had attended the 3 week f/u. Young women who request EC are a high risk group for new unintended pregnancies. The rate for this study was 4x higher than the national rate. None of the women tested positive for chlamydia at either the primary or the return visit BUT it's to be noted that the young women in this study didn't have a significant past history of many STD infections & their lifetime sexual partners was fairly low.	Level 2c

Irving et al	2005	A National Study Examining the Effect of Making Emergency Hormonal Contraception Available Without Prescription	Whether having EC available (to those 16 and older via a pharmacist without prescription) led to any improvements or deterioration in the service provided for the women who need it.	Questionnaires were distributed to EC users through a single chain of high street pharmacies in England, Scotland & Wales to reach different population profiles. Clients receiving EC were handed ?s & invited to complete & return it in a pre-paid envelope. EC users asked about: how soon after unprotected sex did they take EC, how much knowledge & understanding about EC, & plans re: previous, current & planned future contraceptive use.	Outcome research study	143 (34%) obtained EC via prescription & 274 (65%) directly from a pharmacist. Females under 20 y/o more likely to obtain EC directly from pharmacy (72%); 20-29 y/o (64%); > 29 y/o (66%). No one reported taking first tab > recommended 72 hours 64% of women who got EC via pharmacist directly took their first tab within 24 hours. The majority (123, 29%) took their EC on a Sunday. 15% were embarrassed to ask for EC from their pharmacist. Women getting EC via pharmacist directly were given equally sound advice to those seeing a doctor	Level 2c
Harrison et al	2005	Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff	(1) Evaluate the likelihood that a woman calling a hospital and seeking emergency contraception could access the medication; (2) if EC is not provide, whether hospital staff would provide a referral to another facility (3) the outcome of the referral process	In 2002, 597 US Catholic hospital EDs were compiled from 2 diocesan hospital lists generated by Catholic Health Association. In 2003, 3600 non-catholic hospitals were compiled from American Heart Hospital list; 1000 hospitals were sampled; Trained female interviewers followed a written script and gave 3 attempts per contact. Surveys conducted during weekend ours to simulate experience of a woman who had unprotected sex on a Thursday evening and seeking EC. If hospital doesn't dispense EC, caller asked about sexual assault cases and a pregnancy test. If EC is still not available, caller asked for referral.	Outcome research study	42% non-Catholic and 55% Catholic have EC hospitals did not have EC available. Staff at non-Catholic hospitals were more likely to report that EC is available upon request than staff at Catholic facilities. Staff at non-Catholic hospitals who said that EC is restricted, 45% indicated EC is available only for victims pf sexual assault; 44% said decision to provide EC is up to doctor; 11% said required to take pregnancy test to obtain EC. 79% Catholic facilities said EC was provided only to victims of sexual assault; 19% indicated that dispensing EC was left up to doctor's decision. Staff at catholic hospitals were consistently more likely to report restricted access to EC. 52% non-Catholic and 47% Catholic facilities who did not provide EC gave callers a valid referral; when asked specifically, 84% NC and 80% Catholic didn't know if the referral facility provided EC	Level 2c

Freedman et al	2000	Knowledge and Willingness to Use Emergency Contraception Among Low-Income Post-Partum Women	Factors associated with knowledge and willingness to use emergency contraception in a sample of women from an inner-city public hospital.	Surveyed 371 post-partum women on day of discharge from San Francisco General Hospital. Included all consecutive English & Spanish-speaking women with a live birth who would be available for f/u in 1 year.	Cohort study	<p>82% had used contraception in past with 72% using condoms, 49% OCPs. 11 (3%) reported use of EC in past. 36% had heard of EC, only 19% could name or describe a method to prevent pregnancy after sex & only 7% knew its correct timing. Teens 3x more likely to know correct timing, multiparous 4x less likely. None of the monolingual Spanish speakers knew correct timing. Only 36% have heard of EC. Of those who have heard of EC, 44% thought it was safe, 33% didn't know it available in US or that Rx is required. 32% believed EC induces abortion. Only 7% knew correct timing for use.</p> <p>Willingness to use EC had 3 associations: multiparous more likely to use EC, family incomes > \$20,00 or who had moral or religious objections to EC less likely.</p>	Level 3b
----------------	------	---	---	---	--------------	---	----------

**Appendix B:
Excluded Articles**

Author	Study Year	Title of Article	Research Addresses	Methodological Design	Type of Study	Findings / Results	Level of Evidence
McCarthy et al	2002	Availability of Emergency Contraceptive Pills at University and College Student Health Centers	<p>To examine the status of availability of ECPs at university and college student health centers across the nation.</p> <p>In addition, to also attempt to answer the benefits of and barriers to the availability of ECPs, promotion and publicizing of ECPs, and whether health centers had restrictions that hindered the use of ECPs.</p>	<p>471 universities or colleges in the US and its territories of the 955 institutional members of the American College Health Association were randomly chosen.</p> <p>13 were excluded due to inadequate mailing information or because they participated in an earlier re-test for instrument stability.</p> <p>Participation was voluntary and individual institution information obtained was confidential.</p>	Individual cohort study	<p>> 1/2 said they offered ECPs. Of these 1/5 were listed in the directory of providers maintained by the EC Hotline, another 1/5 weren't sure if they were listed & > 1/2 said they weren't listed. < 1/2 said that they did not offer ECPs. Of these, 75% referred students to other providers and 1/6 did not refer students anywhere. Reasons for not offering ECPs were administrative objections, clinical staff objections, liability concerns, desire not to undermine students' routine contraception & "not needed" Almost 75% of student health centers dispensed ECPs directly to students with written Rx, 50% provided written Rx, 66% routinely provided ECP info. This article was excluded due to</p>	EXCLUDED ARTICLE

VITA

Name: Alicia V. Nguyen

Date of Birth: January 17, 1983

Place of Birth: Wichita, Kansas

Education:

2005-2007 Master of Physician Assistant (M.P.A.)
 Wichita State University, Wichita Kansas

2001-2005 Bachelor of Arts, Major: Spanish
 Wichita State University, Wichita, Kansas