Plan B, The Switch to OTC

By

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Plan B is a progesterone-only emergency contraceptive medication used to prevent pregnancy following unprotected intercourse, including sexual assault, or a known or suspected contraceptive failure. The Food and Drug Administration approved this medication also known as the “morning-after pill” in July 1999 for emergency contraception because it prevents ovulation or fertilization by altering the tubal transportation of the sperm or ova. It can also discourage implantation by changing the endometrium, which is the mucous membrane that lines the uterus and is what the fertilized egg must embed into in order to develop into an embryo.

Emergency contraception, including Plan B, has always been a subject of much debate because of the moral and ethical issues surrounding its use. Recently Plan B has also raised discussion because of its switch from prescription only, to over-the-counter status for women 18 years of age and older. This switch was approved in August 2006 and the product was released for purchasing in pharmacies at the beginning of November 2006. However, Barr (drug manufacturer of Plan B) had been trying to get approval for over-the-counter use since April 2003. The first New Drug Application (NDA) was for over-the-counter status including all ages, however this was not approved because the data did not demonstrate that the product was safe and effective in use for women under age 16. It then was resubmitted in July 2004 for over-the-counter use in women over 16 years old however this also was not approved, which leads us to the current NDA that was approved for women 18 years old and over.

It also was approved to have a new dual label (OTC/Rx) on the same packaging because it will be over-the-counter for women 18 and older, but still prescription only for those 17 and under. This label includes drug facts, ingredients and directions for use as required for an OTC product and also has a place to adhere a prescription label and clearly states its Rx only for age 17 and younger which is required for its prescription only labeling. Some of the debates I will discuss are whether it is ethical to have a dual label medication, whether it is safe and effective to be over-the-counter and the ethical issues surrounding its use and distribution.
The United States isn’t the first country to make an emergency contraceptive available over-the-counter. Women in the United Kingdom, France, and other European countries have been able to buy emergency contraceptives without a prescription for a number of years. Plan B was also granted over-the-counter status to our neighbors, in Canada, in 2005.

Like the United States, in Canada, Plan B is kept “behind the counter.” This means that it is considered a nonprescription medication, but sales are restricted to only back in the pharmacy. You wouldn’t be able to purchase it at the front store or at gas stations and other stores where over-the-counter products can be found. You also must present valid government-issued photo identification, such as a driver’s license, confirming that the patient is at least 18 years old before purchase. This “behind the counter” restriction is not a new design and seems to be becoming more and more common. For example, some “behind the counter” medications are nicotine replacement products and pseudoephedrine containing products, which are restricted in an attempt to reduce the production of methamphetamine from pseudoephedrine.

Does making a medication, like Plan B, “behind the counter” really restrict patients under the age of 18 from receiving it without a prescription? Realistically, I think not. Although it may hinder the patient or add an extra step in obtaining the medication, if an underage minor wants or needs this medication they will be able to find a way to get a hold of it. It’s not really any different than alcohol these days. It's illegal to drink if you are under 21 but I don’t see that stopping any teen that wants to drink from getting a beer.

There are many loopholes in this system that can lead to just about anyone buying this medication for a minor. Any family member, friend or even a stranger off the streets who is over 18 could buy this medication for a minor. There are also no restrictions or purchasing limits associated with gender. So an older male could easily buy this medication for a younger female. The only way I could see to stop this from occurring would be to require that the first dose of the medication be taken while the patient is still at the pharmacy. Is this too extreme? If it is apparent that it is unsafe for minor females to take the medication without a prescription and therefore without supervision of a physician, then I don’t think it is too extreme. But is there evidence to show that it is unsafe for minors?

Is Plan B safe for young girls to take without any medical supervision? If it is then why not make it over-the-counter for everyone? Why limit its availability to those who are over 18 years old? First off, there are two main requirements needed to allow a medication to be available over the counter and they are, safety and efficacy without medical supervision. The safety issues regarding the use in minors have nothing to do with chemistry or physiology because Plan B is very safe. There are no serious side effects or adverse events associate with its
Plan B contains one of the same active ingredients used in ordinary birth control medications, only in the case of Plan B; each tablet contains a much higher dose and is taken in a different way. Birth control is available by prescription only, no matter what age. So why can emergency contraceptives like Plan B be available over-the-counter when it is the exact same ingredient? This has to do with how the medication is taken and how often. It also can be used at any time during the menstrual cycle.

The other criteria Plan B meets for over-the-counter use includes, low toxicity, no potential for overdose or addiction, no teratogenicity (malformations of an embryo or fetus), no need for medical screening, uniform dose requirements and lack of significant drug-drug interactions. Theoretically, the effectiveness of Plan B can be reduced by drugs which have hepatic enzyme-inducing properties. These drugs include phenytoin, carbamazepine, barbiturates, and rifampin. Broad-spectrum antibiotics have also not shown any significant interaction with Plan B unlike broad-spectrum antibiotics and other birth control medications.

The most common side effect is nausea. But other mild side effects like vomiting, diarrhea, dizziness, fatigue, abdominal pain, breast tenderness, headache and menstrual changes can also be seen. The menstrual changes seen are because menstrual bleeding after use can often be irregular. Some women can experience spotting for a few days, bleeding can be more or less than normal and/or the beginning of the next menstrual period may be delayed. If the onset of the next period is delayed for more than one week, the possibility of pregnancy should be considered. Also, if vomiting occurs within one hour of taking the medication, because that is one of the known side effects, contact a doctor to determine if a repeat tablet is necessary.

Plan B is contraindicated in pregnancy, unexplained vaginal bleeding and allergy to the product. Its use is also cautioned and not recommended for routine use as a contraceptive and is not effective in terminating existing pregnancies. It does not protect against HIV infection or other sexually transmitted diseases and is not intended to be used in premenarchal women or those over 65 years of age. Clinical studies have also noted a higher rate of pregnancy in Chinese women compared to the rest of the subject. Nonetheless, these menstrual changes, side effects, precautions and contraindications discussed are the same no matter what age you are. So, why is there a restriction to the over-the-counter accessibility in regards to the age of the patient, especially when the purchaser might not even be the patient? This is evident when a male purchases the product, yet we have no regulations on this situation. Should males really be allowed to purchase Plan B over-the-counter if they are over 18 years old?
The safety issues related to minors has to do more with maturity, which is subjective to each individual. Many people think that at this young age, teens may not have full logical development or mental competency. They may not be fully responsible, or they may not see the consequences of their actions. Because of this, their judgment may be impaired, and many feel that parental and physician involvement is necessary. It’s hard to say where parental control would fit into this situation. If Plan B was available over the counter for minors would the pharmacist need parental consent or would a parent have to be notified before it could be dispensed?

Without medical or parental supervision these impressionable teenagers have easy access to a “morning-after pill” which may promote irresponsible sexual behavior, increasing sexually transmitted diseases and promiscuity. However, there is no reason to think this medication would somehow induce abstinent women into sexual activity and large numbers of users of Plan B aren’t promiscuous. The typical users are rape victims, couples who had a condom break and women who were lured into having sex while drunk or under the influence of drugs.

This product does however; offer a way to feel more secure about unprotected sex, and in this day and age, with the prevalence of sexually transmitted diseases, this could be disastrous. Many people on the other hand would disagree with this statement and think that giving Plan B to sexually active teens at routine visits actually encourages more responsible condom use because of increased sexual education. Some people think if teens are going to have sex anyway why not teach them how to be responsible and how to use all forms of contraceptives the right way? In the future it would be interesting to see if the incidence of sexually transmitted infections increase or decrease at all in regards to the availability of Plan B. Younger patients may also be more likely to abuse this product and instead of using the medication in emergency incidences, it may become their only form of birth control. This however is thought to hopefully be deterred because of the medications price. It will cost around $45.00, which would be very expensive for repeated use. Granted, some people are irresponsible, but at $45 for 2 pills, getting a pack of condoms or a month’s supply of birth control is much more affordable than paying that much money every time a woman has intercourse. Emergency contraceptives should only be used as its name implies, in emergency situations.

Plan B is also being studied and evaluated on is frequent and repeated use regarding its continued safety and efficacy. Some studies evaluated the use of Plan B after each act of intercourse. Despite frequent use, no serious side effects were reported and there was no relationship between the number of tablets taken and the incidence of adverse effects. The efficacy is still being determined though; some studies may show a decrease in efficacy after repeated use and their failure rate may accumulate over time. Although abuse
may exist in younger patients, is it safe to assume that people over 18 have enough common sense not to abuse the product? And does that mean because this product needs a prescription that this abuse will not occur? These safety issues can be said for all ages, so why restrict access of a product to an age group where so many unplanned teen pregnancies occur?

I stated before that the two main requirements needed to allow a medication to be available over the counter are, safety and efficacy without medical supervision. I’ve discussed safety, now I will discuss efficacy. Efficacy in this case is considered whether a patient can take the medication without supervision and still have it be successful to its purpose. Plan B is available in blister packages containing two tablets of 0.75 mg levonorgestel. One tablet of Plan B should be taken within 72 hours after unprotected intercourse and the second tablet is then taken 12 hours after the first dose. The timing of the first dose of plan B is important because it can be more effective if it is taken as soon as possible. It is about 89% effective if used within 72 hours and even more effective, about 95%, if it is taken within the first 24 hours. This importance of timing of the doses has a big impact on the need to have this medication easily accessible in order to prevent delays and to maximize efficacy in patients.

Does making this product prescription only for those under 18 really constrain the access and therefore its efficacy? Obstetrics & Gynecology in 2000 highlight a recent study in which two college-educated investigators posed as women who needed emergency contraception. Two hundred prescribers in forty states, the District of Columbia, and the Virgin Islands who were listed as providers that prescribe emergency contraception at the Emergency Contraception Hotline were called. Overall, only 76% of the attempted calls resulted in an appointment or prescription within 72 hours, 14% were failures defined as no appointment or prescription and in 11% of the calls the women were referred elsewhere. This shows that although the majority of patients were able to receive a prescription in a timely manner, there still was a percentage that did not and had to either make other means to get it or go without it.

Another impact on efficacy is how well the patients can comprehend the material provided with the medication in order to take it appropriately. Under the CARE (Convenient Access, Responsible Education) program, Plan B labeling will be easy-to-understand, conform to both prescription and over-the-counter labeling requirements and include a toll-free telephone number for additional information or guidance. Raymond and colleagues evaluated comprehension of a prototype Plan B OTC label in 656 women between the ages 12 and 50 years. The women varied with respect to race, ethnicity (Hispanic and non-Hispanic), income, marital status, education level and literacy level. After reading the label most women understood the main points it described, 93% understood the product was to prevent pregnancy after unprotected intercourse, 97% understood the first tablet should be taken within 72 hours, 98% understood that the product
should not be used by pregnant women and 94% understood the product would not prevent the transmission of sexually transmitted diseases or HIV.

The study also evaluated the actual use of Plan B and if it was appropriate in regards to timing. 540 women used the medication and took the first tablet a median of 36 hours after unprotected intercourse. The second tablet was taken a majority of 12 hour later, with 136 women failing to take it 12 hours apart and 10 women took it more than 72 hours after intercourse. Overall the studies concluded that most women, including minors, would/could understand the key information on an OTC label to effectively and safely use the product and they were able to correctly self-administer emergency contraception at the appropriate time without medical supervision or consultation.

Another topic for debate is its association with abortion. Many who oppose abortion see this medication as a form of it. This is because the medication may be preventing an already fertilized egg, which has the potential of becoming a fetus, from implanting. So, the pill can be seen as inducing an abortion if one holds the view that non-implanted, fertilized eggs are fetuses. Some have also long opposed emergency contraception because they see the medication as an "abortion" pill. These people may be linking it with Mifepristone (mifeprisone), which like Plan B, is also thought of as an emergency contraceptive. However, it is not approved by the FDA for that purpose. Its FDA approval is for the medical termination of intrauterine pregnancy through the 49th day of pregnancy, which is considered the abortion pill.

Others believe that Plan B is not the same as abortions. They believe this because if a pregnant woman takes it, it will not abort the pregnancy because Plan B is not effective if implantation has already occurred. It also will not affect the pregnancy itself. For the most part the medication simply stops an egg from being available to come in contact with sperm. And even if there happens to be an egg present when sex occurs there is no disruption of an implanted embryo. Although it is contraindicated in pregnant women, this is because it is not effective, and not due to safety issues. According to studies when taking Plan B during early pregnancy, there is no evidence to suggest that it will be harmful to either the pregnant woman or the fetus.

After a single act of intercourse, women who do not use contraception have a 7.2% chance of becoming pregnant. This leads to approximately 6 million pregnancies that occur in the United States every year. Of that 6 million about half, approximately 3 million are unintended and about half of that approximately 1.3 million end in abortions. Widespread availability of emergency contraception, like Plan B could decrease the number of unintended pregnancies and ultimately reduce the number of abortions needed. Planned Parenthood claims that emergency contraceptives will prevent 1.7 million unintended pregnancies and prevent 800,000 abortions each year in the United States. Whether you are pro-
life or pro-choice, I think people can agree that reducing the number of abortions is a good thing.

Roughly, 80 percent of teen pregnancies are unintended and Plan B availability could significantly reduce this amount. Before Plan B was available over-the-counter, patients were advised to be prepared and to have a prescription on hand at all times for emergency contraception. For now, that is what females under 18 are going to need to do since they can not obtain it without either getting a prescription or cheating the system somehow.

Another debate brought up because of the talk about improving accessibility of emergency contraception, are those patients who have a prescription for the emergency contraceptive and still can not receive it since the pharmacist at the pharmacy they went to would not fill it for the reason of moral or religious beliefs. Should a pharmacist have to dispense the medication if it is legally prescribed and clinically appropriate therapy, even if it goes against their beliefs? Just because a pharmacist disagrees with the patient’s personal and cultural beliefs, should the patient have to go without their medication? There is a fine balance between pharmacist and patient needs.

Pharmacists are individuals and bring their own individual beliefs into practice everyday. Without those beliefs, their ability to fulfill their duties and empathize with patients would be compromised. Should pharmacists have to check their personal beliefs at the door and merely follow directions? Is that realistic? Doctors and nurses are not required to participate in activities they find objectionable, shouldn’t that be the same for everyone. You can empathize with the patient or the pharmacist in this situation and there is no right answer. There is however, also a need for a fine balance between personal beliefs and professional responsibilities of the pharmacist.

This is especially important in regards to Plan B where the timing and immediacy of dosing is crucial for its effectiveness. This may not be a problem for urban areas where there is another pharmacy around the corner, but in rural areas finding another pharmacy where you could get the needed medication could be very eventful and time consuming. If a pharmacist does refuse to fill a morally objectionable prescription, there should be a plan in place to ensure the patient still receives their medication.

Legislation was recently introduced in the Senate and House call the “Access to Legal Pharmaceuticals Act” which if passed this law would require pharmacies to ensure a legal prescription is filled in a timely manner. The American Pharmacists Association (APha) also recognizes the individual pharmacist’s right to exercise conscientious refusal and supports the establishment of systems to ensure patient’s access to legally prescribed therapy but without compromising the pharmacist’s right of conscientious refusal. Wouldn’t it be easier if Plan B were available OTC for all patients so a pharmacist
wouldn’t have to fill/refuse to fill the prescription? Even then, if the pharmacy were independently owned the pharmacist could refuse to stock the medication, then the patient would be in the same predicament, but according to the new law and the APhA the pharmacy would have to have some plan in place for the patient to receive their medication.

In the near future I believe the next topic of debate is going to be for the FDA to abandon the proposed rulemaking, and to approve over-the-counter availability of Plan B for women of all reproductive ages. This is occurring already in a total of nine states including Washington, California, New Mexico, Alaska, Hawaii, Maine, New Hampshire, Massachusetts, and Vermont. These states have collaborative agreement with prescribers, and women of all ages can obtain Plan B from a pharmacist without a prescription.

Also an estimated 41 countries allow emergency contraceptives to be sold without a prescription. Yet, despite strong evidence from other countries and other states that the medication is both safe and effective without a prescription for all ages. We are still one-step behind the rest of the world when it comes to minors and availability of emergency contraceptives. A drug is either considered safe enough or it isn’t. Should you really make a distinction that it is safe in one age group and not the other despite its impressive safety record?

My opinion on the topic is that I’d rather see the general availability of the medication with a restriction for minors than not have it allowed at all. Besides, I doubt that women will be flocking into their local pharmacy for the morning after pill. It's nice to be aware that it is available in case of an accident. Accidents happen and they don’t just happen to irresponsible people. If you find the availability of this pill disagreeable, then don’t take it. Perhaps you are the type of incredibly responsible and careful human that never allows for the possibility of making a mistake or having an accident occur in your life. However, even if you are careful, you never know when a condom may break or even slip off. Accidents do occur and so does rape and sexual assault. Having Plan B available and easily accessible is much better than the tense waiting and eventual discover of pregnancy, and in some cases, the abortion.

What does the nation think about this switch of Plan B from prescription only to over-the-counter for those over 18 years old? A recent online survey on MSNBC of over 45,000 responses provides some insight. They asked, “Did the FDA do the right thing by approving the Plan B morning-after pill for use without a prescription?” 52% said yes, and it's about time. It's important that women have all options available. 28% said yes, but I hope that it will be a last resort and not the primary means of birth control for some women. 13% said no, I feel there’s not much difference between that pill and an abortion. Both are wrong. 5.6% said no, the Plan B pill should be available, but only with a prescription for someone under a doctor's care. And 1.3% said I don't know. It's a complex issue. From this you could conclude that approximately 80% of the online population
agreed with Plan B being available over-the-counter. This seems like a huge percentage, I didn’t realize that it had that much approval.

The online survey also asked a second question, “Do you agree that Plan B should only be available without prescription to those 18 and above? 56% said no, if a female is old enough to potentially get pregnant, she should be old enough to have access to everything that could help prevent an unwanted pregnancy. And 44% said yes, those younger than 18 need to have the guidance of an adult. The votes on this topic are still pretty close, which is another reason why I think it will be the next subject of debate in the future.

In conclusion, is it ethical to have a product available for over-the-counter access for only one age group? And in contrast would it be ethical to have this product be accessible over-the-counter to an age group who may not be mature enough to use it appropriately? As pharmacists, it is our job to make sure that patients are taking their medication accurately and to help minimize adverse events. Having Plan B available “behind the counter” is a great opportunity for pharmacists to be able to counsel the patient on its use before it is purchased, whether it is with a prescription or not. A reason why Plan B is still prescription only for those under 18 years old is because of concern about its use in this age group without medical supervision. Why couldn’t this medication be available to every age group when it is most likely safe enough? And why can’t the pharmacist dispensing the medication, like some states, be the medical supervision that most people think is necessary for minors? I think this would be a great area for pharmacist to be involved in and it would be a great way to show the level of expertise pharmacists have as drug experts.
References: