



NATIVE AMERICAN WOMEN'S
HEALTH EDUCATION RESOURCE CENTER

Indigenous Women's Reproductive Justice

A SURVEY OF THE AVAILABILITY OF PLAN B[®] AND
EMERGENCY CONTRACEPTIVES WITHIN
INDIAN HEALTH SERVICE

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Their support makes this important programming possible.

In memory of all those that have gone before us.



NATIVE AMERICAN WOMEN'S HEALTH EDUCATION RESOURCE CENTER
A PROJECT OF THE NATIVE AMERICAN COMMUNITY BOARD

INDIGENOUS WOMEN'S REPRODUCTIVE JUSTICE

A SURVEY OF THE AVAILABILITY OF PLAN B® AND EMERGENCY CONTRACEPTIVES
WITHIN INDIAN HEALTH SERVICE

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INTRODUCTION BY CHARON ASETOYER

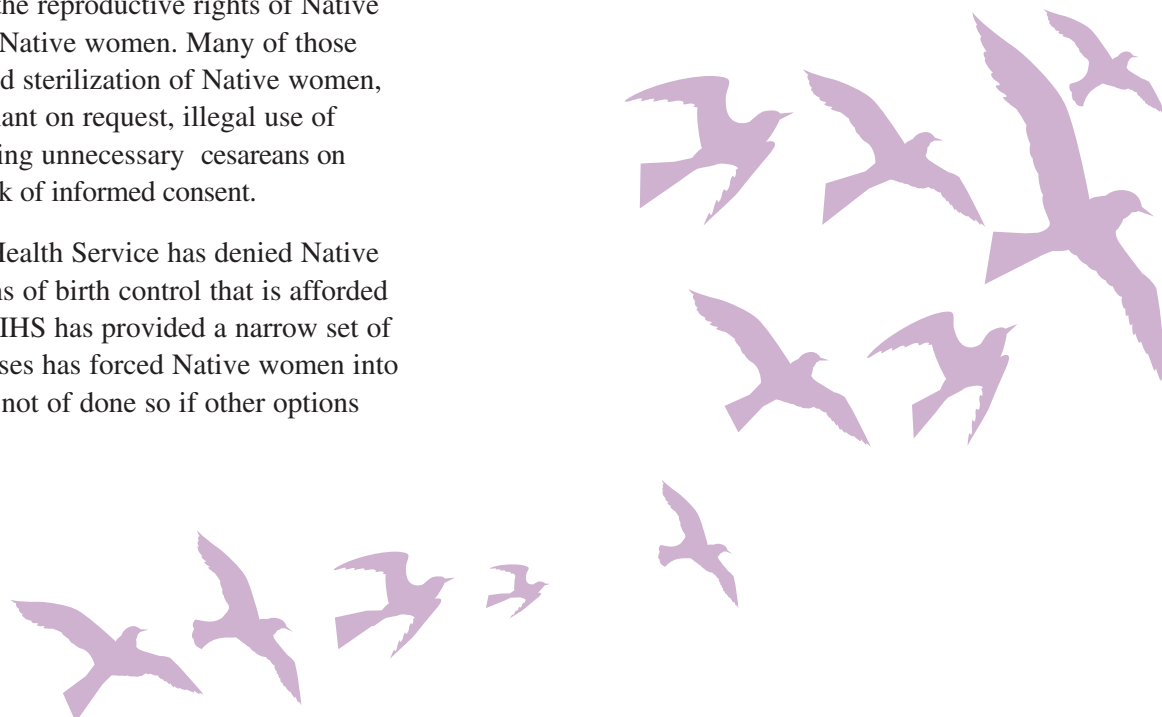
Over the past twenty-two years the Native American Women's Health Education Resource Center's programs have worked to serve the unmet needs of Native American women within our community as well as regionally, nationally, and internationally. Issues worked on include but are not limited to the prevention of violence against women, HIV/AIDS prevention, consumer advocacy, reproductive justice issues and more.

Currently the issues being addressed by the Native American Women's Health Education Resource Center focus on sexual violence against Native American and Alaskan Native women and the need to improve services for victims of rape within the Indian Health Service System. It is no secret that the Indian Health Service has been under scrutiny for not providing the same level of health care to Native Americans and Alaskan Natives as the general public receives from the medical community. In fact Indian Health Service has a history of committing Human Rights abuses and has been brought up before Congress for violating the reproductive rights of Native American and Alaskan Native women. Many of those violations include forced sterilization of Native women, failure to remove Norplant on request, illegal use of Depo-Provera, performing unnecessary cesareans on Native women and a lack of informed consent.

Over the years Indian Health Service has denied Native women the same options of birth control that is afforded to mainstream women. IHS has provided a narrow set of options that in many cases has forced Native women into sterilization that would not of done so if other options were available.

The lack of standardized policies that govern reproductive services within this Federal system has allowed this history of Human Rights abuses to occur. It has denied Native women services that other women have access to. As in the case of emergency contraceptives this situation has created an environment that forces women to carry unplanned and unwanted pregnancies to term. This situation has occurred in history during Hitler's years of control in Germany, when women were raped and forced to have babies for the Third Riche and when Black women in the US were raped by slave masters to produce more children to be forced into slavery. Forcing women to have children against their will is an act of slavery and denying them health care and services to terminate a pregnancy under these circumstances are truly Human Rights violations.

This survey examines the access and inconsistent application of emergency contraceptives within the Indian Health Service system. 🦋





HISTORY OF THE ISSUE

Emergency contraception (EC), commonly referred to as the morning after pill, is a post-coital, back-up method of birth control used since the 1960s. Known as the Yuzpe method, the regimen consists of higher doses of daily combined oral contraceptive pills containing both estrogen and progestin taken in 2 doses of 2-5 pills based on brand.^{1,2} The second dose is administered 12 hours after the first. In 1999 the federal Food and Drug Administration (FDA) approved Plan B®, a progestin-only method of emergency contraception, for prescription use.³ Progestin-only contraceptives used as emergency contraceptives were found to have a higher efficacy and fewer side effects than combined pills; however, the high number of pills necessary for a progestin-only regimen (20 pills per dose) makes its use difficult and inconvenient.⁴ Plan B® consists of only 2 pills (each containing 0.75 mg of levonorgestrel), one taken 12 hours after the first, and has an 89% efficacy.⁵

Barr Laboratories, the manufacturers of Plan B®, applied for the drug's over-the-counter (OTC) status in 2004. Despite the suggestion of the FDA's internal review board to approve the status, the FDA denied the approval in a purely political move.⁶ While the FDA claimed the decision concerned the lack of data on women under 16 years of age the judgments were based on misconceptions and patronizing perspectives of women, sexuality and reproductive health. It is obvious that politics and religion were of a higher priority than the assessment of the safety and efficacy as an OTC drug.

After addressing packaging and administrative issues, the FDA approved Plan B® for OTC use for women 18 years of age and older in 2006.⁷ Women under 18 still need a prescription to access the drug therefore it must be kept behind the counter. This creates two potential barriers to access as proof of age must be presented and buyers must interact with a pharmacist in order to obtain the drug. Pharmacists could potentially refuse to dispense the medication based on personal beliefs. Currently 4 states,

Arkansas, Georgia, Mississippi and South Dakota, have policy explicitly allowing a pharmacist to refuse to dispense EC based on personal beliefs, 5 states, Colorado, Florida, Illinois, Maine and Tennessee, have broadly defined refusal policies that could include pharmacists but do not address them specifically while 6 states, California, Delaware, New York, North Carolina, Oregon and Texas, allow pharmacists to refuse but prohibit the obstruction of access through mandatory referrals and ensured timely access.^{8,9} In communities where only one pharmacy exists, as is in many rural communities and on reservations where financial hardship is great and resources are scarce, pharmacist refusals could completely bar access to Plan B® as the next pharmacy may be hours and miles away and transportation may not be available. Vital time is unnecessarily wasted if a woman is sent from pharmacy to pharmacy in search of a provider who will dispense the drug or if a woman under 17 must schedule an appointment to first access a prescription before obtaining the drug.

Time is of the essence with EC. The first dose of the Yuzpe regimen must be taken within 72 hours (3 days) of unprotected intercourse and Plan B® was found to be effective up to 120 hours (5 days) after unprotected intercourse.¹⁰ Women's health is compromised by the narrow window of effectiveness that is cut even shorter when pharmacists refuse to dispense the drug or when a lack of resources creates an inability to travel to different pharmacies. Additionally, the risk of pregnancy doubles with every 12-hour delay in the onset of the regimen.¹¹ Plan B® is thus more effective the earlier it is begun. For this reason it is also beneficial for women to have Plan B® on hand before it is needed. Over-the-counter availability allows this to be possible.

Emergency contraceptives have the same mechanisms of action as hormonal contraceptives. Plan B® as well as the old regimens prevent pregnancy by stopping the release of an egg from the ovary, thickening the cervical mucus and thus inhibiting sperm mobility and changing the lining of

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the uterus so that it is inhospitable for a fertilized egg to implant. EC will not affect an established pregnancy and is thus not an abortifacient.¹²

The American College of Obstetricians and Gynecologists projects that Plan B® has the potential to prevent half of the unintended pregnancies (2,000,000) per year and half of US abortions (500,000) per year.¹³ This includes pregnancies resulting from rape or incest. According to the Department of Justice 176,540 women reported being raped or sexually assaulted in 2005.¹⁴ The rates are higher for American Indian and Alaska Native women, who are 3.5 times more likely than other women in the US to be raped or sexually assaulted.¹⁵ According to the Rape, Abuse and Incest National Network half of sexual assaults go unreported.¹⁶ Additionally many women may not seek medical help. The need for EC is still, however, prominent. Eliminating interactions with an intermediary would alleviate one barrier to access. This is critically important as EC is the best way to prevent unintended pregnancy in the cases of rape, incest and contraceptive failure—it is safe, effective, administered after the act and controlled entirely by the woman.

Immediate access to EC is also important in preventing the need for abortion, particularly in the case of American Indian and Alaska Native women as the Indian Health Service has a history of inadequately providing abortion services. Only 25 abortions were performed between the years of 1981 and 2001 and Service Units were found to be noncompliant with IHS policy that enables the provision of abortion, even with the restrictions of the Hyde amendment that cut Medicaid funding for the procedures.¹⁷

Other emergency services were also found to be administered inconsistently throughout IHS. According to the Native American Women's Health Education Resource Center's study, *A Survey of Sexual Assault Policies and Protocols within Indian Health Service Emergency Rooms* (2005), IHS is lacking in Service Units with uniform and accessible policy regarding sexual assault as well as

trained staff to provide these services. The inconsistent existence and implementation of such policy endangers women's health and safety as the ability to prevent disease and unwanted pregnancy is lessened. This is particularly important as more than 1 in 3 Native women is raped or sexually assaulted.¹⁹

Furthermore, IHS has a long history of compromising women's reproductive health. This includes the abuse of sterilization procedures, the coercive abuse of provider controlled contraceptives such as Norplant and Depo-Provera and the limited provisions of abortion services. As the primary and often sole providers of health care for American Indians and Alaska Natives, IHS is obligated to fulfill its mission and goals as stated on the IHS website:

- To raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level.
- To assure that comprehensive, culturally acceptable personal and public health services are available and accessible....²⁰

Unfortunately, IHS has barred women from receiving care up to these standards and has stripped them of their autonomy and self-determination. Often American Indian and Alaska Native women have no other health care options based on eligibility, cost and geographic location. Thus it is imperative that IHS is responsible for providing quality care. Having Plan B® available over-the-counter would be one step toward restoring self-determination, dignity, autonomy and basic human rights. 🐦





HISTORY OF THE ISSUES AND POLICIES WITHIN IHS

Part 3, Chapter 13, Section 12 of the online Indian Health Manual addresses family planning services and states,

All available Food and Drug Administration (FDA) approved types of contraceptive (mechanical, chemical and natural) methods should be available to those clients requesting such services.²¹

Therefore Plan B® should be readily available throughout IHS. However, IHS operates on a three-tiered formulary system that was implemented in an effort to improve standardization and curb pharmaceutical costs. The formularies are working lists of drugs chosen based on cost and efficacy that are kept in stock at pharmacies. The IHS National Core Formulary is a listing of core medications that all IHS sites are expected to have in stock and are recommended to Tribally operated facilities to have available for use. Drugs on this formulary address only certain classes of diseases and conditions and are chosen based of cost and efficacy. A national Pharmacy and Therapeutics (P&T) Committee was established to manage the core formulary while area P&T committees were formed to manage area formularies. Only three of the IHS areas, Aberdeen, Albuquerque and Oklahoma utilize area-wide formularies that theoretically standardize the drugs available throughout the areas. Finally, individual

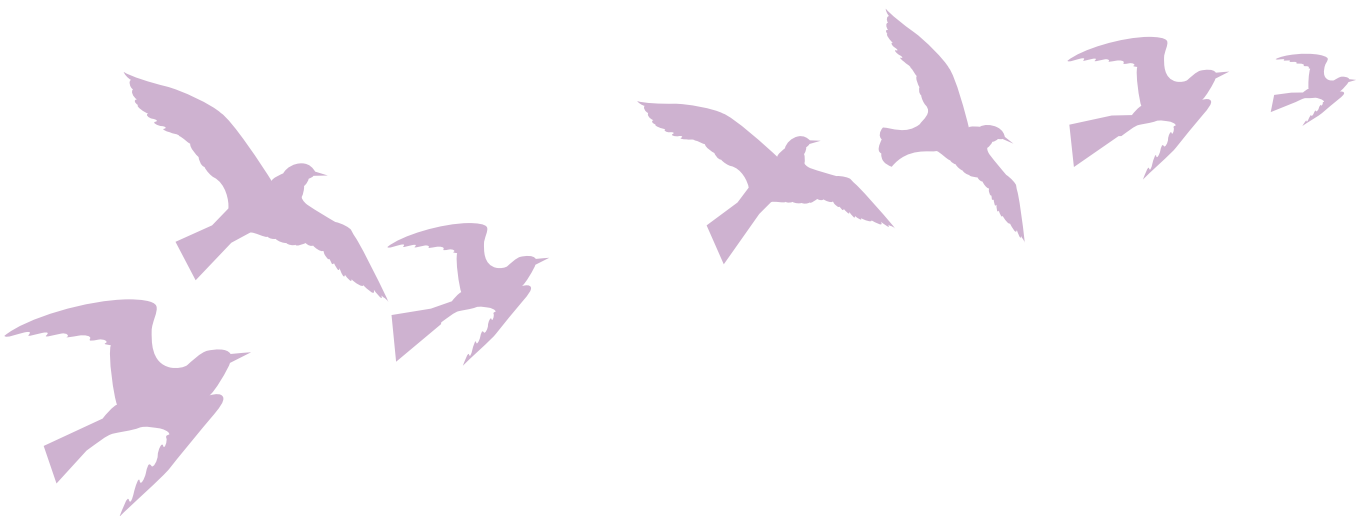
Service Units and facilities use local formularies. These formularies allow sites within the same area to carry different drugs from each other and are built based on resources and demand. Area and local formularies must incorporate and include the National Core Formulary. Additions must be proposed to the P&T committees at the appropriate level.²²

Plan B® and all other contraceptives must appear on a formulary to be accessed by IHS patients. A Non-Formulary request process exists and in emergency situations can be approved by clinical directors or chief pharmacists.

Part 3, Chapter 13, Section 12 of The Indian Health Manual also states:

IHS personnel will not be forced to personally provide family planning services against their will but it will be their responsibility to refer the client requesting such services to the proper available resource.²³

This directly addresses pharmacist refusals and the importance of prioritizing patients' health needs. ✈



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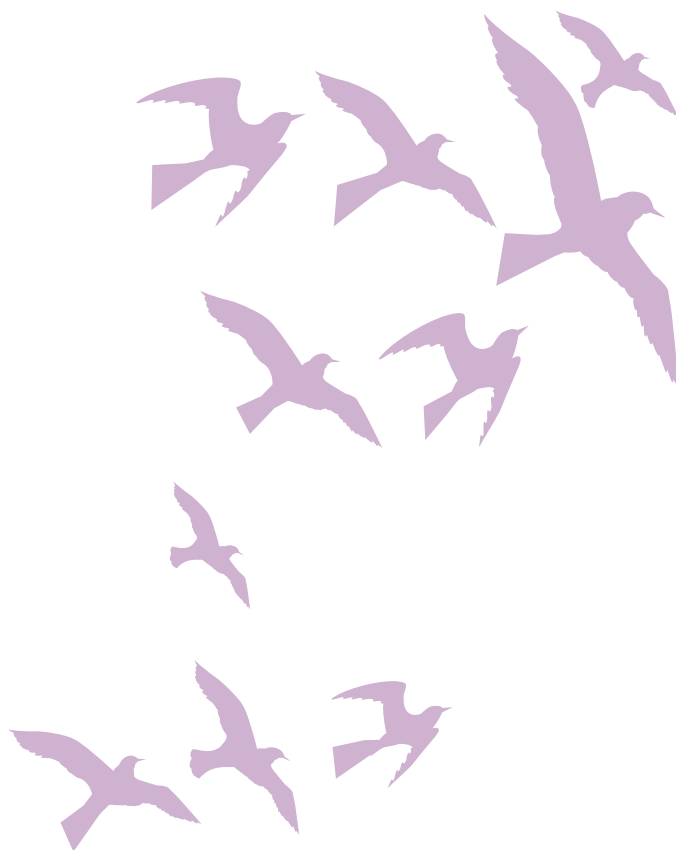
METHODOLOGY

The Indian Health Service (IHS) is the principal and primary care provider for American Indians and Alaska Natives. Health care is administered through facilities managed directly by IHS, facilities contracted by IHS and through Tribally operated facilities. This study focused on IHS operated facilities in the 12 service areas: Alaska, Aberdeen, Albuquerque, Bemidji, Billings, California, Nashville, Navajo, Oklahoma, Portland, Phoenix and Tucson, which make up nearly half of all IHS Service Units.

Four strings of systematic phone calls were conducted beginning at the area level with area Chief Medical Officers (CMO) and Area Pharmacy Consultants and moving to the level of individual Service Units including pharmacies and IHS hospital emergency rooms. A distinction was made between Service Unit hospitals and clinics when contacting emergency rooms in accordance with the online IHS directory available through the website. Only hospital emergency rooms were surveyed. Various attempts were made to speak with area Chief Medical Officers and Pharmacy Consultants and as many were reached as possible. Forty percent of individual Service Unit pharmacies and emergency rooms were contacted in each area and randomly called until 40% was reached. Chief pharmacists were requested and a knowledgeable pharmacist was spoken to only when the chief pharmacist was unavailable. In emergency rooms, nursing supervisors were requested although the calls were often redirected when the nursing supervisor was unavailable or unable to answer the questions.

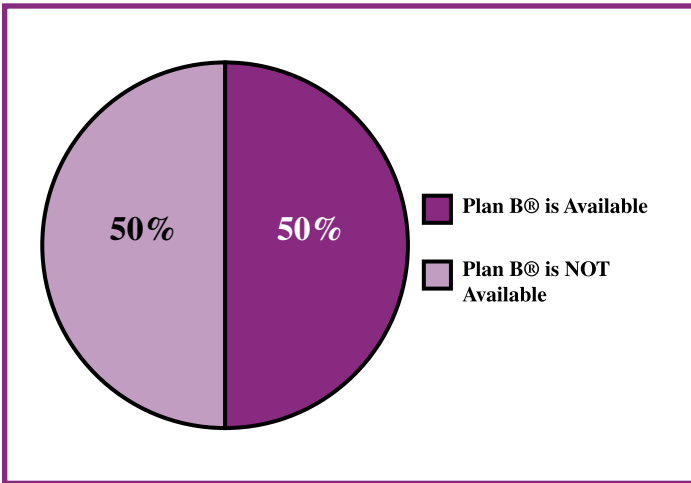
Similar survey questions were drafted and tailored for each survey group based on known barriers to accessing EC and the Indian Health Service's structure and obligations. The Indian Health Service Chief Medical Officers and emergency room staff were asked if Service Units were offering Plan B® or EC during the delivery of sexual

assault services and if the drug could be refused by a provider based on personal beliefs. The Indian Health Service Area Pharmacy Consultants and Service Unit pharmacists were asked if pharmacies had Plan B® on their formularies, if Plan B® or EC was available over-the-counter and if a pharmacist could refuse to dispense the medication based on personal beliefs. If the policies existed in written form and were accessible, respondents were requested to fax them to our office for review. ✈



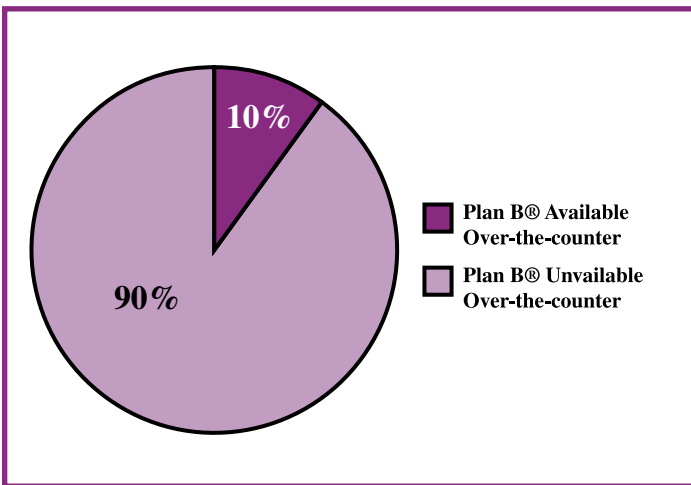


RESULTS OF SURVEY



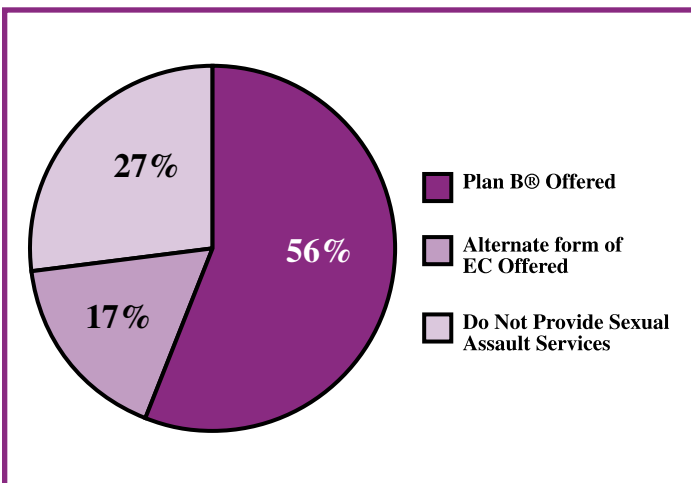
Availability of Plan B® through IHS Pharmacies

Of the IHS pharmacies surveyed (n = 40) 50% (20) have Plan B® available while 50% (20) do not. An alternate form of emergency contraception (EC) is available at 37.5% (15) of the pharmacies surveyed while the remaining 12.5% (5) have no form of EC available. The results show that policy regarding family planning as stated in the Indian Health Manual is not upheld through the recently implemented formulary system.



Availability of Plan B® Upon Request as an Over-The-Counter (OTC) Drug through IHS Pharmacies

Only 10% of IHS Service Unit pharmacies surveyed have Plan B® available over-the-counter. Access is therefore limited as women must see a provider before being able to receive Plan B®, which is approved for OTC availability.



Availability of Emergency Contraception (EC) at IHS Hospitals

Twenty-seven percent (5) of the IHS hospital emergency rooms surveyed (n = 18) do not provide sexual assault services but contract them to other facilities to perform exams and provide care. This lengthens the amount of time it takes to receive care, lessens the efficacy of emergency contraceptives and could bar a woman from receiving care based on transportation and financial limitations. All IHS hospitals surveyed that provide sexual assault services offer a form of emergency contraception. However, only slightly more than half the emergency rooms contacted offer Plan B®. Many hospitals that contract out sexual assault services often still have a form of EC available.

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IMPACT OF RESULTS

This study looked at two major issues: the availability of Plan B® as an OTC drug and the availability of Plan B® during the delivery of sexual assault services.

The results from the survey show a lack of accessibility of emergency contraceptives and Plan B® through IHS Service Unit pharmacies as 12.5% of the Service Units surveyed do not carry a form of emergency contraception. This negatively impacts the overall health and well being of American Indian and Alaska Native women and could potentially force a woman to carry an unplanned or unwanted pregnancy to term. Based on the 50% of Service Units surveyed without Plan B® in stock, it is clear that IHS is not in compliance with its own policy requiring the availability of all FDA approved contraceptive methods.

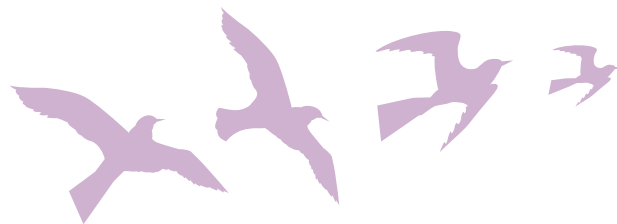
Many IHS Service Units administer the Yuzpe method of EC, usually using Ovral®, Lo-Ovral® or Levlen®, whichever may be on the formulary. Plan B®, however, has a higher efficacy with fewer side effects and contraindications as it contains only one hormone (progestin) compared to the combination of estrogen and progestin in the three oral contraceptive pills. Also, unlike Plan B® the three methods of combined oral contraceptive pills are not available over-the-counter.

The minimal availability of Plan B® is due, based on pharmacists' responses, to Pharmacy and Therapeutics Committees neglecting to put the drug on formularies, medical staff deciding Plan B®'s inclusion on the formulary is not necessary, the expense of the drug, the existence of another method of EC of the same efficacy, pharmacies not handling "symptoms" of this nature (despite carrying daily oral contraceptive pills), the drug not being requested by doctors and to the low overall number of requests for EC. The decision to exclude Plan B® from formularies has been made despite the safety and efficacy of the drug, its minimal number of contraindications, the ease and convenience of use as well as administration and cost efficacy, especially when

compared to the cost of carrying a pregnancy to term or accessing abortion services.

Many respondents noted the low number of requests for EC despite the high incidence of rape of Native American and Alaska Native women and the number of unintended pregnancies and abortions Plan B® has been predicted to prevent annually. One pharmacist saw only 1-3 requests per year while another had not received any requests in 12 years. This is a strong indicator that women are unaware of the existence of EC. It also illustrates the fact that IHS doctors and nurses are not informing women of its existence although it is the duty of IHS employees to provide women with this information as a means of providing comprehensive care. Furthermore, withholding emergency contraceptives not only contradicts IHS policy but is also a denial of human rights to American Indian and Alaska Native women.

Not only do merely half of the Service Units surveyed carry Plan B®, only 15% provide Plan B® over-the-counter. The drug should be available without being documented each time it is requested based on the FDA's decision to make Plan B® available over-the-counter. Although one Service Unit pharmacy's policy on emergency contraception indicates Plan B® can be provided upon request, patients must undergo a screening before receiving the regimen. Again, this introduces an unnecessary step into the process as the drug's OTC status enables providers to dispense it by merely screening for age. The





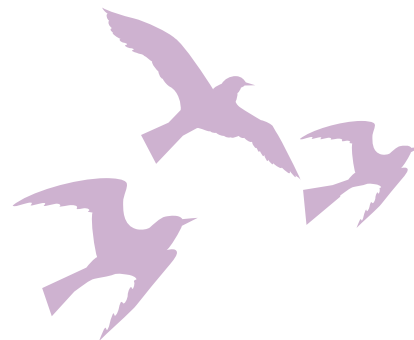
low percentage of Service Units offering Plan B® over-the-counter lowers the timely accessibility of the drug for American Indian and Alaska Native women and denies them adequate health care. This places an additional burden on American Indian and Alaska Native women who rely on IHS as their primary care provider and who often cannot access commercial pharmacies because of rural isolation or lack of resources. The fact that many rapes go unreported further necessitates the need for Plan B® to be accessible over-the-counter. A woman should not be punished for exercising her right to choose whether or not to report rape by withholding care.

Even more alarming than the low number of Service Units surveyed providing Plan B® as an OTC medication is the lack of clarity and standardization regarding sexual assault policies both in general and in regard to EC within Service Unit hospitals. This mirrors the findings of the 2005 Native American Women’s Health Education Resource Center study²⁴ as well as the recent Amnesty International report, *Maze of Injustice* (2007).²⁵ While talking with emergency room staff, nursing supervisors and nurses often passed off questions to other staff members, and were sometimes unsure of which department or personnel treat patients in cases of sexual assault and exactly who would administer family planning options. The confusion regarding departmental responsibility is an indisputable barrier to care and a great injustice to patients seeking services.

Twenty-seven percent of Service Unit hospitals surveyed contract out sexual assault services. This extends the time a patient must wait before receiving care and introduces unnecessary burdens to an already traumatic situation. While many hospitals were working to develop and implement policy regarding Sexual Assault Nurse Examiners (SANE), a disconnect in communication is evident as one respondent explained that SANEs are not permitted by the federal government. The lack of internal communication as well as comprehensive and standard

policy regarding sexual assault services throughout IHS demonstrates a breakdown in continuity and consistency in providing care to women.

Inconsistency in the knowledge of policies regarding the right of providers to refuse to dispense EC is also alarming. The Indian Health Manual provides policy on a provider’s right to refuse, but the majority of respondents were unaware of the existence of such policy. Many respondents believed that the denial of medication based on personal beliefs was not a concern because other pharmacists or providers could be asked to dispense the medication should one refuse. While this process is consistent with IHS policy, which directs providers who refuse to dispense certain medications to seek another provider or pharmacist to dispense it in their place, the lack of awareness of the official policy is cause for concern. Also, the policy could prove to be problematic where only one pharmacist or provider is available to dispense the medication. Further inaccurate understanding of policy surfaced, as some respondents believed a local exemption could be obtained and others thought refusals could be permitted only if they were addressed in initial contracts. Many respondents had never addressed the possibility of refusal. The policy should be widely distributed and practiced so women’s health needs are not compromised. Even where Omnicell systems, automated organizing and dispensing systems, are used, a provider is still necessary to dispense medications. Policies should thus be accessible where Omnicell systems are used. 🐦



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CONCLUSION

The Indian Health Service's failure to comply with its policy regarding contraceptive options and its failure to provide currently available contraceptive methods is an injustice and disservice to its patients. It is clear that IHS has inadequately served American Indian and Alaska Native women's health needs regarding family planning and sexual assault services historically as well as presently. While the formulary system was implemented in part to increase standardization, its effectiveness regarding Plan B® seems to fall short. It is an injustice that American Indian and Alaska Native women cannot obtain Plan B® over the counter through IHS (with few exceptions) while the FDA has indiscriminately granted its OTC status. This decision not only enables greater assistance to women in managing family size but also enhances women's overall health and well being. The FDA's approval was a major contribution to family planning that IHS has yet to adopt and implement.

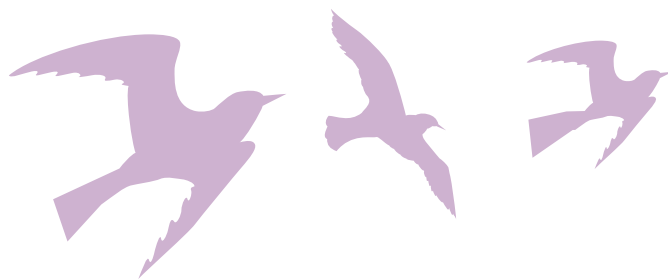
The denial of appropriate access to Plan B® through IHS is not only blatant racial discrimination as IHS serves only American Indians and Alaska Natives but it is also a direct attack on women and women's reproductive health. What we are seeing is history repeating itself through the Indian Health Service's abuse of power and failure to inform women of the full range of available contraceptives and their effects. It is the duty and obligation of IHS and IHS providers to do everything within their power to inform women of medical advances, options and technologies so women are able to make their own informed decisions about their health. Failure to do so undermines women's autonomy and self-determination.

The Indian Health Service must make a conscious effort to improve services that will have a positive impact on the overall health and well being of American Indian and Alaska Native women. This includes adopting standardized sexual assault policy and protocol that incorporate the provision of emergency contraceptives as well as a policy

that makes Plan B® available as an OTC medication for all women seeking the drug whether as a result of rape or a failed contraceptive. It is not enough for only *a few* IHS Service Units to provide Plan B® over-the-counter. Over-the-counter access to Plan B® must reach universally throughout IHS operated facilities, including hospitals, clinics and emergency rooms in order to ensure that it is available to all women in emergency situations and even before an emergency situation arises.

Implementation of standardized sexual assault policies as well as policy regarding Plan B® would be merely one step forward in truly heightening women's reproductive health and overall well being that would bring IHS into the new millennium while ensuring the provision of quality, up to date health care. Women must be provided with safe and cost effective contraceptive options with high efficacy that will allow them to make decisions about their own health and family size instead of being forced to carry an unplanned or unwanted pregnancy to term.

It is likely that the Native American Women's Health Education Resource Center will convene a roundtable of women from reservation communities to discuss the findings and impact of the survey. Recommendations that will have a positive impact on the health and well being of American Indian and Alaska Native women including improvements to policy will be made then. 🦋



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