

# Testing strategies to improve access to emergency contraception pills:

Prescription vs Prophylactic
Distribution

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March 1999

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The overall objective of the Africa OR/TA Project II is to broaden understanding of how to improve family planning services in Sub-Saharan Africa, and to apply operations research and technical assistance to improve services by:

- increasing access to a full range of family planning services and methods;
- developing service delivery strategies that are client-oriented and acceptable to various population groups;
- improving the operations of programs to make them more efficient and financially sustainable;
- improving the quality of services;
- strengthening the capabilities of family planning program managers to use operations research to diagnose and solve service delivery problems.

This project was supported by the Population Council's Operations Research and Technical Assistance Project II, Project No. 936-3030 funded by the United States Agency for International Development (USAID).

### **ABSTRACT**

This report is the second in a series of research summaries produced in connection with the operations research project, Enhancing Access to Family Planning Services through the Introduction of Emergency Contraception. Launched in September 1997, the project explores the many issues surrounding the introduction and delivery of emergency contraception services in a developing country context.

The study described in this report compares two different approaches to overcoming barriers that prevent women from accessing emergency contraception during the 72 hour period when the first dosage of emergency contraception pills (ECPs) must be taken. In one approach, new family planning acceptors were given a pack of ECPs for later use in the event of method failure, rape, or unprotected intercourse. In the other approach, acceptors were given an advanced prescription which, if necessary, could be redeemed for an actual pack of ECPs at participating health centers. Implemented at four public sector clinics in Lusaka, Zambia, the strategies are compared in terms of their effectiveness at communicating appropriate information on emergency contraception; reducing wastage of ECPs; facilitating timely access to emergency contraception; and limiting use of emergency contraception for emergencies only. The study adopted an experimental design using three equivalent groups: two experimental (one for each intervention) and one control. Each group consisted of 150 new acceptors of the pill and 150 new acceptors of the condom as their exclusive family planning method

On the issue of communicating appropriate information, study results suggest few appreciable differences between the two intervention strategies. Both strategies were equally likely to enhance recall of the time frame within which emergency contraception must be initiated; the number of ECPs needed; the frequency with which they should be taken; the brand-name of the emergency contraception pill; and the location where it could be obtained. What these findings suggest, therefore, is that fears over inadequate client knowledge or potential recall should not serve as a basis for doubting the safety or practicality of dispensing ECPs, either prophylactically or under advanced prescription.

With respect to product wastage, direct comparisons were complicated by the fact that one strategy entailed the distribution of actual ECPs, while the other involved the delivery of prescriptions only. Any assessment of outcomes, therefore, hinged on the relative importance attributed to losses to the service delivery system as opposed to product loss by individuals. On the side of prophylactic provision, actual individual loss was fairly minimal. Only about 10 percent of the women who did not use their prophylactically-provided ECPs, for example, had actually lost them. But because fewer than half the prophylactic recipients of emergency contraception ever used ECPs, loss to the system (of unused packets) was indeed significant. Advance prescription, by contrast, saw higher losses of the prescription cards themselves. But because those who eventually redeemed their prescriptions actually used the product, the loss to the system was minimal.

With regards to timeliness of access, prophylactic administration of ECPs dramatically reduced the length of time between unprotected intercourse and the administration of the first dose of pills. Almost half of emergency contraception users who received their pills prophylactically had taken their first pills within 12 hours of unprotected intercourse. The impact of this increased access may even be more significant given recent data suggesting that emergency contraception is more effective at preventing pregnancy the earlier the pills are taken. The advanced prescription intervention, by contrast, had virtually no effect at decreasing the timeliness of access. Two factors may have accounted for this. One was the study's client base, which underrepresented the categories of women (young, unmarried women) most likely to value the additional privacy associated with anonymous prescription cards. The other may have been the narrow scope and inconsistent application of the intervention itself.

Perhaps the most critical issue addressed during this study, however, was whether increased access to ECPs encouraged its use for reasons other than "emergencies". A comparison of the two strategies showed that women with prior access to ECPs were indeed over three times more likely to use them than those who received prescriptions. Two reasons accounted for this discrepancy. First, poor contraceptive use among all study participants suggests that at least some percentage of emergency contraception use had nothing to do with the prophylactic provision. In such cases, the only advantage to accrue to those who received pills prophylactically would have been their ability to react more quickly to the consequences of unprotected intercourse.

But it was clear that prophylactic provision of ECPs could also change the environment within which contraceptive decisions were made. In some cases, it created new pressures (such as enhancing men's ability to negotiate condom use); and in others it made it easier to respond to those pressures by abandoning routine

methods in favor of ECPs. Prophylactic provision also seemed to draw increased attention to the perceived inconveniences of other hormonal methods – particularly the pill. In such cases, prophylactic provision of ECPs clearly did lead to non-use of routine family planning methods.

Prophylactic provision of dedicated ECPs can be a safe and effective approach for enhancing access to the method. Realistically speaking, however, it is not an approach that is ever likely to be applied routinely to all new family planning acceptors. What this study advocates, therefore, is greater provider-awareness of the use-dynamics of emergency contraception so that when prophylactic provision is requested or deemed appropriate, it can be used more effectively. Training and other informational materials must be candid about the "unintended consequences" of prophylactic provision so providers are better able to anticipate how the method is likely to be used. They must also be better informed if they are expected to minimize the factors that have often led to its unnecessary use: unrealistic perceptions about its efficacy; the belief that emergency contraception represents a practical alternative to negotiating condom use; or even the notion that all acts of unprotected intercourse present the same risk of pregnancy and therefore must be followed by emergency contraception.

The study also recommends, however, that the role of advanced prescription be further explored, particularly since it has the potential of offering many of the advantages of prophylactic distribution, but at a considerably lower cost to the system. It can reduce the timeframe between unprotected intercourse and the first dosage of emergency contraception pills by eliminating the need for counseling precisely when time is at a premium. It offers privacy insofar as it avoids the potential embarrassment of having to "explain oneself" before a health care provider. It eliminates wastage to the service delivery system since the method itself is only distributed when needed. And because the cost of the cards is marginal, advanced prescription could be routinely implemented for all new condom and pill users — at least those within easy reach of a chemist, dispensary or other outlet of contraceptive products.

## NOTE DE SYNTHESE

Ce rapport est le deuxième d'une série de comptes rendus de recherche produits dans le cadre d'un projet de recherche opérationnelle intitulé: La promotion de l'accès aux services de planning familial par l'intermédiaire de la contraception d'urgence. Initié en septembre 1997, le projet étudie les divers aspects relatifs à l'introduction et à la mise à disposition de services de contraception d'urgence dans un environnement de pays en développement.

L'étude qui est exposée dans ce rapport met en parallèle deux démarches destinées à éliminer les obstacles qui empêchent les femmes d'avoir accès à la contraception d'urgence dans les 72 heures- période durant laquelle la dose initiale de pilules contraceptives d'urgence (PCU) doit être prise. Dans le premier cas, les nouvelles adeptes du planning familial ont reçu un paquet de PCU, pour une utilisation ultérieure, en cas d'échec de la méthode, de viol ou de rapport non protégé. Dans l'autre cas, les bénéficiaires ont reçu une ordonnance par anticipation qui pouvait, en cas de besoin, être échangée contre un paquet complet de PCU dans les centres de santé qui participent au projet. Mise en œuvre dans quatre cliniques publiques à Lusaka, Zambie, cette étude compare les deux stratégies selon leur capacité réelle: à transmettre l'information appropriée sur la contraception d'urgence, à réduire le gaspillage de PCU, à faciliter l'accès sans délai à la contraception d'urgence, à ne limiter l'usage de cette contraception qu'aux seuls cas d'urgence. L'étude est de conception expérimentale en ce qu'elle a utilisé trois groupes équivalents: deux groupes expérimentaux (un pour chaque intervention) et un groupe de contrôle. Chaque groupe était composé de 150 personnes qui venaient d'adopter la pilule et de 150 personnes qui venaient d'adopter le préservatif comme méthode exclusive de planification familiale.

En ce qui concerne la transmission de l'information appropriée, les résultats de l'étude ne montrent pratiquement pas de différences notables entre les deux stratégies d'intervention. Les deux sont également de nature à renforcer la capacité à se souvenir de la période durant laquelle la contraception d'urgence doit être commencée, du nombre de PCU nécessaires, de la fréquence des prises, de la marque de la pilule, et de l'endroit où elle est disponible. Il apparaît, à la lumière de ces résultats, que la crainte d'une mauvaise compréhension par les clientes, ou leur incapacité à se souvenir ne doit pas être mis en avant pour douter de l'innocuité ou de la nature pratique de la mise à disposition des PCU, aussi bien dans le cadre de mesures prophylactiques que par le biais d'une ordonnance par anticipation.

Quant au gaspillage du produit, la comparaison directe était rendue difficile par le fait que l'une des approches reposait sur la distribution effective de PCU, cependant que l'autre supposait uniquement la délivrance d'ordonnances. L'appréciation des résultats est par conséquent basée sur l'importance relative attribuée aux pertes relatives au système de mise à disposition du service, par opposition à la perte du produit imputable aux individus. Par rapport à la fourniture à des fins prophylactiques, les pertes imputables aux individus étaient relativement minimes. Seules 10 pour cent environ des femmes qui n'avaient pas utilisé leur PUC fournies dans un cadre prophylactique, par exemple, les avaient effectivement perdues. Cependant, étant donné que moins de la moitié des bénéficiaires de la contraception d'urgence, dans le cadre prophylactique avaient au moins une fois utilisé la PCU, la perte par rapport au système (paquets non utilisés) était assez importante. Par opposition, dans le cadre de l'ordonnance par anticipation, l'on a enregistré des pertes plus élevées de fiches de ordonnance ellesmêmes. Mais parce que celles qui en définitive échangeaient leurs ordonnances utilisaient effectivement le produit, la perte par rapport au système était minime.

Pour ce qui est de l'accès sans délai, l'administration prophylactique de la pilule contraceptive d'urgence a réduit de manière significative le temps qui s'écoule entre les rapports non protégés et l'administration de la première dose de pilule. Près de la moitié des utilisatrices de la contraception d'urgence qui ont reçu leurs pilules dans le cadre du traitement prophylactique ont pris leur première pilule dans les 12 heures qui ont suivi le rapport non protégé. L'impact de cet accès plus aisé sera d'autant plus significatif que les données les plus récentes tendent à montrer que la contraception d'urgence est plus efficace lorsque les pilules sont prises au plus tôt. L'ordonnance par anticipation n'a pratiquement pas eu d'effet sur la réduction des délais d'accès. Deux facteurs peuvent expliquer cette situation : d'abord la sous-représentation des catégories de femmes (jeunes et célibataires) qui probablement favorisent le plus le caractère privé lié aux ordonnances anonymes; ensuite, le champ limité et la mise en œuvre insuffisamment systématique de l'intervention elle-même.

La question la plus importante probablement abordée par cette étude était de déterminer si un plus grand accès à la pilule contraceptive d'urgence allait inciter à son utilisation pour des raisons autres que "d'urgence". Une comparaison des deux stratégies montre que les femmes qui avaient déjà eu accès à la pilule contraceptive d'urgence étaient 3,5 fois plus portées à les utiliser que celles qui avaient reçu une ordonnance. Deux raisons

expliquent cet écart. D'abord, la faible utilisation de contraceptif parmi toutes les participantes à l'étude montre qu'au moins un certain pourcentage d'utilisation de la contraception d'urgence n'avait rien à voir avec la fourniture de pilule dans le cadre prophylactique. En l'espèce, le seul avantage à l'actif de celles qui ont reçu les pilules dans le cadre de mesures prophylactiques se situe dans leur capacité à réagir plus rapidement face aux conséquences d'un rapport sexuel non protégé.

Il est cependant clairement apparu que la mise à disposition de pilules contraceptives d'urgence dans un cadre prophylactique pouvait aussi changer le contexte dans lequel sont prises les décisions relatives à la contraception. Dans certains cas, de nouvelles pressions ont vu le jour (comme la plus grande capacité des hommes à négocier l'utilisation du préservatif); et dans d'autres, elle a facilité la réaction face à ces pressions, par l'abandon des méthodes habituelles en faveur de la pilule contraceptive d'urgence. La mise à disposition dans le cadre de mesures prophylactiques semble aussi mettre en lumière les désavantages patents des autres méthodes hormonales- la pilule en particulier. En l'occurrence, la mise à disposition de pilules contraceptives d'urgence dans un cadre prophylactique a induit un abandon des méthodes habituelles de planning familial.

La mise à disposition de pilules contraceptives d'urgence dans un cadre prophylactique peut être une mesure efficace et sans danger qui facilite l'accès à la méthode. Pour être réalistes, il faut cependant dire que cette méthode ne peut vraisemblablement pas s'appliquer couramment à toutes celles qui utilisent le planning familial pour la première fois. Cette étude préconise donc une plus grande prise de conscience de la part des prestataires quant à la dynamique de l'utilisation de la contraception d'urgence de sorte que lorsque sa mise à disposition prophylactique est sollicitée ou jugée opportune, elle soit utilisée avec une plus grande efficacité. La formation et les autres matériels d'information doivent être très explicites sur les "conséquences imprévues" de la contraception d'urgence afin que les prestataires soient mieux à même de déterminer à l'avance comment la méthode sera utilisée. Ils doivent aussi être mieux informés s'ils veulent être en mesure de minimiser les facteurs qui ont souvent conduit à son utilisation superflue, à une fausse perception de son efficacité, à la croyance que la contraception d'urgence représente une solution de rechange à la négociation de l'utilisation de préservatif ou même à l'idée que tous les rapports non protégés présentent le même risque de grossesse et que par conséquent ils doivent être suivis de contraception d'urgence.

Cependant l'étude recommande aussi que le rôle de l'ordonnance par anticipation soit davantage étudié, singulièrement parce qu'elle peut offrir plusieurs des avantages de l'ordonnance prophylactique, mais à des coûts considérablement moins élevés pour le système. Elle peut réduire la période entre le rapport non protégé et la première prise de pilule contraceptive d'urgence, en éliminant le besoin de counselling alors que précisément le temps a une grande importance. Elle garantit le caractère privé puisqu'elle évite l'embarras que l'on ressentirait à "s'expliquer" devant un agent de santé. Elle élimine le gaspillage car la méthode n'est mise à disposition que lorsqu'elle est nécessaire. Et parce que son coût est marginal, l'ordonnance par anticipation peut, de façon tout à fait normale être délivrée à des personnes qui utilisent le planning familial pour la première fois- au moins à celles qui ont facilement accès à un pharmacien, un dispensaire ou à d'autres points de distribution de produits contraceptifs.

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## **ACKNOWLEDGEMENTS**

The authors would like to express their gratitude to a number of people whose collaboration and support have made possible the activities and findings described in this report. Special thanks go to Ms. Valerie Koscelnik of USAID whose enthusiasm, interest and personal involvement in the study have had a profound impact on both the quality and quantity of our findings. Many thanks are also due to Dr. Marge Horn of USAID, a long-term supporter of this study whose critical editorial eye has made it possible to share these results with health planners and policy makers alike. Finally, the authors wish to thank Ms. Moonga Simuyandi, Mr. Joseph Banda, and Mr. Clement Mwakamui who, on more occasions than we would like to admit, rescued us with their data processing skills and sacrifices of personal time.

One of the truly distinctive features of this study is the fact that it has been, ever since its inception, a highly participatory exercise. Most of the project's service delivery, training and even data collection components are managed by a steering committee whose membership is drawn from providers at each of the service delivery points involved in the project. To these providers and their respective institutions, we convey our gratitude.

And finally, none of the activities described in this report would have been possible without the generous support of the project's funding agencies. For that support, we wish to thank the United States Agency for International Development, the World Health Organization, the Canadian Public Health Association, and the British Department for International Development.

# 1. Introduction

This report is the second in a series of research summaries produced in connection with the operations research project, Enhancing Access to Family Planning Services through the Introduction of Emergency Contraception (Ahmed et al 1998). Launched in September 1997, the project explores the broad range of issues surrounding the introduction and delivery of emergency contraception services in a developing country context. The first phase of the project, which concluded in March 1998, was an exploratory exercise, designed to identify strategies for overcoming difficulties associated with the introduction of emergency contraception. The second phase, now underway, uses operations research to test the problem-solving strategies identified in Phase One.

The study described in this report is the first to be carried out under the project's second phase. Initiated in April 1998 and completed nine months later, the study tests the efficacy and viability of two different approaches to overcoming barriers that prevent women from accessing emergency contraception within 72 hours -- the period within which the initial dosage of emergency contraception pills must be taken. Implemented at four public sector clinics in Lusaka, Zambia, the study compared prophylactic distribution with advanced prescription of emergency contraception pills. The strategies were compared in terms of their effectiveness at communicating appropriate information on emergency contraception; reducing wastage of emergency contraception pills; facilitating timely access to emergency contraception; and limiting use of emergency contraception for emergencies only.

This report is divided into four major sections. The first recounts the events and circumstances that led to the development of this study; it details the interventions tested; and it describes the rationale underlying the selection of these particular interventions. The second section follows with a summary of the study's research methodology and principal data collection activities. The third section details the research findings as they relate to each of the four criteria outlined above and it outlines their implications for future programmatic activities. Finally, the fourth section focuses on future directions and identifies areas for subsequent research and action.

<sup>&</sup>lt;sup>1</sup> Emergency contraception refers to methods women can use to prevent pregnancy following unprotected intercourse. Although there are several types of emergency contraception, this study refers specifically to the provision of two high dose oral contraceptive tablets (each containing levonorgestrel,  $250\mu g$  plus ethinyl estradiol,  $50\mu g$ ) within 72 hours of intercourse followed by a further two tablets 12 hours later. This regimen is also commonly referred to as the "Yuzpe method" of emergency contraception.

# 2. BACKGROUND

In September 1997, the Population Council's Africa OR/TA II project launched an operations research project entitled *Enhancing Access to Family Planning Services through the Introduction of Emergency Contraception*. Implemented in two distinct phases, the project is designed to explore a broad range of issues relating to the introduction and delivery of emergency contraception services in a developing country context. Through the involvement of four major providers of reproductive health services (University Teaching Hospital, the Ministry of Health/Central Board of Health, the Planned Parenthood Association of Zambia, and the University of Zambia) emergency contraception is now available at more than 21 health care facilities across Lusaka and the rural Copperbelt. To date, over 1,500 packets of emergency contraception pills have been dispensed through the project.<sup>2</sup>

One critical finding of the first phase results was the degree to which sociocultural and institutional factors limit access to emergency contraception *services* and to the *information* a woman must have before she will seek such services out. Youth, for example, tend to eschew traditional clinic-based settings for what they perceive to be their absence of privacy. Other potential users, by contrast, are constrained from accessing emergency contraception because the information they receive about it fails to reflect issues of concern to them.<sup>3</sup>

There is, however, a third kind of barrier to emergency contraception. Often referred to as a "time barrier", it consists of any hindrance or obstacle that delays a woman from accessing services within the narrow 72 hour window available to her, irrespective of the institutional channels or sources through which the product (or information about the product) was originally obtained.

Alternative strategies for *administering* emergency contraception provide perhaps the most effective means for breaking down these so-called "time barriers". One option, recently employed in certain developed countries, is to provide emergency contraception to women before they ever need it. This could vary from dispensing a dedicated product (oral contraceptives packaged exclusively for emergency contraception) to distributing coupons or prescriptions that can be redeemed anonymously in a pharmacy or clinic dispensary.

Each of these solutions has their advocates and opponents. Family planning clients, for example, often request packets of emergency contraception pills just so they can be "kept on hand" in case the need arises. For these clients, many of whom live at some distance from the health center,

<sup>2</sup> Manufactured under the brand name PC-4, each packet of emergency contraception pills comprises four oral contraceptive tablets containing levonorgestrel, 250 $\mu$ g plus ethinyl estradiol, 50 $\mu$ g.

<sup>&</sup>lt;sup>3</sup> Interviews carried out during the initial phase of this study suggest that women's interests in emergency contraception vary widely. All women express at least some concern over such issues as the potential side effects of emergency contraception, its accessibility, and its role in protecting against STDs. But within that broad spectrum, certain questions appear much more critical than others. Family planning users, for example, typically showed greatest interest over the safety of emergency contraception, while non-users stood out for their curiosity about the method itself: what it looks like, what its name is, and what form it takes. One important lesson to be derived from these findings was the need to ensure that health care providers and developers of IEC materials gear their communication efforts to meet the specific needs and interests of different target populations. For more information on this issue, see Ahmed et al (1998: 13-16).

prophylactic distribution represents a great convenience, both in time and cost. Younger clients – particularly university students – also find prophylactic distribution attractive insofar as it allows for greater privacy and discretion. For them, picking up emergency contraception "in advance" offers far greater anonymity and emotional distance than doing so when it is actually needed.

Within the health community, however, feelings towards prophylactic distribution are far more divided. There are, it is true, many providers who see the strategy as an effective mechanism for reducing the numbers of women who arrive at health centers too late for emergency contraception. But there are many other providers who believe that prophylactic provision threatens continued use of regular family planning methods. During Phase One of this study, for example, over 12 percent of inquiries about emergency contraception related in some way to its use as a convenient alternative to a regular contraceptive method, particularly during the transition period between injections or before beginning a new cycle of pills. Providers were also suspicious about distributing methods without any certainty the method would be ever be needed or used. In a resource poor environment such as Zambia where contraceptive stockouts are endemic and supplies are limited, the risk of "wastage" represents a powerful critique.

Among the many critics of prophylactic provision, however, are those who believe that in the final instance, the greatest barriers to accessing emergency contraception are less related to time and distance than they are to the lack of knowledge about the product or to the limited range of locations where it can be obtained. What they propose, therefore, is the issuance of advanced prescriptions that could be redeemed by clients, when needed, at any pharmacy or clinic dispensary. If emergency contraception could be made more widely available around the clock, they claim, there would be little need to distribute actual pills, and little need to run the various risks associated with it.

Clearly, there are no simple answers to these contentious issues. Nor do we have – at least in a developing country context -- concrete data capable of shedding light on them. For that reason, the present study was designed to explore further the issue of "time barriers" and identify strategies that might be developed to overcome them.

# 3. OPERATIONS RESEARCH PROJECT

Launched in April 1998, the ultimate objective of this study was to explore different approaches for overcoming barriers that prevent women from accessing emergency contraception within the narrow 72 hour window available to them. To accomplish this, the study assisted four public sector clinics in Lusaka (Chawama, Mtendere, Kanyama, and Chipata) to introduce the following two strategies for administering emergency contraception:

- Prophylactic distribution of emergency contraception pills.
- Distribution of a printed informational card to new family planning acceptors that could be redeemed for an actual pack of emergency contraception pills at any participating health center.

The strategies were then compared in terms of their effectiveness at:

- communicating appropriate information on emergency contraception,
- reducing wastage of emergency contraception pills,
- facilitating timely access to emergency contraception pills, and
- limiting use of emergency contraception for emergencies only

The following describes the rationale behind each intervention and the form it took under the present study:

#### Experimental Group 1: Prophylactic distribution of emergency contraception pills

The introduction of a dedicated emergency contraception product under Phase One of this study represented a critical first step in expanding access to emergency contraception. But it was still an intervention that required clients to travel to a health center and explain to someone else the circumstances leading to their current situation. Distributing pills before they are ever needed is one way users of emergency contraception can overcome barriers of distance and time, or even the embarrassment of confronting a provider face to face once unprotected intercourse has occurred. But prophylactic distribution of emergency contraception is an intervention whose impact is potentially complex and, in a developing country setting, largely unpredictable. While it is reasonable to assume that having emergency contraception pills on hand would effectively remove any remaining barriers to its use, it is not certain what the other consequences of such a practice might be. To skeptics, it could lead to misuse of the product, to unnecessary wastage, or even to discontinuation of one's regular family planning method. And even among those providers who accept the possibility that prophylactic distribution might increase knowledge and utilization of emergency contraception, many still question whether such increases were really worth the additional costs.

In April, 1998, prophylactic distribution of emergency contraception pills was introduced on a limited scale at all four health centers involved in the study. Three hundred new family

planning acceptors (75 per site) were provided with a pack of emergency contraception pills (PC-4) to take with them at the same time they received their initial family planning method. For the purposes of this study, PC-4 was provided prophylactically only to new users of oral contraceptives and condoms since these two groups were found during Phase One of the study to be more likely than users of any other method to obtain emergency contraception. Condom users, for example, made up only 4.6 percent of all family planning users in Phase One, yet they accounted for almost 37 percent of emergency contraception clients. Pill users, though obviously representing a considerably larger percentage of family planning users overall, still accounted for a sizable 30 percent of all emergency contraception clients.

Under this intervention, each client received a packet of *PC-4* (see Figure 1); was instructed on how the pills were to be taken; the circumstances under which it was necessary to do so; and the appropriate follow-up protocols to be followed should the recipient decide to use it<sup>4</sup>

Figure 1

Health care provider distributing emergency contraception pills prophylactically along with a routine family planning method.



#### Experimental Group 2: Advanced prescription of emergency contraception

As noted previously, many in the health field question both the practicality and the utility of prophylactic distribution. Making emergency contraception too accessible, they argue, can present its own set of risks, particularly if it makes mis-use or even non-use of regular family planning methods that much easier. To this group, the critical barriers affecting access to emergency contraception are less related to factors such as time and distance than they are to knowledge about the product or the location where it could be obtained. If emergency contraception could be made available around the clock, they claim, the disadvantages of

<sup>&</sup>lt;sup>4</sup> Under Phase One of the study, all women having received PC-4 were requested to return to the health facility for a follow-up visit either at the resumption of their menstrual period or at any point by which time they felt their period should have already begun. This protocol was continued under the present study.

distributing pills in advance would likely outweigh any advantages such a policy might otherwise yield.

The second intervention to be undertaken in this project, therefore, was to introduce a strategy that would address the concerns expressed by both proponents and opponents of prophylactic distribution. To satisfy the informational priorities of the latter group, the project issued prescription cards to 300 new family planning acceptors at the same time they received their initial supply of oral contraceptives or condoms. The card contained a colored picture of a packet of *PC-4*, so that it could be identified by name and sight. It included instructions on how *PC-4* was to be taken and it described the circumstances under which it was necessary to do so. Finally, to satisfy those who were especially concerned about the embarrassment of confronting health care providers, the card also included a statement indicating that the card could be redeemed for an actual pack of *PC-4* at the general dispensary of any one of the four participating health centers, 24 hours a day, 7 days a week – no questions asked.

Figure 2
Exchanging a prescription card for a packet of emergency contraception pills at the OPD dispensary of a participating health center.



Clearly, for this intervention to work, it was necessary to ensure that emergency contraception pills would be made available at all participating health centers on a continuous basis. Under Phase One of this project, for example, the introduction of emergency contraception pills was restricted exclusively to MCH/FP Departments and, by extension, to the time schedules under which they operate: typically from 8:00 to 17:00, Monday to Friday. Anyone requiring emergency contraception outside these hours stood little chance of obtaining it. For one thing, few providers apart from MCH/FP staff were really familiar with emergency contraception. And secondly, even if a client were fortunate enough to encounter

a knowledgeable provider, chances are she would still not have had access to emergency contraception pills since they, like any other "contraceptive method", would have been stored exclusively in the MCH/FP unit.

To ensure that advanced prescription would indeed provide continuous access to emergency contraception, the study assisted all four participating clinics to offer emergency contraception pills around the clock either through MCH/FP services or, when that was closed, through the Outpatient Department (see Figure 2). This intervention involved familiarizing all clinic staff with the dedicated emergency contraception pill available at that facility. It involved training those providers likely to dispense it, and it required stocking the product in the general outpatient dispensary where it would be accessible to all clinic staff.

#### Control group: Routine counseling on emergency contraception

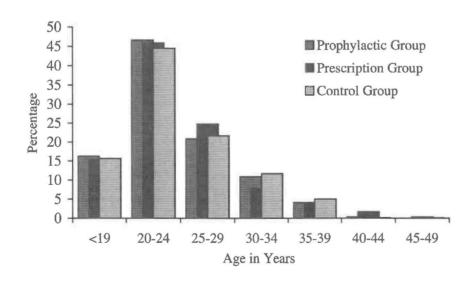
All 300 women comprising the control group were simply informed about emergency contraception at the same time they received their initial supply of oral contraceptives or condoms. They were shown a package of *PC-4* so that it could be identified by name and sight; and they were told how it was taken. Finally, they were told that if they should have unprotected intercourse and feel they were at risk of becoming pregnant, they could return to the current health center at any time for an actual pack of *PC-4*.

# 4. STUDY DESIGN AND DESCRIPTION OF ACTIVITIES

To compare the utility and feasibility of the two new intervention strategies, the study adopted an experimental design using three equivalent groups: two experimental (one for each intervention) and one control. Each group consisted of 150 new acceptors of the pill and 150 new acceptors of the condom as their exclusive family planning method.<sup>5</sup>

All participants comprising the three groups were recruited over a seven week period, between 6 June and 27 July 1998. Prior to their involvement in the study, participants were given a brief description of the aims of the project and of the importance of completing both the admission and follow-up interviews. After verbal and written consent had been obtained, participants were randomly assigned to one of the three groups, in accordance with the order in which they received their new contraceptive method (ie. the first new pill acceptor at each clinic was assigned to Group 1, the second to Group 2, and the third to the Control Group 3, before the process was repeated). Composition of the groups was distributed evenly among the four participating health centers (75 subjects per clinic per Group). Age distribution of the three groups was also comparable (see Figure 3).

Figure 3
Age Distribution of All Study Participants by Group



<sup>&</sup>lt;sup>5</sup> The category of "exclusive condom users" did not include those using the condom in conjunction with another method (dual protection). Any pill user, however, -- even those using the condom for dual protection -- would have been included in the pill group.

### **DATA COLLECTION ACTIVITIES**

Informational Questionnaire: At the time of admission to the study, all 900 women completed a brief informational questionnaire. Respondents were asked to provide general biographical information about themselves, including history of contraceptive use and earlier pregnancies. They were also asked to describe the circumstances surrounding any previous history of regular unprotected intercourse; their sense of reproductive risk at the time; and the reasons behind their current decision to adopt a family planning method. Finally, they were asked to specify their current reproductive intentions: their seriousness about avoiding pregnancy and their intentions of becoming pregnant in the future.

Follow-up Interview: At the time of admission to the study, all 900 participants were assigned a date (approximately three months following the initial interview) when they were expected to return to the health center for a second interview. Generally, the date corresponded to the point at which the pill users would have been expected to return anyway for their resupply of pills. Condom users were also scheduled to return for an interview in three months, though many returned before that date for resupply visits.

The follow-up interview consisted of a series of questions, designed to solicit information on the four variables by which the two intervention strategies were compared: knowledge retention; product wastage; timeliness of access; and use for emergency purposes only. Any woman not having reported to the health center within two weeks of the date assigned to her was visited at home if permission had been given to do so. By the end of the study, all but 8 women had returned for follow-up.<sup>6</sup>

Focus Groups: In addition to data collected through the informational and follow-up questionnaires, focus group discussions were held during the last month of the study. The objective of the discussions was to understand better certain trends and patterns that emerged from the more quantitative survey results. The discussions were also intended to gather more detailed information on such issues as perceived risk of pregnancy among women in the intervention groups, users' confidence with the "self-medication" regimen entailed by the prophylactic intervention; and finally, users' overall perceptions of the general utility of the intervention strategies.

Focus group participants were recruited as women reported for their follow-up interviews. Altogether, seven focus group discussions were held during the week of 23-27 November, 1998, with at least one discussion occurring at each of the four participating health centers. Six discussions were held with pill and condom users distributed across each of the intervention groups. One additional focus group was held with men whose partners had used emergency contraception.

<sup>&</sup>lt;sup>6</sup> In the view of project staff, the high follow-up rate could have been attributable to at least three factors. The first was the decision by clinic staff to assign each study participant a specific follow-up appointment (verbally and in writing) at the time they received their original family planning method. Second, because the majority of participants came from the communities surrounding each health center, the time and effort required to return to their respective centers was relatively minimal. In fact, during the course of the intervening three months, many of the subjects had actually returned to the clinics for other reasons. And finally, for those who did live at a distance from the health centers, the project agreed ahead of time to reimburse all transport costs.

# 5. RESEARCH FINDINGS AND PROGRAMMATIC IMPLICATIONS

As noted previously, the present study compares the relative effectiveness of the three intervention strategies in terms of the following four criteria or "impact indicators":

- communicating appropriate information on emergency contraception,
- reducing wastage of emergency contraception pills,
- · facilitating timely access to emergency contraception pills, and
- limiting use of emergency contraception for emergencies only

This chapter examines the research results collected to date under the study. The chapter is structured by indicator, with each section addressing at least three broad issues. The first defines each criterion operationally and explains the rationale for including it as an indicator of each intervention's relative impact. The second issue concerns the research findings – both qualitative and quantitative — as they relate to each criterion. And the third discusses the broader programmatic implications to be derived from the research results.

## APPROPRIATE INFORMATION

I was told all the instructions. I understood the instructions. When I was in that situation, I took [PC-4] because I was able to recall all that [the sister] had told me (focus group participant, Kanyama Clinic)

Within the reproductive health field, it is generally accepted that for emergency contraception to represent a truly viable contraceptive option, women must know about it before it is actually needed. This assumption reflects the view that unless one is already aware that pregnancy can be avoided, the chances of discovering emergency contraception within 72 hours are minimal. But while there may be general agreement over the need for prior knowledge, there is little agreement over just how detailed that knowledge should be or how realistic it is to expect women to remember it. Indeed, one of the most common arguments against prophylactic administration or even advanced prescription of emergency contraception pills is that women will not remember how to take them correctly.

At the conclusion of the project's first phase, therefore, health care providers agreed that in order to access emergency contraception in a timely and appropriate manner, potential users must at the very least be counseled to identify the following three attributes of the method: the timeframe within which emergency contraception pills must be taken; the generic or brand name of the product ("emergency contraception" or "PC-4"); and the location of at least one source where the pills can be obtained. In the case of those receiving emergency contraception pills prophylactically, providers quite naturally expected users to also know the correct dosage of pills.<sup>7</sup>

One objective of the present study, therefore, was to gauge whether such expectations are, in fact, reasonable and, if so, what their implications might be, both for the content of dissemination materials on emergency contraception and for the implementation of strategies involving prophylactic administration. The study also sought to determine whether the ways in which emergency contraception pills were administered could themselves influence client knowledge or their ability to recall information provided during initial counseling sessions.

**Recognition of the 72 hour timeframe:** During the follow-up interviews, all study participants were asked questions regarding their general knowledge of emergency contraception. They were asked about likely side effects, whether emergency contraception pills could be taken before intercourse or after missing a menstrual period, and whether they could be taken any way other than orally. Participants were also asked how long after unprotected intercourse, emergency contraception pills should be taken.

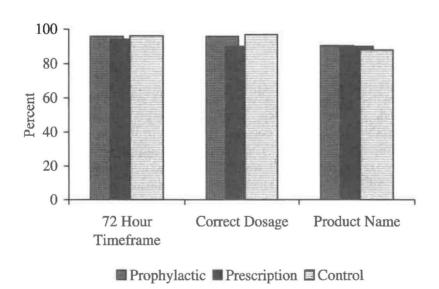
In general, the participants' knowledge and familiarity with emergency contraception was, even after three months, exceptionally high. Over 90 percent of all women, for example, identified correctly the time period (72 hours) within which the first dose of emergency contraception pills had to be taken.

<sup>&</sup>lt;sup>7</sup> It is important to note that these criteria only represented those points on which all health care providers could agree. The list should not be taken as an endorsement by the study as to the minimal informational requirements of emergency contraception users.

Correct dosage: Knowledge of the correct number of pills to be taken was also practically universal across groups. In fact, the few incorrect responses (only six percent of all respondents) were probably attributable to a misunderstanding of the question itself. Sixty percent of the incorrect answers, for example, mentioned "2 pills" which is, in fact, the correct number of pills to be taken as the first dosage during the initial 72 hours. Also contributing to the high rate of recall may have been the brand name of the product itself. The results of a survey carried out simultaneously among 1,600 MCH/FP clients in Lusaka suggest that the brand name "PC-4" is already well-known in Zambia and has even become synonymous with emergency contraception itself.

**Product name:** Perhaps because of such strong brand recognition, the percentage of respondents able to identify either the name *PC-4* or the expression "emergency contraception" was not only high, but virtually identical across intervention groups. In fact, judging from the responses to all three informational indicators discussed thus far, it seems clear that the intervention strategies had little, if any, bearing on the ability of women to recall what providers deemed was critical about emergency contraception.

Figure 4
Percentage of all Participants
with Correct Answers to Key Knowledge Indicators



**Supply Sources:** In keeping with knowledge levels of previous indicators, the ability to identify major sources of emergency contraception pills was also high. Respondents from all three groups were not only familiar with the range of available supply points, but were equally likely to identify one or more of the correct sources: hospitals/community health centers; private physicians; and chemists.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> Though not involved in the present study, anecdotal information suggests that PC-4 is currently available in Zambia through hospitals, private physicians; and chemists.

#### **Programmatic Implications:**

In conclusion, the existing data suggest few appreciable differences among the intervention strategies with respect to the participants' ability to recall appropriate information about emergency contraception. All three groups were equally likely to remember the time frame within which emergency contraception must be initiated; the number of emergency contraception pills needed; the frequency with which they should be taken; the name of the emergency contraception pill; and the location where it can be obtained.

In practical terms, therefore, what these findings suggest is that fears over inadequate client knowledge or poor recall of critical information do not represent a valid basis for doubting the safety or practicality of dispensing emergency contraception pills, either prophylactically or under advanced prescription. The evidence also reveals the importance of *good provider counseling* and the fact that counseling alone is probably far more important in ensuring adequate user knowledge than the particular way in which emergency contraception is packaged and dispensed. This finding is important because it questions the need to develop complicated or detailed instructions on how the method ought to be used. Packages of *PC-4*, for example, contain an attractive 51 page booklet documenting a wide range indications, contraindications, and licensing details. The advanced prescription cards, by contrast included only four basic instructions regarding dosage, timing, and suggestions to deal with nausea and/or vomiting. Ultimately, both groups evidenced equally high knowledge about emergency contraception.

# PRODUCT WASTAGE

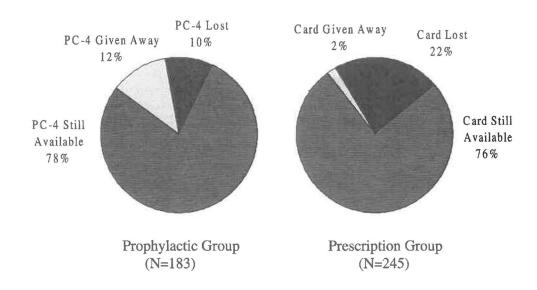
I did not first hear about it from the nurse but from those who had come to the clinic and were given PC-4...

I got worried that I could be pregnant. I told my friend who gave me PC-4 and I took it. (focus group participants, Kanyama Clinic).

In discussing the potential advantages and disadvantages of providing emergency contraception pills prophylactically, one concern expressed by many providers was the implications of distributing methods without any certainty they would be ever be needed or used. In a resource poor environment such as Zambia where contraceptive stockouts are endemic and supplies of all medical commodities limited, the risk of "wastage" represented a powerful critique.

During the present study, therefore, all the women in the two experimental groups (those receiving PC-4 in advance; and those receiving a prescription card) who never used emergency contraception were asked during their follow-up visit whether they still had on hand either the PC-4 packet or the prescription card (see Figure 5). Of all the women comprising the prophylactic group, for example, 134 ended up using their packet of PC-4, leaving 183 (58 percent) who did not. Of these 183 women, however, only 18 (10 percent) reported not being able to remember where their unused packet of PC-4 was. The vast majority (78 percent) either still had the pills at the time of the follow-up interview or claimed to have had them at home. Twenty-two (12 percent) reported having "given them away" to friends or relatives.

Figure 5
Location of unused *PC-4* packets and prescription cards (among non-users of emergency contraception)



In the case of the 300 women who received prescription cards, only 39 or about 13 percent ended up redeeming their cards for an actual packet of *PC-4*, theoretically leaving 255 women with cards still in hand. Of these women, however, 55 (22 percent) reported not knowing the whereabouts of the card. Although this represented a higher percentage of loss than in the prophylactic group, the vast majority of women (75 percent) still had the card with them at the time of the follow-up interview or claimed to have it at home. Only 5 women (2 percent) reported having "given it away".

#### **Programmatic Implications:**

In the resource-poor environments that characterize much of the developing world, health care providers have good reason to be concerned over any new intervention that might threaten the availability of scarce equipment and supplies, including contraceptive commodities. For reasons that are fairly self-evident, prophylactic provision of emergency contraception pills was seen by a number of providers as one such threat.

In the case of product wastage, comparisons between prophylactic distribution and advanced prescription are obviously complicated by the fact that only one strategy actually distributed emergency contraception pills. The other (with the exception of those cards that were redeemed) distributed only prescriptions. How one interprets the outcomes, therefore, depends very much on whether one's focus of inquiry rests with the general programmatic consequences of losses to the service delivery system as a whole, or with the potential for method mis-use that might result from product losses by individuals.<sup>9</sup>

As noted earlier, in the case of prophylactic provision, individual loss was fairly minimal. Only about 10 percent of the women who did not use their emergency contraception pills, for example, had actually lost them. But because almost half the prophylactic recipients of emergency contraception never actually used their emergency contraception pills, loss to the system (of unused packets) was actually quite significant. Indeed, non-use alone would represent an overall loss to the system of over 58 percent. Obviously, the number of unused packets of *PC-4* can be expected to decrease as women have longer to use them. Nonetheless, even studies carried out over a year suggest that losses to the system from non-use can be significant (Glasier et al 1998).

Advance prescription, by contrast, clearly saw higher losses of the prescription cards themselves. But unless those who reported having lost their cards had actually redeemed them for a still unused packet of *PC-4*, losses to the service delivery system itself was minimal. Indeed, even if all of those reporting lost cards had actually redeemed, but never used them, loss to the system would still not have exceeded 22 percent.

As the following chapters reveal in greater detail, prophylactic provision of emergency contraception pills is extremely effective at enhancing access to emergency contraception. But it is also clear from the results of this chapter, that the routine application of such a strategy – at least in the case of a dedicated product such as *PC-4* -- would be both costly and, from a programmatic point of view, relatively inefficient.

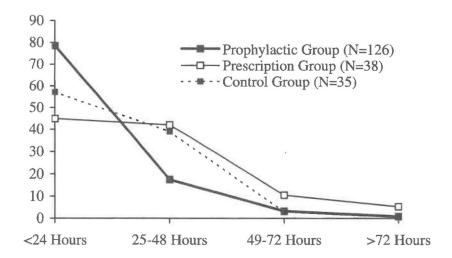
<sup>&</sup>lt;sup>9</sup> The latter might include, for example, misuse of the product by women who redeem lost cards without previous guidance on correct method use; or indeed by anyone who might find and use lost packages of *PC-4*.

# TIMELY ACCESS TO EMERGENCY CONTRACEPTION SERVICES

PC-4 is good and not good at the same time. When you are on the pill, you are very much sure that you will find the pill or get the pill from somewhere; but the only place... [that has] PC-4 is the clinic. What would happen if you are in the village? It is only good as long as you are close to the clinic. (focus group participant, Mtendere Clinic)

A major objective of this study was to test the efficacy of different strategies for increasing women's access to emergency contraception. One critical measure of a strategy's effectiveness, therefore, is the degree to which it reduces the length of time between a single act of unprotected intercourse and the administration of the first dose of emergency contraception pills. For that reason, all users of emergency contraception in this study were asked during the follow-up interview how soon after having unprotected intercourse they began taking *PC-4*.

Figure 6
Time Interval Between Unprotected Intercourse and Administration of Emergency Contraception



Although study participants were only instructed to take their first dosage of emergency contraception pills within the 72 hours of unprotected intercourse, the average time interval between these two events varied dramatically among the intervention strategies. As one might have predicted, those women with emergency contraception pills already on hand (Prophylactic Group) started their first dosage considerably earlier than did either of the other two groups. As indicated above in Figure 6, nearly 80 percent of the Prophylactic Group who took *PC-4*, took their first pills within 24 hours of unprotected intercourse.

The advanced prescription intervention, by contrast, had virtually no effect whatsoever at decreasing the time interval between unprotected intercourse and the initiation of emergency contraception. Indeed, emergency contraception users among the prescription group were even less likely to begin treatment within the first 24 hours than those in the control group. This prompts one to ask then, what possible advantage "advanced prescription" might offer? One possibility is that it offers anonymity - specifically to the extent it obviates the need to "explain oneself" immediately after having had unprotected intercourse. If that were the case, then the impact of this strategy would not be evidenced in greater timeliness of access. but in a higher use of emergency contraception – at least relative to the control group. But as Figure 7 reveals, that did not occur either (emergency contraception users accounted for an identical 13 percent of women in both the advanced prescription and control groups). Two factors may account for this. One was the nature of the client base involved in the study. According to the results of the study's first phase, those most likely to value anonymity were not regular clients of family planning clinics (the client base of this study), but rather young and unmarried women who often feel marginalized or even rejected by the existing service delivery system. Consequently, if the participants involved in this study really were atypical of that group, then one would see little or no difference in the use of emergency contraception.10

Another explanation for the limited impact of the prophylactic intervention, however, may have been the narrow scope and inconsistent application of the intervention itself. Under the study, for example, clients were still required to return to a health center, even if the source of supply was the OPD rather than MCH/FP dispensary. If anonymity were really a critical factor in the success of advanced prescription, then a more effective assessment of its role might have been to broaden the range of facilities where prescription cards could have been redeemed.

#### **Programmatic Implications:**

Had all study participants been instructed to take their first dosage of emergency contraception pills as early as possible, rather than just within 72 hours, it is quite possible that Figure 6 would have seen at least some shift to the left on the part of all three intervention groups. Even so, insofar as all but three emergency contraception users did comply with the instructions given them, ultimately, the three strategies did indeed prove equally effective at ensuring compliance with the recommended regimen.

Such figures notwithstanding, however, the very fact that almost half (44.4 percent) of *PC-4* users within the Prophylactic Group – and only that group – began their pills within 12 hours of unprotected intercourse, leaves little doubt that having emergency contraception pills on hand when they are needed dramatically enhances access to them. Moreover, the importance of such increased accessibility has recently been highlighted by research suggesting that the efficacy of both the Yuzpe and levonorgestrel emergency contraception regimens is "significantly and inversely related to time since unprotected coitus" (Task Force 1998: 432;

<sup>&</sup>lt;sup>10</sup> Even if the sample had been suitably representative, however, a more accurate assessment would have entailed comparing all incidences of unprotected intercourse against those that were actually followed by emergency contraception. The current design assumes levels of unprotected intercourse to be comparable across all three groups.

von Hertzen et al 1998: 1939). Conducted under the auspices of the WHO Task Force on Postovulatory Methods of Fertility Regulation, the study found pregnancy rates increasing from 2 percent among those initiating emergency contraception within 24 hours of unprotected intercourse, to 4.1 percent among women beginning treatment within 25-48 hours; to 4.7 percent among those initiating treatment between 49 and 72 hours.

One clear message to emerge from these findings is that prophylactic administration of emergency contraception pills can have a dramatic appreciable effect on reducing the length of time between unprotected intercourse and the administration of the first dose of emergency contraception pills. Though all but three emergency contraception users were ultimately able to begin treatment within the first 72 hours, the WHO data nevertheless demonstrates that there are indeed clear advantages to starting early. This message should be communicated to all potential users of emergency contraception.

# USE OF EMERGENCY CONTRACEPTION FOR EMERGENCIES ONLY

I would encourage those who manufacture PC-4 because it helped me. I would like to be taking it regularly. There are some who take Microgynon but get pregnant. By the time they [learn they are pregnant]..., the fetus would have started making movements in the womb. I would be happy if we were told to continue taking PC-4 and stop taking Microgynon (focus group participant, Chipata Clinic)

In many respects, the role of emergency contraception within a family planning program represents a paradox for health care providers. Under ordinary circumstances, for example, the increased usage of a contraceptive method would readily be seen as a sign of a success. But in the case of emergency contraception, increased usage is often seen as a sign of program failure. How can this paradox be explained?

For one thing, it is often argued that despite the relative efficacy of emergency contraception, it is a method that has certain drawbacks. It requires prior user-awareness; it has a short window of opportunity; it is less effective than many routine contraceptives and it can have unpleasant side effects. It is, in the eyes of many, a method that ought to remain precisely what its name suggests, "emergency". Further, the argument is often made that if counseling were adequate, and method selection appropriate, then barring unforeseen accidents such as condom breakage or rape, there ought to be little need for emergency contraception in the first place.

The paradox surrounding emergency contraception, therefore, is the fear that the greater one's access to it becomes, the less likely it will be used for emergencies. Indeed, one of the arguments put forward by health care providers during Phase One of this study was that prophylactic distribution of emergency contraception would encourage women to abandon regular family planning under the belief that emergency contraception would always be there "in an emergency". After all, they pointed out, over 12 percent of all inquiries about emergency contraception related in some way to the use of emergency contraception as a convenient alternative to a regular contraceptive method, particularly during the transition period between injections or before beginning a new cycle of pills.

One of the most critical issues addressed during this study, therefore, was to determine whether increased access to emergency contraception did indeed encourage non-use of routine family methods or enhance the likelihood that it would be used for reasons other than rape, method failure, or other unplanned acts of unprotected intercourse.

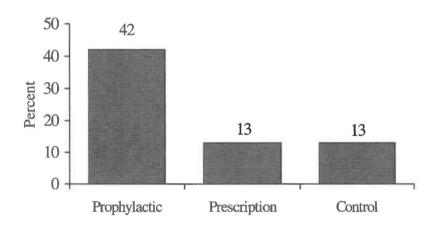
#### **Research findings:**

As shown in Figure 7, a comparison of the three intervention groups reveals that women with prior access to emergency contraception pills were over three and a half times more likely to use them than either those who received prescriptions or those in the control group. But the critical question is whether this higher use resulted from factors attributable to having emergency contraception pills on hand; or to the fact that having emergency contraception

pills enabled women to better deal with circumstances and needs common to all three groups. The answer, it seems, involved both explanations.

As to the factors affecting all groups, one of the most striking was the degree of inconsistency in the use of routine planning methods, specifically the condom and pill. Already within the first three months of receiving their new method, a large percentage of women reported having forgotten to take them, having misplaced them, or simply of having abandoned them because of side effects. Certain events, such as funerals (which typically involve travel, high alcohol consumption, etc.), were frequently mentioned as reasons for having forgotten methods and, subsequently, for high levels of unprotected intercourse. Method failure, particularly condom breakage, was also common.

Figure 7
Percentage of Emergency Contraception Users by Group



Given the similar patterns of poor contraceptive use across all three groups, it is clear that at least some percentage of emergency contraception use had nothing to do with the presence, absence, or even prior knowledge of emergency contraception pills. All women, to some degree, abandoned methods, forgot them or misused them. In such cases, the only advantage to accrue to the prophylactic group would have been their ability to react more quickly to the consequences of unprotected intercourse. For these women, then, greater use of emergency contraception pills could be explained in part, by their greater access to them.

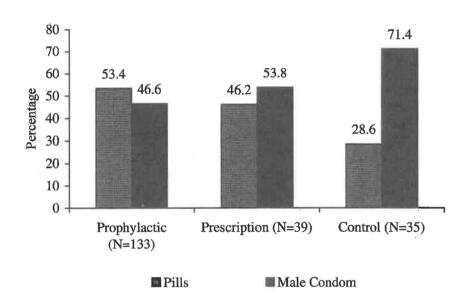
But it is also clear that in addition to enhancing accessibility, prophylactic provision of emergency contraception pills can change the environment within which contraceptive decisions are made. In some cases, it creates pressures that would not otherwise exist; and in others it makes it easier to respond to those pressures by abandoning routine methods in favor of emergency contraception pills. One such change was the apparent leverage prophylactic provision provided men in negotiating condom use with their partners. In focus group discussions and even during follow-up interviews, women often claimed that their partners had refused to use a condom after learning that they had had emergency contraception pills on hand. But the focus groups also revealed the extent to which women themselves valued emergency contraception. In some cases, they said it offered welcomed respite from what

were often long-standing sources of domestic argument; but in others they said that it also provided them with an opportunity to enjoy "skin-to-skin" contact.

Sometimes men become difficult to negotiate [with]. You may have been using condoms, but when he comes he just wants to have sex. If you try to take a condom he will refuse. If you try to take tablets, he will refuse it as well. You have no alternative but to have sex quickly and use PC-4 (focus group participant, Kanyama Clinic).

While focus group discussions identified linkages between prophylactic provision and nonuse of condoms, perhaps even more significant was the seeming ability of prophylactic provision to draw attention to the perceived inconveniences of other hormonal methods – particularly the pill. Indeed, results from the follow-up questionnaire revealed that among the prophylactic group, it was actually pill users who were more likely to use their packet of PC-4 (see Figure 8)<sup>11</sup>. Only among the control group did condom acceptors represent the majority of emergency contraception users. What, then, were these supposed "disadvantages" of alternative hormonal methods?

Figure 8
Choice of Family Planning Method
by Those Who Eventually Used Emergency Contraception



For one thing, prophylactic provision provided women with greater opportunities to act on perceptions and beliefs, regardless of whether those perceptions had any basis in fact. During the first phase of the study, for example, many women were attracted to emergency

<sup>&</sup>lt;sup>11</sup> Figure 8 groups emergency contraception users by the "routine" family planning method (condom or pills) they were given at the beginning of the study. During the interval between their admission to the study and the point when they took PC-4, many subjects had actually switched their routine method. To assess the impact of this switching on emergency contraception use, participants were also asked to indicate the method they were actually using when they took emergency contraception. The results, though similar to those represented in Figure 8, showed an even higher proportion of pill to condom users (59:34) in the prophylactic group. The reason for this was that many original condom users had already switched to another method by the time they had taken PC-4.

contraception's post-coital nature and simplicity of use. In fact, it was this appeal that led many providers to fear that prophylactic provision might only encourage women to abandon their regular methods in favor of emergency contraception. But the current phase of the study revealed still other factors that made emergency contraception "more appealing" than the pill.

One such factor was the widespread perception that emergency contraception was actually *more* effective than the pill. Though incorrect, the logic behind this argument was at least intuitively sound: "if pregnancy can be prevented by four "emergency" pills instead of 28 regular ones, then clearly the former must be more powerful than the latter. Ironically, even the unpleasant side effects of *PC-4* were seen to be proof of its relative strength and efficacy. Unfortunately, such views were often reinforced – albeit unwittingly -- by health care providers. One woman, for example, reported asking the nurse how effective *PC-4* was:

... because I thought that someone may get pregnant even if it was used within a short period of time. She explained that no one who got it from here came up with a complaint that they had got pregnant. I am sure that was why she said it was effective (focus group participant, Mtendere Clinic).

A similar argument was put forth by women who compared their own experience or that of their friends who had become pregnant while taking the pill, with claims by providers that "[so far] that has never happened with someone who was taking *PC-4*." Some women (and men) even attributed the greater efficacy of emergency contraception to its name:

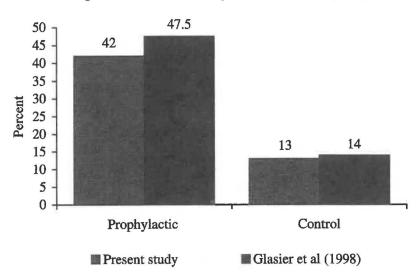
What convinced me that it was very powerful was the word "emergency" and the explanation that ... it could be used in cases of rape. If a rape victim reports within 24 hours, there will be no pregnancy. I said to myself that if that is the case, then it must be very powerful (focus group participant, Mtendere Clinic).

One additional consequence of providing emergency contraception pills prophylactically was the tendency it had to instill curiosity among those who received it. Though providers were instructed to avoid sounding as though they might be *encouraging* use of the pills, the fact is that many women admitted to using them precisely because they were "already there". Obviously, this initial curiosity, once satisfied, would not be likely to sustain itself indefinitely. Nevertheless, the results of focus group discussions do suggest that prophylactic administration played a notable role in encouraging at least first-time use of emergency contraception pills.

In short, whether it was because of new pressures on women or because of greater access to the method itself, prophylactic provision of emergency contraception pills did, to some extent, encourage non-use of routine family planning methods for reasons other than method failure, rape or accident. Furthermore, the data also show that once a woman's packet of emergency contraception pills has been used up, she is no more likely to use it again than women who do not have a prophylactic supply. This finding was critical because it addressed some early suspicions that the greater use of emergency contraception by the prophylactic group might have been attributable to some factor that placed them at a higher risk of unprotected intercourse and, therefore, in *greater need* of emergency contraception. If that were the case, then one would still expect to find a comparatively higher use of emergency contraception even after their initial packet of *PC-4* had been used up. But the research shows no such pattern. Clearly, having emergency contraception pills on hand made an important difference.

It is also worth pointing out that the current findings are supported in the literature; most recently by a study of emergency contraception use by Glasier et al (1998). According to Glasier's research, women with emergency contraception pills on hand are not only more likely to use them than those who do not, but will continue to do so irrespective of the number of times they have used them before. As in the present study, utilization of emergency contraception pills was compared between two groups: one consisting of women who received emergency contraception pills prophylactically, the other of women who received only information. As the present study showed, women in the prophylactic group were over three times more likely to use emergency contraception than women in the control group (47.5 percent vs. 14 percent). Such utilization rates were especially noteworthy since, in contrast to the present study, over 60 percent of the subjects in Glasier's study had already used emergency contraception once before. A comparison of utilization rates between the two studies is shown below in Figure 9.

Figure 9
Percentage of Emergency Contraception Users by Group:
Comparison of Present Study and Glasier et al (1998)



Glasier's data also showed, as did this study, that when members of the prophylactic group no longer had emergency contraception pills on hand, they were no more likely to use them than women from the control group. But of the 74 women in her prophylactic group who actually returned to the clinic for another packet (and, therefore, were the only group of "potentially repeat users" to still have pills on hand), 27 of them, or 36.5 percent, used emergency contraception again. And with the percentage of repeat emergency contraception users in the control group dropping to 10 percent, the relationship between the two groups remained fairly constant: women with pills on hand continued to be over three times more likely to use emergency contraception than those without.<sup>12</sup>

<sup>&</sup>lt;sup>12</sup> It is necessary to acknowledge that Glasier, herself, has interpreted the results of her study to suggest that prophylactic administration is associated only with higher *initial* use of emergency contraception, but not higher *subsequent* use. This interpretation, however, results from not having excluded two groups from her analysis of repeat use: 1) those in the prophylactic group who never used emergency contraception even once (and

#### **Programmatic Implications:**

Given the fact that increased use of emergency contraception for "non-emergencies" was associated only with prophylactic provision, it is important to ask what these findings suggest about the utility or even appropriateness of providing emergency contraception pills prophylactically? Does the fact that prophylactic provision results in some non-use of routine methods argue against self-administration? Or do the benefits of having emergency contraception pills on hand clearly outweigh the potential risks? And if those risks do exist, then how can they best be addressed?

In the authors' opinion, prophylactic provision of emergency contraception pills can indeed represent a useful approach for assisting women to address the consequences of unprotected intercourse. Two factors argue for this conclusion. The first is the finding that prophylactic administration reduces dramatically the length of time between an act of unprotected intercourse and the administration of the first dose of emergency contraception pills. Not only is this a clear sign that prophylactic provision is enhancing access to the product, but this enhanced accessibility may also very well have direct implications for the efficacy of emergency contraception itself.

The second factor supporting prophylactic provision is the endorsement of study participants, themselves, all of whom were virtually unanimous in wanting greater access to emergency contraception. Although support was highest among those who had actually used emergency contraception pills (93 percent), even non-users overwhelmingly recommended (80 percent) that prophylactic provision be offered to all first-time users of a family planning method.

As for the risk of prophylactic provision encouraging non-use of routine family planning methods, the issue is a complex one. In the first place, the study results showed that the comparatively higher use of emergency contraception by the Prophylactic Group was attributable to their better access to it and, to some extent, their over-use of it. But it also reflected, to some extent, the comparative under-use of emergency contraception on the part of those who lacked ready access to the appropriate pills. If indeed the ultimate objective of service provision is to address the reproductive health needs of women, then solution to this discrepancy should not be to reduce all family planning users to the level of those with limited access. Rather, it should be to expand access for those whose need for emergency contraception is perceived to be greatest, while at the same time minimizing those factors that typically lead to its unnecessary use: unrealistic or inaccurate perceptions about its efficacy; the belief that it represents a practical alternative to negotiating condom use; or even the notion that all acts of unprotected intercourse present the same risk of pregnancy and therefore must be followed by emergency contraception<sup>13</sup>. What this study advocates, therefore, is greater awareness on the part of providers as to the dynamics of emergency

therefore, could never be classified as repeat users); and 2) those emergency contraception users in the prophylactic group who never came back for a resupply of pills (and therefore, no longer even had pills on hand to self-administer).

<sup>&</sup>lt;sup>13</sup> The present study did not record when, during the subject's menstrual cycle, emergency contraception was taken. It is quite possible that the greater utilization of emergency contraception by the prophylactic group reflected the comparative ease with which the pills could be taken, even though the actual risk of pregnancy was minimal. By contrast, those who did not already have pills may have been more selective in their use of emergency contraception and restricted its use to those acts where the risk of pregnancy was felt to be highest.

contraception use. Training and other informational materials must be candid about the many "unintended consequences" of emergency contraception because it is, as we have seen, a method that can be used in variety of ways – even as a routine family planning method. With a greater understanding of such use-dynamics, providers will be better able to anticipate how the method is likely to be used, which in turn should assist them in providing information that better addresses clients' own reproductive health needs and circumstances.

# 5. FROM RESEARCH TO ACTION: THE NEXT STEPS

The results of this study have documented both the strengths and weaknesses of two strategies for enhancing access to emergency contraception. They have illustrated the ability of prophylactic provision to reduce the time between unprotected intercourse and the administration of emergency contraception pills; and they reveal the benefits of advanced prescription, particularly its reduction in wastage. But as positive as the study results have been in general, they also highlight certain *realities* associated with the adoption of these two strategies. They reveal how prophylactic provision may increase non-use of routine family planning methods; and they point to the need for expanding provider awareness of the dynamics of emergency contraception use.

The challenge that lies ahead, therefore, is to explore ways of incorporating these findings into the design and implementation of actual service delivery programs. It is one thing to recommend greater provider awareness of the use-dynamics of emergency contraception, but quite another to suggest how best this might this be achieved -- particularly since provider counseling of even routine methods often remains so poor. In many respects, this study and the research leading to it has shown precisely how complex emergency contraception can be. It can take various forms: either dedicated products or various combinations of existing oral contraceptives. Because it is post-coital, it can be administered in advance like most other methods, or it can be provided afterwards. And unlike most other contraceptives (with the exception of the condom), emergency contraception is usually expected to supplement rather than replace more routine family planning methods. All of these issues confront service providers as they seek to introduce emergency contraception into their routine service delivery programs. There is no question that providers must be better equipped to anticipate how the method is likely to be used. The real issue, however, is how can this best be achieved?

One approach inspired by the work of an ongoing WHO Task Force on Technologies for Fertility Regulation is to use the introduction of a new method as a means for improving the quality of reproductive health services overall (Simmons et al 1997: 88). In many respects, emergency contraception represents an ideal candidate for such an exercise precisely because it is designed to *supplement* rather than replace existing contraceptive technologies. What this means is that many of the service delivery attributes deemed essential for the provision of emergency contraception would also be directly applicable to the delivery of technologies it would be expected to supplement. This is especially critical in the case of emergency contraception because any additional investment in training or improved services would not just benefit the quality that method, but of all methods in general.

A second important issue to emerge from the present study is the applicability of prophylactic provision itself. Research results have clearly shown that providing pills before they are needed is both effective and safe. But it would be, without a doubt, both costly and impractical to implement such a strategy for all first-time family planning users. Even if product wastage were less than the minimal levels already suggested, the fact of the matter is that most women who receive emergency contraception prophylactically will never actually

use it. This poses the question, then, as to when, under what circumstances, and for whom prophylactic administration would be most appropriate. It also raises concerns over the form prophylactic provision might take. Should it be restricted to dedicated products where the risk of incorrect usage is presumably less? Or should health care planners explore the possibility of cutting up existing cycles of oral contraceptives? And if the latter is chosen, then who would do the "cutting"? Providers or the users at home?

The last issue to be addressed is the need to explore further the role of advanced prescription in enhancing access to emergency contraception services. This is important because in many respects, advanced prescription has the potential of offering many of the same advantages as prophylactic prescription, but at a considerably lower cost to the system. It can reduce the timeframe between unprotected intercourse and the first dosage of emergency contraception pills by eliminating the need for counseling precisely when *time* is at a premium. It offers privacy insofar as it avoids the potential embarrassment of having to "explain oneself" before a health care provider. It eliminates the threat (however minimal) of wastage since the method itself is only distributed when needed. And because the cost is marginal, advanced prescription could be routinely implemented for all first time family planning users — at least those within easy reach of a chemist, dispensary or other outlet of contraceptive products.

In short, the time has come to move beyond asking whether alternative distribution strategies make sense; and instead focus on discovering how the lessons of this study can finally be brought to scale. This will entail some future research and perhaps, on occasion some ongoing debate. But most important, it will require a commitment on the part of Zambia's health care providers and planners to acknowledge the potential role of emergency contraception and broaden its availability so that it is finally within the reach of all women.

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