

Original research article

Comprehension of a prototype emergency contraception package label by female adolescents^{☆,☆☆}

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Abstract

Background: We evaluated female adolescents' comprehension of a prototype over-the-counter package label for an emergency contraceptive pill product.

Study Design: Volunteers aged 12–17 years who could read English were recruited at malls and clinics in six United States metropolitan areas. After completing a literacy assessment, subjects examined the prototype package and answered 20 questions that assessed understanding of six key concepts related to appropriate use of the product.

Results: The analysis population included 335 subjects, 54 to 59 of each year of age between 12 and 17 years. When asked what the product is used for, 264 respondents (79%) specifically indicated contraception. The six key concepts were each understood by 83–96% of subjects. In all 24 population subgroups examined, each key concept was understood by at least 72% of subjects.

Conclusion: Female adolescents aged 17 years and younger understand the prototype package label well enough to enable safe and effective use without assistance from a clinician.

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1. Introduction

In August 2006, the United States Food and Drug Administration (FDA) granted approval for a brand of emergency contraceptive pills (Plan B[®], Barr Pharmaceuticals, Pomona, NY, USA) to be marketed over-the-counter to people aged 18 years and older. However, the FDA's ruling maintained prescription status for younger people. The FDA's stated primary rationale for this dual status was that insufficient evidence was available to establish that the product could be used safely and effectively by young girls

without the professional supervision of a licensed practitioner (A. Eschenbach, 23 August 2006, <http://www.fda.gov/cder/drug/infopage/planB/avememo.pdf>, accessed 28 March 2008). In making its decision, the FDA relied in part on data from a study that had been conducted in 2001 to assess women's comprehension of a proposed over-the-counter product package label [1]. Although that study did not find substantial evidence of differences in understanding by age, it included only 76 subjects aged 16 years and younger.

To address this deficiency, we recently conducted a second label comprehension study in female adolescents aged 12–17 years. The prototype label that we tested was similar in format and content to that of the currently marketed Plan B[®] product. The primary goal of our study was to determine how well female adolescents understand six key concepts felt to be important for safe and effective use of the emergency contraceptive product based on

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reading the label. We finalized the key concepts and other aspects of the study design after consultation with the FDA.

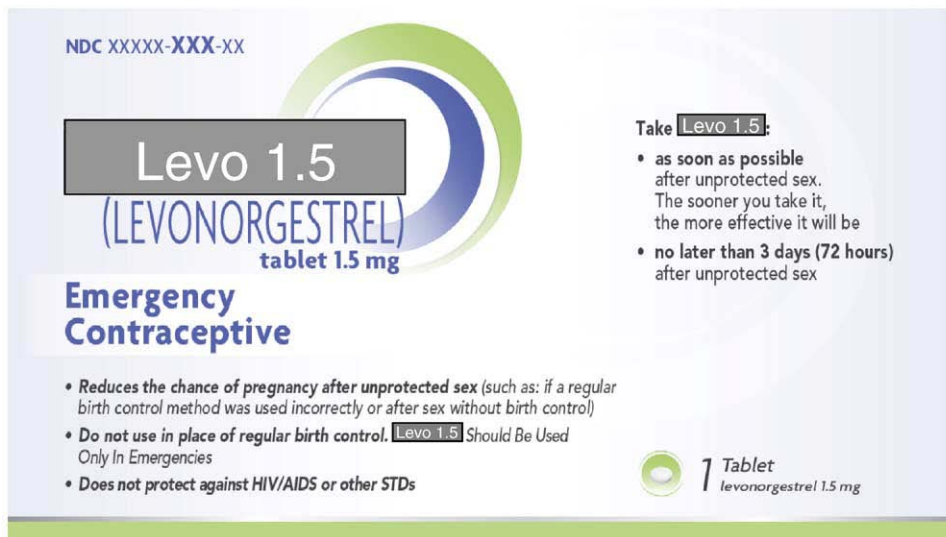
2. Methods

Between 22 October 2007 and 2 February 2008, we recruited a convenience sample of volunteers from shopping malls and family planning clinics in eight metropolitan areas in the United States. To be eligible, subjects had to be female, aged 12–17 years, able to read and understand English, comfortable being interviewed in English, and without a history of participation in any prior study about any medication package. We obtained oral consent from each subject as well as consent of a parent or guardian if the volunteer was 14 years old or younger and was interviewed in the mall setting. To ensure that parents could not

influence subjects’ responses during the interview, we prevented parents and subjects from communicating with each other during the consent and interview process. At the request of the FDA, we aimed to recruit at least 300 subjects across all study sites, including at least 50 of each age between 12 and 17 years. In addition, we set quotas to ensure enrollment of at least 75 self-identified black subjects, 60 Latinas, 60 subjects with a seventh grade literacy level or lower, and 225 subjects who had not previously used emergency contraceptive pills.

Trained female data collectors conducted interviews in private rooms in the malls and clinics. After confirming study eligibility, the interviewer assessed each subject’s literacy level using the Rapid Estimate of Adolescent Literacy in Medicine [2]. This test measures the number of words the subject pronounces correctly from a list of 66 words. Each word was considered to be correct if it matched the pronunciation in a standard dictionary; words

A Front



B Back

<p>Drug Facts</p> <p>Active ingredient Levonorgestrel 1.5 mg.....</p> <p>Purpose Emergency contraceptive</p> <p>Use reduces the chance of pregnancy after unprotected sex (such as: if a regular birth control method was used incorrectly or after sex without birth control)</p> <p>Warnings Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel</p> <p>Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs. If your partner uses a latex condom correctly each and every time you have sex with him, this will help reduce, but not eliminate, the chance that you will catch an STD.</p> <p>Do not use ■ if you are already pregnant (because it will not work) ■ for regular birth control</p> <p>When using this product you may have ■ nausea ■ vomiting ■ stomach pain ■ tiredness ■ diarrhea ■ dizziness ■ menstrual changes ■ breast pain ■ headache</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away. ▶</p>		<p>Drug Facts (continued)</p> <p>Directions Take the tablet: ■ as soon as possible after unprotected sex. The sooner you take it, the more effective it will be ■ no later than 3 days (72 hours) after unprotected sex</p> <p>Other information ■ before using this product read the enclosed consumer information leaflet for complete directions and information ■ this product is not recommended for regular birth control. It does not work as well as most other birth control methods when they are used correctly. ■ this product works mainly by stopping ovulation (egg release). It may also stop fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation). See consumer information leaflet. ■ do not use if carton is opened or if blister unit is broken ■ store at 20-25°C (68-77°F)</p> <p>Inactive ingredients colloidal silicon dioxide, corn starch, gelatin, lactose monohydrate, magnesium stearate, potato starch, talc</p> <p>Questions or comments? For more information or to speak to a healthcare professional, call 1-800-XXX-XXXX, 24 hours a day/7 days a week. Visit our Web site at www.XXXXXXXXXX.com</p>
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Fig. 1. Front and back of prototype label.

pronounced with an accent were counted as correct as long as the subject made no additions or deletions. The interviewer then gave the subject an empty prototype drug package for a hypothetical product with information printed on the outside front and back panels (Fig. 1). Throughout this paper, we have replaced the proprietary name of the hypothetical product used in the study with “Levo 1.5.” The interviewer instructed the subject to read the information on the package as if she were “thinking about whether to buy the product.” The interviewer then read aloud a series of 20 questions about the label and recorded the subject’s answers on paper data forms. Each subject was provided a set of laminated cards on which the questions were printed so she could read silently along with the interviewer. The first question asked what the product was used for. Interviewers recorded verbatim open-ended responses, which were later coded by two independent coders. Each of the other 19 questions was specifically designed to address one of the six key concepts (two to four questions per key concept). If the subject indicated that she could not choose one of the prespecified responses, the interviewer recorded “don’t know.” The subject was permitted to refer to the package label while answering all 20 questions. The interviewer then collected data on demographic characteristics. Finally, the subject completed a self-administered paper survey that included questions about sexual and contraceptive experience and education. Each subject who stayed through the entire process received \$20 in compensation.

Five weeks after data collection started, we discovered research misconduct in two of the eight data collection offices. Specifically, interview data were recorded by unauthorized individuals and mislabeled as having been recorded by authorized study staff. The individuals involved acknowledged that four data forms from each of the two sites were affected, but because we could not conclusively eliminate the possibility that additional forms were also affected, we decided at that time to exclude all data from these two sites from this planned report. We suspended recruitment at the two errant sites and increased targets at the other six sites to ensure that 300 subjects would be enrolled and all previously set demographic quotas would be met.

The analysis was conducted according to an analysis plan prepared prior to data collection. The analysis population included all subjects who met eligibility criteria at the six valid sites. Our primary focus was to estimate the proportion of respondents who understood each of the six key concepts. We considered a subject to have demonstrated understanding if she gave correct answers to at least a prespecified number of the questions related to each key concept. We counted missing answers as incorrect. We performed all reported analyses as planned, except for the following: we changed the planned racial subgroups to correspond to the preset quota categories of black/not black instead of white/not white; we added additional subgroups felt to be of interest; and we compared differences in

proportions using Fisher’s exact tests rather than asymptotic methods and calculated 95% confidence limits for proportions and relative risks using asymptotic methods rather than exact methods. We considered p values of $<.05$ to be statistically significant, with no adjustments made for multiple comparisons.

Before initiation of this study, we conducted a pretest of the label, the study procedures and the questionnaire at the same malls as the current study. We collected 136 data forms in the pretest. We identified no research misconduct in the pretest either at the time or subsequently on rereview of the data. Between the pretest and this study, we made only minor changes to the label, procedures and questionnaire except for the planned addition of clinics as recruitment sites.

The ethics review board of Family Health International approved this study.

3. Results

At the six sites included in the analysis, we screened 377 subjects, of whom 335 met all admission criteria. The most common reasons for ineligibility were previous participation in a survey about a medication package, inability to obtain parental consent and inability to read English. The analysis sample included 54 to 59 subjects of each age between 12 and 17 years. All prespecified demographic quotas were met (Table 1). The median score on the literacy assessment was 60/66, which corresponded to an eighth–ninth grade reading level [2]. Most subjects had had some sex education, and about a third had previously had sex.

In responding to the initial general question about the indication for use of the product, most subjects (264/335; 79%) cited contraception; of these respondents, 160 noted that the product is intended for use after sex (Table 2). Most of the responses that did not specifically indicate contraception were nevertheless not explicitly incorrect (e.g., “after unprotected sex” or “only for emergencies”). Of the 19

Table 1
Characteristics of eligible subjects

	Age (years)				Total (N=335)	
	12–14 (n=164)		15–17 (n=171)		n	%
	n	%	n	%		
Hispanic ethnicity	36	22	34	20	70	21
Black race	36	22	52	30	88	27
Education 8th grade or less	158	96	24	14	182	54
Literacy assessment of 7th grade or less (score \leq 58/66)	93	57	47	27	140	42
Ever received education about how women get pregnant	117	71	158	92	275	82
Ever had sex	17	10	102	60	119	36
Ever experienced condom break	4	2	32	19	36	11
Had sex in past 3 months	10	6	83	49	93	28
Ever used emergency contraceptives	2	1	22	13	24	7
Recruited in a family planning clinic	7	4	38	22	45	13

Table 2
Responses to questions about label, by relation to key concept

Question	Subjects who gave indicated answer*(N=335)	
	n	%
General question: What is Levo 1.5 used for?		
contraception after sex	160	48
contraception	104	31
after sex, purpose unspecified	48	14
emergency or as soon as possible (sex not mentioned)	10	3
other, including no response	13	4
Key concept 1. Levo 1.5 is indicated for prevention of pregnancy after unprotected sex.		
Q 1.1 Theresa and her boyfriend used a condom during sex, but the condom broke. The next morning, Theresa used Levo 1.5 to prevent pregnancy. Was this a correct use of Levo 1.5? (YES)	309	92
Q 1.2 Denise was going to a party. She expected to meet up with a guy who she might want to have sex with. She took Levo 1.5 before the party to prevent pregnancy. Was this a correct use of Levo 1.5? (NO)	261	78
Q 1.3 Jasmine had unprotected sex 2 days ago. Today, she used Levo 1.5 to prevent pregnancy. Was this a correct use of Levo 1.5? (YES)	288	86
Q 1.4 Kendra and her boyfriend were watching TV. They got carried away and ended up having sex with no birth control. The next day, Kendra took Levo 1.5 to prevent pregnancy. Was this a correct use of Levo 1.5? (YES)	303	90
Key concept 2. Levo 1.5 should be taken as soon as possible after sex.		
Q 2.1 Ellie had unprotected sex on Thursday afternoon. That night, she thought about taking Levo 1.5. She could have gotten it right then, but she decided to wait until Saturday to buy it. When was the best time to take it?		
THURSDAY NIGHT	264	79
Saturday	13	4
doesn't matter	43	13
don't know or no response	15	4
Q 2.2 After unprotected sex, when is the best time to take Levo 1.5?		
AS SOON AS POSSIBLE AND WITHIN 72 HOURS	10	3
within 72 hours	19	6
AS SOON AS POSSIBLE	263	79
72 hours	16	5
other or no response	27	8
Q 2.3 Will Levo 1.5 be more effective if a woman takes it 1 day after unprotected sex or if she takes it 2 days after unprotected sex, or doesn't it matter?		
1 DAY	269	80
2 days	9	3
doesn't matter	49	15
no response given	8	2
Q 2.4 Which is the best time for a woman to take Levo 1.5 after unprotected sex: (a) right away; (b) 72 hours later; (c) it doesn't matter when the product is taken?		
RIGHT AWAY	292	87
72 hours later	21	6
doesn't matter	13	4
Key concept 3. Levo 1.5 does not prevent sexually transmitted diseases or HIV/AIDS.		
Q 3.1 Does Levo 1.5 protect against HIV or AIDS or other sexually transmitted diseases? (NO)	323	96
Q 3.2 Kate used Levo 1.5 because she wanted to be sure she didn't get any sexually transmitted diseases. Was this a correct use of Levo 1.5? (NO)	313	93
Key concept 4. Levo 1.5 should not be used in place of regular contraception		
Q 4.1 Should Levo 1.5 be used as a regular birth control method? (NO)	296	88
Q 4.2 Maria used Levo 1.5 every day instead of her regular birth control pills. Was this a correct use of Levo 1.5? (NO)	309	92
Q 4.3 Crystal was taking birth control pills as her regular method to prevent pregnancy. She heard about Levo 1.5 at school. She then decided to stop taking her birth control pills and to use Levo 1.5 as her only birth control method. Was this a correct use of Levo 1.5? (NO)	299	89
Key concept 5. Levo 1.5 should be taken within 72 hours after sex.		
Q 5.1 Tanya had unprotected sex a week ago. Today she used Levo 1.5 to prevent pregnancy. Was this a correct use of Levo 1.5? (NO)	311	93

Table 2 (continued)

Question	Subjects who gave indicated answer*(N=335)	
	n	%
Q 5.2 Karen had unprotected sex on Sunday. For the rest of the week, she worried about getting pregnant. On Friday, she took Levo 1.5 to prevent pregnancy. Was this a correct use of Levo 1.5? (NO)	312	93
Q 5.3 How many days is the longest after sex a woman should wait before taking Levo 1.5?		
FULLY CORRECT RESPONSE	314	94
insufficient response	7	2
incorrect or no response	14	4
don't know or no response	9	3
Key concept 6. Levo 1.5 should not be used by women who are already pregnant.		
Q 6.1 Should a pregnant woman use Levo 1.5? (NO)	319	95
Q 6.2 Vivian used Levo 1.5 when she was 2 months pregnant. as this a correct use of Levo 1.5? (NO)	319	95
Q 6.3 Lila did a home pregnancy test. It showed that she was now pregnant. She then used Levo 1.5 because she didn't want to be pregnant. as this a correct use of Levo 1.5? (NO)	309	92

* Answers in capital letters were considered correct.

subsequent questions related to the key concepts, 11 were answered correctly by at least 90% of subjects, four were answered correctly by 85–89%, two were answered correctly by 80–85% and two were answered correctly by less than 80%. The most difficult question for the subjects — Q1.2, which described a scenario about use of the product in anticipation of having sex — was answered correctly by 78% of respondents. Almost one-quarter of 12- to 14-year-olds (40/164; 24%) and 13% (22/171) of 15- to 17-year-olds gave nonmissing incorrect answers to this question.

The six key concepts were each understood by 83–96% of all subjects (Table 3). The proportions who understood each concept were compared in subgroups defined by the following 12 characteristics: geographic region (west/east of the Mississippi River), interview site (mall or clinic), age, race (black/not black), ethnicity (Hispanic/not Hispanic), literacy level (score corresponding to \leq / $>$ seventh grade), mother's and father's educational level (\leq / $>$ high school), whether or not parental consent was obtained, previous sexual experience, prior pregnancy and prior use of emergency contraceptive pills. Among these 72 comparisons, 16 statistically significant differences were found (data not shown). Lower literacy was significantly

associated with lower likelihood of understanding of each of the six key concepts. The biggest difference between higher and lower literacy subjects was in understanding of key concept 2 (Levo 1.5 should be taken as soon as possible after sex); the relative proportion of subjects who understood was 0.84 (95% confidence limits 0.75, 0.93). Younger subjects were significantly less likely than older subjects to understand four of the key concepts, although the difference in understanding between 12- to 14-year-olds and 15- to 17-year-olds was no more than 10 percentage points for any one concept. On an absolute scale, no subgroup examined had less than a 72% chance of understanding any concept, and more than 82% of every subgroup understood every concept except concept 2.

4. Discussion

This study found that more than 82% of respondents interviewed understood each of six key concepts that the prototype package label was designed to convey. Four of the concepts were each understood by more than 92% of subjects. Although younger and less literate subjects were

Table 3
Proportion of subjects who understood key concepts, by age

Key concept	Age (years)				Total		p value*
	12–14 (n=164)		15–17 (n=171)		n	%	
	n	%	n	%			
Levo 1.5 is indicated for prevention of pregnancy after unprotected sex	139	85	161	94	300	90	.01
Levo 1.5 should be taken as soon as possible after sex	130	79	147	86	277	83	.11
Levo 1.5 does not prevent sexually transmitted diseases or HIV/AIDS	145	88	165	96	310	93	.01
Levo 1.5 should not be used in place of regular contraception	148	90	161	94	309	92	.22
Levo 1.5 should be taken within 72 h after sex	151	92	168	98	319	95	.01
Levo 1.5 should not be used by women who are already pregnant	153	93	167	98	320	96	.07
Either concept 2 or concept 5	154	94	168	98	322	96	.05

* p value for differences between age groups calculated using Fisher's exact test.

significantly less likely than other respondents to show understanding of some or all concepts, no subgroup examined had alarmingly poor understanding of any concept. In particular, a high majority (79% or more) of younger subjects correctly understood each of the six key concepts.

Key concept 2 (Levo 1.5 should be taken as soon as possible after sex) was the least well understood of the six concepts. Three of the four questions designed to test this concept each elicited correct responses from less than 82% of subjects. In contrast, 95% of subjects understood key concept 5 (Levo 1.5 should be taken within 72 h after sex). The instruction to use the product as soon as possible was prominently printed on both the front and the back of the package along with a seemingly clear and compelling rationale (“the sooner you take it, the more effective it will be”). Nevertheless, the difference in understanding of the two concepts may reflect the tendency of adolescents to demonstrate concrete rather than abstract cognitive patterns [3]. Certainly the phrase “as soon as possible” is not specific, whereas the 3-day deadline provides a specific defined benchmark.

Changes to the label design, such as increasing the font size or enhancing the color of the instruction to use the product as soon as possible, might improve understanding of key concept 2. Alternatively, combining the two timing instructions into a single statement (e.g., Levo 1.5 should be taken as soon as possible after unprotected sex but not more than 72 h later) may be helpful for more literal-minded adolescents. However, in practice, failure of users to recognize the “as soon as possible” instruction on the package itself may not be especially harmful. Once a person has had unprotected sex and has the product in hand so that she can read the label, the likelihood that she would postpone use may be low even if she overlooks the specific instruction. Ultimately, perhaps the most important finding is that the proportion of study subjects who understood either key concept 2 (take as soon as possible) or key concept 5 (take within 72 h) was 96%.

The single question that most often elicited incorrect answers posed a scenario in which a person used the product in anticipation of having unprotected sex. In the full population, 19% of subjects indicated that such use would be correct. Subjects aged 12–14 years were nearly twice as likely as older subjects to give this response. The explanation for this misunderstanding is not clear. The scenario included no indication that use of condoms or another contraceptive would not be possible during sexual activity, but some respondents may have made that assumption. The product label repeatedly directed users to take the tablet after sex, but it did not specifically advise against using it before sex. This absence of guidance may have been interpreted as implying that precoital use is acceptable, especially by younger adolescents who have less well-developed abstract reasoning skills. Further insight into people’s understanding of this product and the actual

circumstances in which they might feel a need to use it would be useful before deciding whether an addition or revision to the label on this point would be beneficial.

Research misconduct discovered at two sites illustrates the difficulty of conducting this type of study rigorously. To avert falsification of data and to identify it if it occurs, a validation practice commonly used in mall-based surveys is to collect information from each subject so that the researchers can later recontact subjects to verify their participation. However, we felt that in our study, this approach risked violating subjects’ confidentiality. Nevertheless, through meticulous electronic data monitoring and reviews of handwritten responses on paper data forms, we were able to identify the misconduct promptly and take corrective action.

This study had other limitations. Although recruitment quotas ensured diversity in age, ethnicity and literacy, the subjects who agreed to join the study were likely not a representative sample of young people who may ultimately use the product. Indeed, two thirds of the study population had never had sex, and this product was thus unlikely to have been relevant to them at the time of the interview. The results presented here are not applicable to the approximately 5% of the US adolescent population who do not speak English well [4].

One previous study of comprehension of a label for an emergency contraceptive product has been published [1]. That study included 656 subjects aged 12–50 years (of whom 580 were aged 17 years and older) interviewed at eight malls in the United States. The study procedures were similar to those of the current study: subjects reviewed the package label and then answered questions designed to test understanding of key concepts. In the earlier study, some questions were asked after the box was retrieved from the subject. Understanding of the concepts in the two studies cannot be directly compared because the criteria defining understanding differed, as did some of the questions. However, 13 of the questions asked in the earlier study were essentially the same as the questions in the current study. The proportions of subjects who gave correct answers to each of the questions in 11 of these 13 question pairs differed between studies by no more than 5 percentage points. The two question pairs that had a greater difference were both related to the concept of taking the medication as soon as possible after sex. These questions were among those that generated the most incorrect responses in both studies, but notably, the proportion of subjects answering correctly was higher in the current study.

Female adolescents aged 17 years and younger can obtain sufficient information from the prototype product label to enable safe and effective use of this product without assistance from a clinician. These results support elimination of the current FDA restriction preventing this age group from obtaining emergency contraceptive pills over-the-counter.

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