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Measuring oral contraceptive adherence using self-report versus pharmacy claims data

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Abstract

Objective—Proportion of Days Covered (PDC) is a measure of medication adherence that uses prescription claims data to describe the proportion of days that the patient possessed medication. The objective of this study is to compare PDC and self-report as measures of oral contraceptive pills (OCPs) adherence and to identify individual-level predictors of adherence.

Study design—In a sample of 384 OCP users, self-report was compared with PDC as measures of adherence over the past 3 months. Patient-level variables were examined for associations with adherence using multivariable logistic regression models.

Results—High adherence, defined as missing 1 pill per month, was 76%, 68% and 54% as measured by self-report, PDC and both measures, respectively. Younger women (ages 18–25 and 26–33 years) were significantly less likely to have high adherence on both measures than women in the 34–40 age group [adjusted odds ratio (OR) 0.20, 95% confidence interval (CI) 0.08–0.51 and adjusted OR 0.26, 95% CI 0.11–0.62, respectively]. Other predictors of high adherence on both self-report and PDC measures included being in a relationship (adjusted OR 2.30, 95% CI 1.14–4.64, compared with unpartnered women), Protestant religion (adjusted OR 2.08, 95% CI 1.07–4.06, compared with women with no religious affiliation) and higher contraceptive self-efficacy (adjusted OR 1.63, 95% CI 1.03–2.58).

Conclusion—PDC derived from pharmacy claims, or a combination of PDC and self-report measures, may be an alternative to self-report alone for measuring OCP adherence.

Implications—PDC may be a potential tool for measuring women's adherence to OCPs and should be validated in future studies.

Keywords

Birth control pills; Proportion days covered

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1. Introduction

Almost half (45%) of all pregnancies during 2011 were unintended [1]. Unintended pregnancies occur when contraception is not used, not used perfectly or fails. During their unintended conception month, half (48%) of women reported using contraception [2]. In the United States, an estimated 20% of the 3.5 million annual unintended pregnancies are attributed to poor adherence or discontinuation of oral contraceptive pills (OCPs) [3].

Interventions aimed at increasing adherence to OCPs require accurate measurement of contraceptive use. Historically, adherence is usually measured by women self-reporting number of missed pills each month either through retrospective recall surveys or daily diaries in clinical trials. These self-report methods have limitations due to recall, social desirability and selection biases, as women tend to overestimate adherence [4]. The optimal way to measure OCP adherence has not been established, but prescription refill data may be a promising alternative to self-reported data. Beyond contraception, many studies attempted to create better methods of measuring medication adherence, such as medication refill data from pharmacy claims [5,6] or costly medication-event monitoring systems, where electronic packaging records when pill bottles are opened [7] or a pill's blister is broken [8]. Using pharmacy claims medication refill data may be superior to self-report by avoiding biases related to self-report; however, these methods have only been compared directly in a few contraception studies. One study indicated a discrepancy between self-report and pharmacy claims data, wherein 59% of 769 women reported continuous use of OCPs for 12 months but only 39% had enough pills supplied for 12 months of continuous use [9], suggesting that self-report data may not be a valid adherence measure [10].

Medication adherence encompasses both use consistency and continuity (i.e., absence of gaps in use). Although medication fill data cannot capture consistency of daily use (e.g., missing a pill and doubling up the next day), it can detect gaps in use. Medication fill data have multiple OCP adherence definitions. Some reports defined high adherence according to timely refills (within 7 or 14 days of needed OCP resupply) [11,12]. Another study defined discontinuation of OCPs as greater than 30 days between refills [9]. Other articles measured time between refills, total number of contraceptive coverage months, number of gaps between refills, number of monthly packs filled per year and if the woman possessed contraception during the last week of the 12-month study [13–15].

In this study, we propose using Proportion of Days Covered (PDC) as a claims-based measure of adherence to OCPs. PDC measures the proportion of days in a defined time frame the patient possesses medication based on medication refill dates and number of days supplied by each fill [16]. PDC is a commonly used claims-based measure of adherence for medications used to treat chronic diseases such as hypertension and diabetes [17]. Additionally, PDC was endorsed by the Pharmacy Quality Alliance as the preferred method for measuring medication adherence of many chronic diseases [18]. However, to our knowledge, PDC has not been used in studies of OCPs. In this study, we use PDC to describe OCP adherence in comparison to traditional retrospective self-report and to identify

any predictors of adherence. Our objective is to describe an alternative measure of quantifying adherence to OCPs for use in future contraceptive research.

2. Methods

2.1. Study sample

Data for these analyses are from the baseline survey of the MyNewOptions randomized controlled trial. The parent study aims to test the effectiveness of web-based intervention to assist insured women in making woman-centered contraceptive choices ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02100124) identifier: [NCT02100124](https://clinicaltrials.gov/ct2/show/study/NCT02100124)). Study participants were members of Highmark Health plans in Pennsylvania and sampled from the Highmark enrollee database. Eligible women were aged 18–40, not intending pregnancy in the next 12 months, not surgically sterile (or current partner with vasectomy) and sexually active with male partner and had Internet access. The baseline survey assessed pregnancy and contraceptive history, current contraceptive use and behaviors, and sociodemographics. Further details regarding the MyNewOptions study protocol are published elsewhere [19].

Each participant was asked her current primary contraceptive method, including prescription and over-the-counter methods, as well as natural family planning and withdrawal. The analytic sample was limited to women who reported current OCP use at baseline and responded to self-report OCP adherence questions. Out of the 987 My New Options study participants, 384 met these criteria and were included in these analyses. The MyNewOptions study was approved by the Penn State College of Medicine's Institutional Review Board.

2.2. Measures

2.2.1. Measure of adherence: self-report—Self-reported contraceptive adherence questions ascertained number of pills missed within previous 3 months with the question, “In the past 3 months, altogether how many days did you completely miss a hormone pill that you were supposed to take (even if you remembered later and took two pills the next day)?” Self-reported OCP adherence was categorized as high versus low. High adherence was defined as missing three or fewer pills in the last 3 months. Low adherence was defined as missing four or more pills within the past 3 months. These thresholds were based on the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) recommendation that missing more than one active pill per cycle increases the risk of pregnancy [20,21].

2.2.2. Measure of adherence: PDC using claims data—Pharmacy claims data were used to calculate PDC over the past 90 days (number of covered days in past 90 days/90 days*100) [18]. Consistent with the self-report measure, we used the WHO and CDC recommendations to define high adherence as a PDC of 96% or greater, which is equivalent to missing three or fewer pills in 3 months [20,21]. For each study participant, we used pharmacy claims data from the 6 months prior to study enrollment to calculate PDC-based adherence for the 90-day period prior to study enrollment. A descriptive example of how PDC was calculated is shown in Fig. 1.

2.2.3. Covariates—Variables known or hypothesized to influence OCP adherence were included as covariates (length of pill supply, future pregnancy intention, importance of avoiding pregnancy, feelings about pregnancy, contraceptive self-efficacy, pregnancy history and sociodemographic variables). A three-level variable indicated whether women were dispensed 28-day, 84-day or a combination of 28/84-day supplies. Intention for future pregnancy 5-level variable captured if and when women intended a future pregnancy (in 1–2 years, 2–5 years, 5 or more years, never or not sure). Importance of avoiding pregnancy was categorized as very important vs. all other responses (collapsed from somewhat important, a little important or not at all important). Participants were asked, “Now, imagine that you have just found out today that you are pregnant. How would you feel?” Responses were dichotomized to very upset vs. all other responses (somewhat upset, unsure, somewhat pleased or very pleased). These response categories were collapsed due to our belief that women who find it very important to avoid pregnancy right now and would be very upset if they found out today that they were pregnant would be the most highly motivated to be adherent. Contraceptive self-efficacy was measured with an eight-item scale and dichotomized to the median describing high vs. low self-efficacy. This novel scale was guided by a previously published adolescent contraceptive self-efficacy scale [22] and adapted for adult women to assess their confidence level in preventing pregnancy and talking to their providers/partners about contraception (Cronbach’s alpha=0.71). Pregnancy history variables included number of previous live births (0, 1 or at least 2) and history of any unintended pregnancy.

Sociodemographic characteristics included age group (18–25, 26–33 or 34–40), partnership status (married, living with partner, in relationship or not partnered), race/ethnicity (white or nonwhite), religion (Catholic, Protestant, other or no religion), education status (high school graduate or less, some college or college graduate) and annual household income (<\$25,000, \$25,000–\$49,999, \$50,000–\$74,999 or \$75,000),

2.2.4. Statistical analysis—Prior to any analysis, frequencies and percentages were used to summarize all independent and outcome variables. A χ^2 test looked for bivariate associations between self-reported adherence and PDC-based adherence, and between independent variables and these two outcome variables. Using multivariable logistic regression, all variables were included to identify those associated with high self-reported adherence, high PDC-based adherence and high adherence on both measures.

Independent variables were tested for multicollinearity using variable inflation factor statistics prior to constructing all multivariable models. The Hosmer-Lemeshow goodness-of-fit test assessed fit of multivariable models, and odds ratios of 95% confidence limits quantified magnitude and direction of significant associations. SAS version 9.4 was used to perform all analyses (SAS Institute, Cary, NC, USA).

3. Results

The 384 women using OCPs are described in Table 1. Most women were between 18 and 25 years old, white race, college graduates and considered avoiding pregnancy as very important. Using our definition of high adherence (missing three or fewer pills in the past 3

months), 290 (76%) women were self-reported highly adherent. In comparison, PDC-based adherence indicated that 260 women (68%) were highly adherent (PDC value >96%). Only 207 (54%) women were highly adherent on both measures. There were 83 (22%) women who self-reported high adherence but had low PDC-based adherence, 53 (14%) women were highly adherent according to PDC but self-reported low adherence, and 41(11%) women had low adherence on both measures. Significant predictors of high self-reported adherence in bivariate comparison were Christian (Catholic and Protestant) religion ($p=.03$) and high contraceptive self-efficacy ($p=.02$). There were no significant predictors of high PDC-based adherence (bivariate data not shown).

Multivariable logistic regression model results are shown in Table 2, modeling high adherence using self-report, PDC and both measures. Compared with women not in a relationship, high self-reported adherence was associated with being in a relationship without being married or cohabiting. Women reporting Catholic or Protestant affiliation had at least twice the odds of self-reporting high adherence compared with women without religious affiliation. High contraceptive self-efficacy also doubled the odds of high self-reported adherence. High PDC-based adherence was not predicted by any variables included in the model. In the third model, the oldest age group (34–40), being in a relationship, Protestant religion and higher contraceptive self-efficacy were significantly associated with high adherence on both measures.

4. Discussion

Research studies examining OCP adherence have largely used self-reported measures, which are subject to recall and social desirability biases [4]. Recent studies proposed using pharmacy claims data to measure OCP adherence because they are based on objective measures of medication possession [9,11]. In this insured sample of OCP users, the proportion of women who self-reported high adherence (76%) was greater than the proportion of women who had high PDC-based adherence (68%), while an even smaller proportion of women (54%) had high adherence on both measures. While PDC-based and self-reported adherence measures could be complementary ways of measuring OCP adherence, further study is required to validate these two methods against actual behavior. We suspect that having high adherence on both measures is likely a more valid measure than either self-report or PDC alone, as PDC directly measures possession, while self-report quantifies consumption. Of note, survey participants were asked retrospectively to self-report an aggregate number of missed pills in preceding 3 months; self-reported adherence was not collected prospectively.

The PDC indicates how many days in a specified time interval the patient possessed medication and has been adopted as a standard method of measuring medication adherence for common chronic diseases [6,17,23]. Because it is not subject to recall or social desirability bias, PDC arguably has greater face validity than self-report when gauging OCP adherence. However, measuring medication adherence with claims data also has potential weaknesses [24,25]. Pharmacy refill data measures possession of the drug [26] but not actual consumption. Furthermore, claims-based adherence measurement assumes that women do not have access to and consume more OCPs than those recorded in their pharmacy claims

data. Likewise, PDC does not account for women who missed pills but then caught up over subsequent days, unlike self-report. Furthermore, new initiatives requiring insurance companies to pay for 1-year supplies of OCPs may prove to improve contraceptive adherence; however, PDC would not be a valid adherence measure in that context [15,27].

No association was found between length of pill supply and either PDC-based or self-reported adherence, which was surprising, as prior studies have shown that dispensing a 3-month supply of OCPs is associated with higher adherence [13,15]. We suspect that number of packs dispensed may not have been predictive due to the short 90-day observation period, with fewer opportunities to fill a prescription late than in other 12-month measured adherence studies. In our study, we defined the PDC as 90 days prior to survey completion to correspond with the self-reported medication adherence variable time frame; however, measurement of PDC over longer time frames is desirable and would better elucidate the relationship between pill supply duration and adherence.

The multivariable regression model findings (Table 2) have important clinical implications. Clinicians may attempt to judge whether a patient is a good candidate for OCPs based on perceived likelihood of adherence. However, none of the included covariates were associated with any of our adherence outcomes. Therefore, clinicians are encouraged to be conscientious of both explicit and implicit biases they may have when counseling women on adherence. Women, as well, may unknowingly either over- or underestimate their history of medication adherence; of note, age did not significantly predict either self-reported or PDC adherence, but younger women were significantly less likely to have high adherence when the adherence measures were combined. During counseling, women should be carefully informed about how daily adherence affects the efficacy of OCPs. Painstakingly high levels of OCP adherence (PDC>96%) are needed to effectively avoid pregnancy, which contribute to the high numbers of women with unintended pregnancies while using OCPs each year [3]. Many intervention studies have looked at improving medication adherence through education and text message reminders, most of which did not significantly improve adherence [28]. The typical failure rate in the first year of OCPs is 6% [29]. Women who find that failure rate to be unacceptable should be provided information about more highly effective alternatives, such as intrauterine devices and implants, which do not require daily adherence on the part of the user.

Our sample included privately insured women of a single health plan residing in Pennsylvania. The sampling methodology allowed pharmacy claims data access but also accounts for the largely white, educated population. Thus, study results should be interpreted in this context. Our self-reported measure of OCP adherence assessed number of hormone pills missed in previous 3 months. Someone who missed three pills sequentially would be categorized the same as someone who missed one pill three different times; thus, it did not capture the different unintended pregnancy risks. When in the cycle pills were missed was not assessed, which also would influence risk of unintended pregnancy.

In summary, PDC or combination of PDC and self-report may be a promising tool for measuring women's adherence to OCPs. Using pharmacy claims data is objective and avoids the pitfalls of self-reported data. Additionally, PDC can be seen as complementary to self-

reported adherence, and if self-report data are not available, PDC could be used to analyze OCP adherence. Further work is needed to better understand the strengths and limitations of using PDC for contraception research so it can be effectively used in studies of contraceptive adherence.

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Fig. 1.

Description of how PDC is calculated for two example patients. Pharmacy claims data were used to define the PDC over the past 90 days (number of covered days in past 90 days/90 days*100). Patient 1 filled one 28-day supply of OCPs on day 1, was late to refill her second prescription by 7 days, then filled her third prescription the day she ran out of her second refill. Patient 1's PDC is $(83 \text{ covered days} / 90 \text{ days}) * 100 = 92.2\%$. Patient 2 had 10 days left of a previous refill (denoted with the *) and refilled for her first prescription during this 3-month period on day 10. Patient 2 refilled her second OCP claim 7 days early, which was shifted to the end of her first claim time, assuming she did not consume more than one pill per day. Patient 2's third claim was refilled on the day she ran out of her second prescription claim. Patient 2's PDC is $(90 \text{ covered days} / 90 \text{ days}) * 100 = 100\%$. PDC accounts for all of these deviations (late refill, early refill and previous refill that overlaps with 90-day time frame) when calculating a patient's possession of OCPs.

Table 1Characteristics of women using OCPs as her primary method, $N=384$

Participant characteristics	<i>N</i> (%)
Age group (years)	
18–25	204 (53)
26–33	135 (35)
34–40	45 (12)
Relationship status	
Married	100 (26)
Living with partner	78 (20)
In a relationship	145 (38)
Not partnered	61 (16)
Education level	
High school grad or less	19(5)
Some college	120 (31)
College graduate	245 (64)
Annual household income	
<\$25,000	60 (16)
\$25,000-\$49,999	87 (23)
\$50,000-\$74,999	101 (27)
\$75,000	128 (34)
Race/ethnicity	
White	370 (97)
Nonwhite	12(3)
Religion	
Catholic	134 (35)
Protestant	101 (27)
Other religion	64 (17)
No religion	83 (22)
Intention for future pregnancy	
In 1–2 years	44 (11)
In 2–5 years	110 (29)
In 5 or more years	109 (28)
Never	51 (13)
Not sure	70 (18)
Very important to avoid becoming pregnant right now	280 (73)
Very upset if found out pregnant today	172 (45)
High contraceptive self-efficacy	217 (57)
Length of pill supply	
28 days only	213 (55.5)
84 days only	143 (37.2)
Combination of 28- and 84-day supplies	28 (7.3)

Table 2

Adjusted odds ratios for high adherence based on PDC, self-report, and both measures; $N=371^a$

Characteristics	Adjusted OR (95% CI)		
	High adherence by self-report, $n=281$ (75.7%)	High adherence by PDC, $n=253$ (68.2%)	High adherence by both self-report and PDC, $n=202$ (54.4%)
Age group			
18–25	0.35 (0.11–1.08)	0.38 (0.14–1.01)	0.20 (0.08–0.51)
26–33	0.38 (0.13–1.09)	0.52 (0.21–1.28)	0.26 (0.11–0.62)
34–40	Reference	Reference	Reference
Relationship status			
Married	2.46 (0.94–6.45)	1.40 (0.58–3.37)	1.89 (0.78–4.56)
Living with partner	1.84 (0.77–4.36)	1.48 (0.67–3.31)	1.95 (0.88–4.32)
In relationship	2.67 (1.23–5.81)	1.75 (0.87–3.54)	2.30 (1.14–4.64)
Not partnered	Reference	Reference	Reference
Education level			
High school graduate or less	1.78 (0.45–7.08)	0.48 (0.17–1.37)	0.95 (0.33–2.77)
Some college	0.57 (0.31–1.06)	0.83 (0.47–1.45)	0.69 (0.40–1.18)
College graduate	Reference	Reference	Reference
Annual household income			
<\$25,000	2.17 (0.91–5.20)	1.78 (0.83–3.84)	1.75 (0.84–3.63)
\$25,000–\$49,999	0.80 (0.40–1.58)	0.87 (0.46–1.64)	0.66 (0.35–1.24)
\$50,000–\$74,999	1.34 (0.68–2.63)	1.41 (0.77–2.58)	1.34 (0.75–2.38)
>\$75,000	Reference	Reference	Reference
Race/ethnicity (nonwhite vs. white)	4.17 (0.48–36.52)	1.73 (0.39–7.63)	2.82 (0.71–11.21)
Religion			
Catholic	2.07 (1.05–4.11)	1.07 (0.57–2.00)	1.53 (0.83–2.81)
Protestant	2.72 (1.26–5.87)	1.51 (0.74–3.05)	2.08 (1.07–4.06)
Other	0.99 (0.45–2.19)	0.77 (0.36–1.62)	0.62 (0.30–1.32)
No religion	Reference	Reference	Reference
Intention for future pregnancy			
Within 1–2 years	Reference	Reference	Reference
Within 2–5 years	0.93 (0.37–2.37)	1.45 (0.62–3.39)	1.28 (0.56–2.93)

Characteristics	Adjusted OR (95% CI)		
	High adherence by self-report, <i>n</i> =281 (75.7%)	High adherence by PDC, <i>n</i> =253 (68.2%)	High adherence by both self-report and PDC, <i>n</i> =202 (54.4%)
5 or more years	1.79 (0.57–5.59)	1.24 (0.45–3.42)	2.03 (0.75–5.49)
Never	0.98 (0.31–3.10)	1.25 (0.44–3.50)	0.95 (0.35–2.54)
Not sure	0.88 (0.32–2.40)	0.80 (0.32–1.98)	0.85 (0.34–2.12)
Very important to avoid becoming pregnant right now	1.28 (0.64–2.56)	1.56 (0.83–2.93)	1.36 (0.74–2.51)
Very upset if found out pregnant today	1.05 (0.53–2.06)	1.02 (0.56–1.87)	1.23 (0.69–2.18)
High contraceptive self-efficacy	1.99 (1.18–3.37)	1.16 (0.72–1.87)	1.63 (1.03–2.58)
Length of pill supply			
28 days only	Reference	Reference	Reference
84 days only	0.95 (0.54–1.66)	1.35 (0.80–2.26)	1.18 (0.73–1.92)
Mixed length	0.79 (0.29–2.19)	0.67 (0.28–1.63)	0.73 (0.30–1.78)

The boldface entries indicates a significant difference between comparison groups.

OR, odds ratio; CI, confidence interval.

^a Out of the 384 women in the study sample, 13 were removed due to listwise deletions, leaving 371 in the multivariable models. ORs from multivariable logistic regression included and adjusted for all variables in table.