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A Comparison of Self-reported Oral Contraceptive Use and Automated Pharmacy Data in Peri- and Early Postmenopausal Women

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Abstract

Purpose—Oral contraceptive (OC) use can occur throughout a woman's reproductive lifespan with the potential for long-term impacts on health. To assess potential measurement error in prior OC use, this study compared level of agreement between self-reported prior OC use and pharmacy dispensing data in peri-/early postmenopausal women.

Methods—The study's 1,399 women (ages 45–59 years) were participants in a population based case-control study of the association between OC use and fracture risk. Episodes of lifetime self-reported OC use (in months) were collected, by telephone interview, for 1/1/2008 through 11/25/2012. Pharmacy fills, back to 1980, were collected from automated data. Agreement was measured using the Prevalence Adjusted and Bias Adjusted Kappa Index (PABAK).

Results—The number of women with OC pharmacy fills was 11–45% higher than those who reported OC use during each time period. Between-measures agreement was better for more recent use. PABAK values ranged from 0.88 (95% CI 0.85–0.90) within 5 years from the reference date to 0.65 (95% CI 0.59–0.71) within 15–20 years.

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Conclusion—For studies designed to assess the long term effects of OC use, the current results are reassuring in noting moderate agreement between self-reported OC use and pharmacy data for up to 15–20 years before the interview.

Keywords

Contraceptives; Oral; Reproducibility of Results

Introduction

Oral contraceptives (OCs) continue to be the most widely used method of contraception in the US. Seventeen percent of US women between the ages of 15 and 44 years use oral contraceptives (OCs).(1) Currently, there is no standard method used in research to collect information on OC use.(1) OC use has been measured in a variety of ways. The most accurate and resource intensive methods include direct observation of pill ingestion, hormone level or chemical marker measurement, and manual and electronic pill counts.(1) However, the majority of studies that have evaluated OC use patterns and outcomes have employed self-reported information, which is also resource-intensive and may be subject to recall or social desirability bias.(1) Health plan automated pharmacy databases offer another, less resource-intensive data source, and their use is increasing. Although pharmacy databases also have limitations (they may not provide information on patient adherence, free samples, or on prescriptions filled outside of a health plan, for example), there is evidence that pharmacy records are more complete than medical record abstraction(2–4) and pharmacy databases have been used by some as a comparator for self-reported medication use.(5)

Better measurement leads to better assessment of true exposure. Measurement error and associated misclassification bias can jeopardize a study's internal validity. Random measurement error can dilute the exposure effect and, if related to the outcome, can bias the results. To date most inter-method reliability studies of OC exposure compare self-reported use to information collected from medical records(6–14). While automated pharmacy data may be more complete, only two studies have compared self-reported OC use to automated pharmacy data.(15, 16) These reports focused on current use (15) or longer-term use in younger (20–34 year old) women.(16) However, OC use can occur throughout a woman's reproductive life and there also is scientific interest in the relationship between OC associations with outcomes that are common in older women such as bone health, breast cancer, cardiovascular events, ovarian cancer, and diabetes. The objective of the current study was to evaluate the inter-method reliability between measures of OC use obtained from self-report and automated pharmacy data for different time points during the life course and relative to the interview in a sample of peri- and early post-menopausal women.

Methods

POPULATION

The study population consisted of women aged 45 through 59 years who agreed to participate in a telephone interview between January 1, 2008 and November 25, 2012 as part

of a population based case-control study of the association between OC use and fracture risk around the menopausal transition. Women were enrollees of Group Health Cooperative, a Washington State health care system. Case women had experienced an adjudicated incident osteoporotic fracture occurring after January 1, 2008, the beginning of the study recruitment interval. The reference date was the date of the incident fracture and data were collected prior to that date. For each case, two controls were randomly selected using a randomized recruitment approach(17) to achieve approximately equal age frequency distributions in cases and controls. Controls were randomly assigned reference dates based on the distribution of case reference dates.

The study sample for this analysis included women (cases and controls) who reported during the interview that they always or usually filled their prescriptions at a Group Health pharmacy (versus rarely or never), consented to have their medical records reviewed, and had at least 5 years of continuous enrollment prior to their reference date. Before the interview, we excluded women with any of the following prior to the study reference date: 1) a previous osteoporotic fracture after the age of 45, 2) hysterectomy or removal of ovaries, 3) current regular use of two years or more of prescription hormone therapy with estrogen to treat symptoms of menopause. All study procedures were approved by the Group Health Institutional Review Board.

INTERVIEW DATA

Telephone interviews were conducted using a structured computer-assisted telephone interviewing questionnaire. Interviewers received a minimum of 8 hours of training, were required to pass certification, and had 10% of their calls monitored throughout the study. A life event calendar was available for interviewer use if needed. We asked women if they had ever used birth control pills (for 3 months or more) prior to the reference date, even if they were used for something other than birth control. We did not include the morning after pill. For women who had used OCs, we then asked a repeating series of questions about OC episodes of use: 1) "How old were you when you first started using birth control pills?" 2) "How long did you use pills (in years and months) that time without a 6 month or longer break?" (no minimum duration) and if applicable, 3) "How old were you the next time you started using birth control pills?". These questions could be asked for up to 14 episodes of OC use. Start and stop dates of self-reported OC use were used to derive eight variables indicating any OC use during the following time periods; 0–5, 5.1–10, 10.1–15, and 15.1–20 years prior to the reference date; and after ages 30, 35 and 40 years. To ensure availability of automated data, participants included in these analyses were required to be continuously enrolled for the entire time window of interest.

Additional variables were obtained from the interview data for use in describing the sample population and for use in stratified analyses to describe the inter-method agreement in different subpopulations. These include age at reference date in years, age greater or less than 52 (to correspond to the average age of menopause), race (white and non- white), history of fracture (case/control status), general health around reference date (excellent or very good versus good, fair, or poor), marital status at reference date (married or living with a partner versus not partnered, divorced or widowed), number of pregnancies (1 or more

versus none), highest education at reference date (some college to post graduate degree versus high school graduate, GED or less) and ever use of female hormones (besides birth control pills). These other hormones may have been used for contraception to prevent pregnancy, for menopausal symptoms, or for other reasons and could include pills, creams, shots, patches, or rings that they used for 3 months or more before the reference date.

AUTOMATED DATA

Detailed data on prescriptions filled at the Group Health outpatient pharmacies have been maintained in an automated database dating back to March 1977 and have been used extensively for research.(5, 18) Data on Group Health enrollment date back to 1980. Using the pharmacy data, subjects were considered OC users based on dispensing (fill) dates. Within the time windows noted above, our primary analysis examined OC use defined as at least 1 prescription fill per observation period, but we also assessed OC use defined as 2 or more fills <12 months apart per observation period. OC medications were identified in automated data using National Drug Codes (Appendix 1).

ANALYSIS

The primary measure of agreement used to compare self-reported and automated pharmacy OC use data was the Prevalence Adjusted and Bias Adjusted Kappa (PABAK).(19, 20) The PABAK equals +1 when there is no disagreement between measures, 0 when the observed agreement is equal to 50%, and -1 when there is no agreement between measures. To construct PABAK, we calculated two indices: the Prevalence Index (PI) is the difference between the probability of “OC use” and the probability of “no OC use”. Without correction, larger differences result in smaller Kappa (K) statistics. The Bias index (BI) corrects for the difference in the proportion of OC users assessed by the two data sources (self-report and automated fills).(21) Given an observed agreement, without correction, the resultant unbalanced marginal distributions result in higher values of K. The unadjusted Kappa (K) agreement also was calculated. We interpreted the K statistics based on the 6-level scale (0=poor, .01-.20=slight, .21-.40=fair, .41-.60=moderate, .61-.80=substantial, and .81-1=almost perfect agreement) suggested by Landis and Koch. (22) Analyses were also stratified by case/control status and select self-reported variables including, age less than or equal to 52, marital status, any pregnancy, race, education level, use of GH pharmacy and use of other hormone-containing medications. Since PABAK is a linear function of the percent of observed agreement ($2 * p_o - 1$), we performed two sample test of proportions on the percent agreements to test equality of PABAK in the stratified analyses.

Results

Within our study population (n=1402), 3 women did not provide self-reported information on OC use and were not included in the analysis (final n=1399). The majority of women was more than 50 years of age, white, married, in very good to excellent health, and experienced at least one pregnancy prior to the reference date (Table 1). Regardless of time from reference date, the number of women with OC use was higher (11–45%) when captured in automated pharmacy data than through self-report, and the majority of women reported no use (88% within 5 years of and 71% 15 to 20 years from the reference date) (Table 2). The

agreement between self-report and automated data decreased with greater distance between time of OC use and the reference date. The adjusted K (PABAK) ranged from 0.88 (unadjusted K 0.62) for OC use in the 5 years prior to the reference date to 0.65 (unadjusted K 0.46) for OC use 15 to 20 years prior to the reference date (Table 3). The PABAK for OC use based on 2 or more prescriptions less than 12 months apart was higher than when OC use was defined as 1 or more fills. When the analysis examined OC use in the 5 years prior to the reference date the magnitude of agreement did not differ in subgroups based on any selected characteristics, except for self-reported use of other hormone-containing medications (Table 4). The PABAK was significantly higher in women who did not use other hormone-containing medications (PABAK 0.89; unadjusted K 0.68) compared to women who reported using these medications (PABAK 0.83; unadjusted K 0.40).

Discussion

OC medication can be used over multiple periods in a woman's life, which can result in a lengthy medication history and potential challenges to recall. In our study of women around the menopausal transition, the adjusted agreement (PABAK= 0.88; unadjusted K=0.62) between self-reported recent OC use (within 5 years of the reference date) and pharmacy fills was similar to what was observed in the two other studies comparing current self-reported OC use to pharmacy data. One study collected information on the use of various medications through a self-administered questionnaire sent to Norwegian women ages 28–75 years. (15) The calculated PABAK for current OC use was 0.79 (K=0.65). The second study collected information on OC use from younger (20–34) Swedish women using a life-calendar and pictures of OC packages during an in-home interview. The calculated PABAK for current OC use was 0.81 (unadjusted K=0.78).(16) As expected, the strength of agreement was highest for more recent use. In our study, for the time periods of greater than 5 to 10 years, greater than 10 to 15 years and greater than 15 to 20 years the adjusted agreement (PABAK) was 0.75, 0.69 and 0.65 respectively. A similar pattern was seen in the study of younger women. The correlation coefficients for duration of OC use within 0–5, 5–10, and 10 years of the interview were 0.82, 0.71, and 0.74(16)

In our study, more OC use was captured in automated data of medication dispensing than by self-report. A similar scenario was reported in a Dutch study that included older women(15) but not in the Swedish study of younger women.(16) One possible explanation for this difference is that medications from fills may not be consumed. However, for the 60 women who were dispensed OCs but did not report OC use in the 5 years prior to the reference date, 51 had OCs dispensed more than one time and 39 had more than 5 fills recorded, which suggests otherwise. The women also may have underreported OC use due to the potentially sensitive nature of the subject. Our data do not allow us to identify which measure most accurately reflects participants' OC use. Defining OC use in automated data as 2 or more fills less than 12 months apart as opposed to 1 fill resulted in a higher PABAK, suggesting that this may be a better definition for use in pharmacy data.

The PABAK statistic adjusts for both bias and prevalence. In our study the adjusted Kappas (PABAK) were generally slightly higher than unadjusted Kappas. And in general, the prevalence effect was high and the bias effect was low. The high Prevalence Index reflects

the high number of women who had no OC use by either data collection method. One criticism of PABAK is that the statistic does not reflect the prevalence of the original scenario in which the comparison was made.(23) However, it may be helpful in assessing agreement across different levels of prevalence.

We did not observe differences in the magnitude of agreement between self-reported OC use and OC prescription fills in subgroups classified by case status, self-reported health, number of pregnancies, education, race, age at reference date, or always or usually using the GH pharmacy for filling prescriptions. However, in this age group of women, agreement was higher in women who did not use other hormone-containing medications compared to those who did. There may be some misclassification of other hormone-containing medications as OCs by either women or pharmacy data and additional attention may be needed to distinguish these classes of medication especially in this age group.

The findings of this study should be interpreted with possible caveats in mind. There may be some misclassification of OC use in automated data because we used date of fill instead of developing episodes of OC as we did with self-reported data. However, we expect the misclassification to be minimal because the maximum quantity of medication that can be dispensed, hence the maximum misclassification is a 90-day supply and 23% of the fills were for 30 day supplies. In addition, we may not have identified all of the National Drug Codes (NDC) for older OC brands, but searching on key ingredients (as we did) should have minimized this misclassification. Our examination of exposure, any OC use during time periods of 5 or more years, was broad. Additional studies assessing the reliability of duration of OC use would add to the literature. Several factors may limit the generalizability of our study. We had the advantage of an unusually long look-back window for our automated data, but only a subset of women were enrolled for that entire time period. Women with many years of continuous enrollment or from one health care system may not be generalizable to the wider population.(24) However, it is rare to have the opportunity to examine data for such a long time period, and in chronic disease contexts, these are the timeframes of interest. In addition, a substantial proportion of our population consisted of quite well-educated white women, although we did not see any significant differences in the adjusted Kappa by race or educational status.

Conclusion

Among women close to the menopausal transition, agreement between self-reported OC use and automated OC prescription fills was substantial for use within 5 years and moderate for up to 20 years prior to the reference date, using the unadjusted chance corrected kappa statistic and interpretation. With prevalence and bias adjustment, agreement was higher. The higher capture of OC use in pharmacy data suggests it may be useful for interview studies to also incorporate pharmacy data, if available and with participant agreement. Basing a definition of use on 2 fills in pharmacy data should be considered. Sensitivity analyses to assess different measurement methods, or combinations of methods, could be used to support study results. Studies assessing the reliability of a more in-depth “duration of OC use” variable across the reproductive lifespan would also be useful.

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List of abbreviations

CI	95% confidence interval
N	number
K	unadjusted Kappa
OC	oral contraceptive
PABAK	Prevalence Adjusted and Bias Adjusted Kappa Index
RX	Medications
SR	self-report

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Appendix 1

To develop a list of National Drug Codes we searched our database (a combination of data from our internal pharmacy, First Data Bank (FDB), and Rxnorm) using brand names [identified through a number of sources including MedlinePlus (<http://www.nlm.nih.gov/medlineplus/>), DailyMed (<http://dailymed.nlm.nih.gov/dailymed>), Lexicomp (www.lexi.com), the Smithsonian Institution (<http://collections.si.edu/>), journal articles and older studies], internal formulary classification and FDB Therapeutic class for Oral Contraceptives, and key ingredients [chlormadinone, desogestrel, dienogest, dimethisterone, drospirenone, ethinyl estradiol, ethynodiol, gestodene, levonorgestrel, mestranol, medroxyprogesterone (combined with an estrogen), megestrol, norethindrone, norethisterone, norethynodrel, norgestrel]. The list was then manually reviewed using additional information on formulation, dose, RxNorm unique identifier, and American Hospital Formulary Service classification to exclude inappropriate medications such as emergency contraceptives or hormone therapy for menopause symptoms.

Table 1

Characteristics of study participants with at least 5 years of continuous health plan enrollment (n=1399)

Characteristic	Percent of Total	Number
Age at reference date		
45–50	16.3	228
51–55	41.4	579
56–60	42.3	592
Non-white and/or multiple race (vs. white)	16.2	226
Education		
High School graduate, GED, or less	12.8	179
Some college, 2-year degree, vocational/technical training	35.1	490
College Graduate	26.5	370
Postgraduate Degree	25.7	359
Marital status		
Married	68.0	951
Living with a partner	5.8	81
Widowed	3.3	46
Divorced or separated	13.7	192
Never married or single	9.2	129
Number of pregnancies (> 6 months)		
0	25.3	354
1	17.4	243
2	36.3	507
3 or more	21.0	293
General health excellent/very good (vs. good, fair, or poor)	63.8	892
Greater than 12 months from reference date to interview date	33.0	461
Drug coverage code (vs. no drug coverage) at reference date	96.0	1343
Always use GH pharmacy for medication fills (vs. usually)	88.4	1237
History of fracture	39.7	555
Enrollment		
5–10 years prior to reference date	23.0	322
10.1–15 years prior to reference date	15.2	212
15.1–20 years prior to reference date	18.0	252
At least 20 years prior to reference date	43.8	613
Since age 30	6.9	97
Since age 35	33.0	461
Since age 40	66.0	924

Table 2

Raw data of the number of OC users and agreement between the two different measures of exposure

Person Level Raw data	Agreement in OC use (Self-reported (SR) and Prescription Fills)										
	Total (N)	SR OC use (N)	SR OC use (%)	OC Prescription Filled (N)	OC Prescription Filled (%)	Percent Observed agreement	Percent Chance agreement	SR = Yes		SR = No	
								Fill = Yes	Fill = No	Fill = Yes	Fill = No
OC use within 0–5 years of reference date ^d											
1+ fill	1399	106	8	140	10	0.94	0.84	80	60	26	1233
2+ fill	1399	106		117	8	0.95	0.85	78	39	28	1254
OC use within 5.1–10 years of reference date											
1+ fill	1077	125	12	228	21	0.88	0.72	111	118	14	834
2+ fill	1077	125		184	17	0.91	0.75	104	80	21	872
OC use within 10.1–15 years of reference date											
1+ fill	865	125	14	203	23	0.85	0.69	98	105	27	635
2+ fill	865	125		162	19	0.88	0.72	91	71	34	669
OC use within 15.1–20 years of reference date											
1+ fill	613	118	19	133	22	0.83	0.67	72	61	46	434
2+ fill	613	118		111	18	0.85	0.70	67	44	51	451
Any OC use from age 30 to reference date											
1+ fill	97	45	46	68	70	0.70	0.49	42	26	3	26
2+ fill	97	45		59	61	0.73	0.49	39	20	6	32
Any OC use from age 35 to reference date											
1+ fill	461	125	27	201	44	0.77	0.53	110	91	15	245
2+ fill	461	125		159	34	0.83	0.57	103	56	22	280
Any OC use from age 40 to reference date											
1+ fill	924	163	18	288	31	0.81	0.62	139	149	24	612

Person Level Raw data	Agreement in OC use (Self-reported (SR) and Prescription Fills)										
	Total (N)	SR OC use (N)	SR OC use (%)	OC Prescription Filled (N)	OC Prescription Filled (%)	Percent Observed agreement	Percent Chance agreement	SR =		SR = No Fill = No	
								Yes	No		
2+ fill	924	163		231	25	0.86	0.66	131	100	32	661

SR self report. OC oral contraceptive. N number

^aParticipants were required to be enrolled for the entire time window of interest e.g. if OC use between 0–5 years was being evaluated; the analysis was restricted to patients with at least 5 years of continuous enrollment.

Agreement between OC prescription fills in automated data and self-reported (SR) OC use from telephone interview at selected time periods prior to reference date*.

Table 3

OC comparison	Results				
	K	95% CI	PABAK	95% CI	PI
OC use within 0–5 years of reference date^a					
SR (Y/N)					
1+ fill	0.62	(0.54–0.70)	0.88	(0.85–0.90)	0.02 –0.82
SR (Y/N)					
2+ fill	0.67	(0.60–0.75)	0.90	(0.88–0.93)	0.01 –0.84
OC use within 5.1–10 years of reference date^a					
SR (Y/N)					
1+ fill	0.56	(0.49–0.63)	0.75	(0.72–0.79)	0.1 –0.67
SR (Y/N)					
2+ fill	0.62	(0.55–0.69)	0.81	(0.78–0.85)	0.05 –0.71
OC use within 10.1–15 years of reference date^a					
SR (Y/N)					
1+ fill	0.51	(0.43–0.59)	0.69	(0.65–0.74)	0.09 –0.62
SR (Y/N)					
2+ fill	0.56	(0.48–0.64)	0.76	(0.71–0.80)	0.04 –0.67
OC use within 15.1–20 years of reference date^a					
SR (Y/N)					
1+ fill	0.46	(0.37–0.56)	0.65	(0.59–0.71)	0.02 –0.59
SR (Y/N)					
2+ fill	0.49	(0.40–0.58)	0.69	(0.63–0.75)	0.01 –0.63
Any OC use from age 30 to reference date					
SR (Y/N)					
1+ fill	0.42	(0.24–0.60)	0.40	(0.22–0.58)	0.24 0.16

OC comparison	Results				
	K	95% CI	PABAK	95% CI	BI PI
SR (Y/N)					
2+ fill	0.47	(0.30–0.65)	0.46	(0.29–0.64)	0.14 0.07
Any OC use from age 35 to reference date					
SR (Y/N)					
1+ fill	0.51	(0.43–0.59)	0.54	(0.46–0.62)	0.16 –0.29
SR (Y/N)					
2+ fill	0.61	(0.53–0.69)	0.66	(0.59–0.73)	0.07 –0.38
Any OC use from age 40 to reference date					
SR (Y/N)					
1+ fill	0.50	(0.44–0.57)	0.63	(0.58–0.68)	0.14 –0.51
SR (Y/N)					
2+ fill	0.58	(0.51–0.64)	0.71	(0.67–0.76)	0.07 –0.57

SR self report. OC oral contraceptive. PABAK Prevalence Adjusted and Bias Adjusted Kappa. PI Prevalence Index. BI Bias index. K unadjusted Kappa

^aParticipants were required to be enrolled for the entire time window of interest s.a. if OC use between 0–5 years was being evaluated, the analysis was restricted to patients with at least 5 years of continuous enrollment

Table 4

Stratified analysis by selected characteristics: Agreement between OC prescription fills in automated data and self-reported (SR) OC use from 0–5 years prior to reference date among women enrolled for at least 5 years.

Characteristic	Total Number ^a	SR OC use (N)	SR OC use (%)	OC fills (N)	OC fills (%)	% observed agreement	K (95% CI)	PABAK (95% CI)
No history of fracture (control)	844	68	8	82	10	0.94	0.63 (0.54–0.73)	0.88 (0.85–0.91)
History of fracture (case)	555	38	7	50	9	0.95	0.59 (0.46–0.72)	0.87 (0.83–0.91)
Health Excellent/Very good	892	71	8	86	10	0.94	0.63 (0.53–0.73)	0.88 (0.85–0.91)
Health Good/Fair/Poor	507	35	7	54	11	0.93	0.60 (0.46–0.73)	0.87 (0.83–0.91)
Married or living with a partner	1032	83	8	107	10	0.94	0.63 (0.54–0.72)	0.88 (0.85–0.91)
Not partnered, divorced, widowed	367	23	6	33	9	0.94	0.58 (0.40–0.75)	0.88 (0.83–0.93)
1 or more Pregnancies	1043	75	7	100	10	0.94	0.61 (0.51–0.70)	0.88 (0.85–0.91)
No Pregnancy	354	31	9	40	11	0.94	0.64 (0.50–0.78)	0.87 (0.82–0.92)
Some college to post graduate degree	1219	93	8	122	10	0.94	0.63 (0.55–0.71)	0.88 (0.85–0.91)
High school graduate, GED or less education	179	13	7	18	10	0.93	0.54 (0.30–0.78)	0.85 (0.78–0.93)
White/Caucasian	1167	93	8	122	10	0.93	0.61 (0.52–0.69)	0.87 (0.84–0.90)
Non-white	226	13	6	18	8	0.96	0.69 (0.49–0.89)	0.92 (0.87–0.97)
Usually fill at a GH pharmacy	1237	100	8	130	11	0.94	0.62 (0.54–0.70)	0.87 (0.84–0.90)
Always fill at a GH pharmacy	162	6	4	10	6	0.96	0.61 (0.30–0.92)	0.93 (0.87–0.98)
LE 52 years at refdate	412	45	11	60	15	0.93	0.68 (0.57–0.80)	0.86 (0.81–0.91)
GT 52 years at refdate	987	61	6	80	8	0.94	0.57 (0.46–0.67)	0.88 (0.86–0.91)
No use of other hormone containing RX	1047	84	8	106	10	0.95	0.68 (0.59–0.76)	0.89 (0.87–0.92)
Used other hormone containing RX	350	21	6	30	9	0.91	0.40 (0.20–0.61)	0.83 (0.77–0.89)

PABAK Prevalence Adjusted and Bias Adjusted Kappa (bold represents statistically significant difference at $\alpha = 0.05$). **K** unadjusted Kappa. **SR** self report. **OC** oral contraceptive. **CI** 95% confidence interval. **RX** Medications.

^aTotal numbers of stratified groups may not sum to 1399 due to missing data in the stratification variable.