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Diagnostic Resolution of Cancer Screening Abnormalities at Community Health Centers

Richard G. Roetzheim, MD, MSPH, Ji-Hyun Lee, DrPH, Ercilia R. Calcano, MPH, Cathy D. Meade, PhD, RN, William J. Fulp, MS, and Kristen J. Wells, PhD, MPH

University of South Florida, College of Medicine (RGR, KJW) and the H. Lee Moffitt Cancer Center & Research Institute (RJR, JHL, ERC, CDM, WJF, KJW)

Abstract

Background—Few studies have examined timeliness of diagnostic evaluation of abnormal cancer screening tests in community health centers.

Methods—Using medical record review, timeliness of diagnosis was assessed among 317 people having either breast or colorectal-related abnormalities.

Results—For 241 subjects (76.0%) who reached clinical resolution, the median time to diagnostic resolution was 37 days. People with breast abnormalities had more than twice the odds (adjusted odds ratio: 2.84) of reaching diagnostic resolution within 180 days compared to patients with colorectal abnormalities. We found, however, no evidence of disparate outcomes according to patient race/ethnicity, insurance status, or spoken language.

Conclusions—Diagnostic evaluations are often either not completed or are delayed after a cancer-related abnormality is discovered. Further research is needed to understand the patient, provider, and health care system factors that contribute to these delays. There was no evidence of cancer disparities in the community health centers studied.

Keywords

Breast cancer; colon cancer; disparities; community health center; diagnostic delay

There are significant racial and socioeconomic disparities in breast and colorectal cancer outcomes. African American and Hispanic women, for example, are more likely than non-Hispanic White women to be diagnosed with late-stage breast cancer and have higher breast cancer mortality.^{1–4} Similar disparities exist for colorectal cancer stage at diagnosis and mortality.^{1, 2, 5–7} Inadequate screening is one factor that contributes to cancer disparities.^{8–10} Another factor that may lead to cancer disparities is delayed diagnosis after an abnormal finding.

Further research is needed to understand timeliness of evaluation once a cancer-related abnormality is identified, and the factors associated with delayed diagnosis. Studies have suggested that a substantial number of men and women do not obtain timely diagnostic evaluation even after a cancer-related abnormality is identified.^{11, 12} Some studies have examined timeliness of diagnosis in hospital settings. Ferrante and colleagues reported a median time to diagnosis of 44 days for women requiring breast biopsies in an urban public hospital.¹³

A study of community hospitals in Connecticut found that 28% of women with abnormal mammograms had not achieved definitive diagnosis by three months.¹⁴ A New York Academic health center reported a median diagnostic time of 20 days for women with abnormal mammograms.¹⁵ Academic health centers in Los Angeles and Connecticut reported that 30% of women with breast abnormalities did not complete appropriate work-up within four months at the former¹⁶ and median time to breast cancer diagnosis was 61 days in the later.¹⁷

While studies of delay have been conducted in a variety of patient populations, there have been relatively few studies conducted in community-based health centers, so outcomes for this setting are uncertain. Community health centers, including federally qualified health centers, and other free or low-costs medical clinics, provide primary care to a high proportion of historically or medically underserved patients.

The Moffitt Cancer Center Patient Navigation Research Program (Moffitt PNRP) is one of nine sites participating in the national Patient Navigation Research Program, a program testing the effectiveness of patient navigators.¹⁸ Baseline data from the Moffitt PNRP provided a unique opportunity to explore timeliness of diagnostic evaluation in community health centers serving medically underserved populations in the Tampa Bay area of Florida. We conducted a retrospective medical record review of people who had breast or colorectal cancer-related abnormalities to determine timeliness of diagnostic evaluation and predictors of timely evaluation. We hypothesized that delayed diagnosis would be more common in racial/ethnic minorities, people who lacked health insurance, and people who were non-English speaking.

Methods

The Moffitt PNRP is one site within a national multicenter study examining patient navigation.¹⁹ We approached health care organizations with primary care clinics that targeted health disparities populations in the Tampa Bay area. Five health care organizations having 12 clinics agreed to participate. One clinic was unable to provide baseline data. The remaining 11 clinics provided data about patients who had received care in the year prior to the implementation of the patient navigation study (before any intervention activities took place).

Subjects were eligible for the Moffitt PNRP if they had a potential breast or colorectal cancer-related abnormality. Breast subjects were eligible if they had an abnormality on clinical breast examination, mammography, ultrasound, or magnetic resonance imaging (MRI) that required referral for further evaluation. Colorectal subjects were eligible if they had any of the following abnormalities requiring referral for further evaluation: rectal bleeding in patients 30 years and older, positive screening fecal occult blood test (FOBT), palpable rectal mass, abnormal sigmoidoscopy, abnormal virtual colonoscopy, abnormal barium enema, or abnormal colonoscopy.

Study outcomes

The Moffitt PNRP had two primary outcomes. Among subjects that achieved a definitive diagnosis, the first outcome (defined as T1) was length of time (in days) between the initial cancer abnormality and the date of definitive diagnosis. Definitive diagnosis was defined as the point in time in which a cancer or non-cancer diagnosis was rendered and no further immediate evaluation was required. Definitive diagnosis could result from biopsy, additional imaging or other diagnostic tests, or by clinical assessment of a medical specialist. The second outcome was whether subjects had received a definitive diagnosis within the minimum follow-up period of six months, treated as a dichotomous variable.

To assess these outcomes at baseline, each clinic systematically identified all subjects with breast or colorectal-related abnormalities in the year prior to the clinic beginning participation in the Moffitt PNRP. Abnormalities occurred during the time period from February 2005 to June of 2008. Clinical follow-up of identified abnormalities occurred through February 2010. Participating clinics searched for eligible subjects using a variety of methods including mammography/FOBT screening logs, information from referral coordinators, and computer searches of relevant diagnostic codes. Clinics thus identified 318 patients having either a breast or colorectal cancer-related abnormality. From this sample we excluded one patient who had both breast and colorectal abnormalities coexisting.

A team of trained research coordinators reviewed subjects' medical records using a standardized medical record abstraction form that recorded sociodemographic information, medical information on comorbidity, family history of cancer, and clinical details of the initial cancer-related abnormality and subsequent evaluation. The data elements to be collected were defined in a data dictionary developed by the national PNRP program.¹⁸ All subjects were specified to have at least six months of follow-up; therefore, medical records were abstracted at least six months after the initial cancer-related abnormality. For those subjects who had not yet achieved a definitive diagnosis, medical records were re-abstracted at approximately six-month intervals until a definitive diagnosis could be verified or until the conclusion of the study.

For 313 of the eligible subjects (98.7%), medical records abstractions were able to determine whether the initial clinical abnormality had reached diagnostic resolution. For the 241 subjects that reached diagnostic resolution, we were also able to determine the exact time (in days) from screening abnormality to diagnostic resolution (T1) for 236 (98%). T1 could not be determined for the remaining five subjects because the exact date of resolution could not be determined from the chart review. There were eight subjects who did not reach resolution but had less than 180 days of follow-up. Reasons for incomplete follow-up include the patient moving (n=4) and inability to obtain patient's chart (n=4).

Statistical analysis

Our analytic approach was based on the cluster-randomized design in which clinics were initially randomized and patients may be clustered by clinic. The continuous outcome, time to definitive resolution (T1), was not normally distributed and was therefore log transformed to facilitate analysis. We were unable to analyze T1 using a generalized linear model with a log link due to a lack of model convergence. We instead used the general (for continuous outcome)/generalized (binary outcome) linear mixed effects model to examine outcomes by sociodemographic and clinical characteristics. The binary outcome, resolution in percentage, is summarized with its 95% confidence interval based on the exact binomial distribution. To account for the expected positive intraclass correlation among patients within a clinic, the clinic nested within intervention arm was included in the models as a random effect.

We examined the following variables as potential explanatory factors of outcomes in univariate and multivariable analyses: age (18–39; 40–49; 50–59; 60+ years), gender, race/ethnicity (White non-Hispanic, non-White), language (English, non-English), marital status (married, not-married), insurance (some form of health insurance, uninsured), cancer site (breast, colorectal), family history of either breast or colorectal cancer, and Charlson Comorbidity index score (0, 1, 2+). The Charlson Comorbidity Index is a weighted index of 19 selected categories of disease that have been found to be associated with mortality and other important health outcomes.²⁰ Because of large amounts of missing data, education, income, and employment were not included in multivariable analyses. Analyses were conducted using SAS version 9.2 (SAS Inc., Cary N.C.).

Results

Demographic characteristics of the sample are presented in Table 1. Most of the subjects were eligible because of a breast-related abnormality, and as a result, there was a preponderance of females in the study. A substantial number of subjects were non-English speaking, and many had either no form of health insurance, or Medicaid or County-provided insurance. Information on level of education and income were frequently missing from medical records, but when available, generally indicated low socioeconomic status.

The most common colon-related abnormalities were either rectal bleeding (44%) or abnormalities on FOBT (55%). In most cases the definitive test pursued was colonoscopy (82%), with other tests (e.g., sigmoidoscopy, barium enema) less commonly performed. For subjects with a breast abnormality, most had either an abnormality on clinical breast exam (62%) or an abnormality on screening mammography (36%). For subjects with a breast abnormality, the most common diagnostic test pursued was additional imaging (ultrasound [43%] or diagnostic mammography [38%] with 19% requiring a breast biopsy to reach diagnostic resolution of the breast abnormality.

The median follow-up period for subjects was 345 days (mean: 512, standard deviation [SD]: 541). There were 241 (77%) subjects who reached clinical resolution at some point during the follow-up period and 201 (64%) subjects who reached resolution within 180 days of their initial abnormality. The proportion of patients reaching diagnostic resolution within 180 days varied among the 11 clinics ranging from a low of 33.3% to a high of 91.3% ($p < .001$ for differences among clinics). Table 2 describes the likelihood of achieving diagnostic resolution by subject characteristics. In bivariable analysis that accounted for clustering of subjects by clinic, only cancer site was significantly associated with resolution. Subjects with breast abnormalities were more likely to achieve definitive diagnosis.

Table 3 presents multivariable predictors of diagnostic resolution within 180 days. Breast patients had more than twice the odds (adjusted odds ratio: 2.8, 95% Confidence Interval: 1.38–5.86, $p = .005$) of reaching diagnostic resolution within 180 days compared with patients with colorectal abnormalities. No other patient characteristics were statistically significant predictors of diagnostic resolution.

For the 241 subjects who reached diagnostic resolution, the median time to diagnostic resolution was 37 days (mean: 85 days, SD: 130 days). Table 4 presents patient characteristics and time to diagnostic resolution. Contrary to our hypotheses, no clinical or sociodemographic characteristic was significantly related to diagnostic resolution time. In multivariable analyses predicting the outcome log of time from screening abnormality until diagnostic resolution, no clinical or sociodemographic variable was a statistically significant predictor (data not presented). There was evidence of clustering of outcomes by clinic in this analysis (ICC=0.12).

We also explored whether outcomes were associated with the nature of the initial clinical abnormality (screening abnormality versus a clinical symptom). The type of clinical abnormality was not associated with the likelihood of diagnostic resolution for either colorectal patients (percent reaching resolution: rectal bleeding: 57%, abnormal FOBT: 34%, $p = .37$) or breast patients (percent reaching resolution: abnormal clinical breast exam: 68%, abnormal mammogram: 76%, $p = .84$). For breast patients who reached resolution, however, the definitive test required was predictive of time needed to reach diagnostic resolution (median time in days; biopsy needed 80 days, additional imaging needed 31 days, $p = .001$).

Discussion

We found that more than one-third of people with potential cancer-related abnormalities had not yet reached a definitive diagnosis after six months of follow-up. Colorectal cancer related abnormalities were especially problematic with less than half achieving a definitive diagnosis by six months. There were surprisingly few patient-level predictors of either having achieved diagnostic resolution or of the timeliness of diagnostic resolution.

A number of previous studies have documented incomplete or delayed evaluation of cancer-related abnormalities. Studies differed in their settings and the patient populations assessed (e.g., non-cancer patients vs. patients ultimately diagnosed with cancer). In addition studies varied in their definition of delayed diagnosis (e.g., 60 days, 90 days, or 180 days).

The median times to diagnostic resolution were 34 days for women with abnormal mammograms and 44 days with palpable abnormalities within a state-funded free breast screening program in South Carolina.²¹ A study of women with breast-related abnormalities attending New York City public clinics found that 28% had not achieved a definitive diagnosis by six months, similar to our findings.²² Battaglia and colleagues reported a median time to diagnosis of 27 days for women with abnormal mammograms diagnosed at CHCs in Boston and found that 8% of women had not completed diagnostic evaluation by six months.²³

A number of studies have assessed diagnostic follow-up within the CDC Breast and Cervical Cancer Treatment Program (BCCTP). One study found that 39% of people with breast abnormalities had not achieved definitive diagnosis by 90 days.²⁴ Another found that 30% of women did not reach diagnostic resolution by 60 days.²⁵ Another CDC BCCTP program reported a median diagnostic time of 65 days for women having an abnormal mammogram.²⁶ Richardson and colleagues examined time to diagnosis for women diagnosed with breast cancer within the National CDC BCCTP program during the years 2001–2005. Median time to diagnosis was 23 days, with 20% taking longer than 60 days. Caplan and colleagues reported similar outcomes for women diagnosed with breast cancer within the national CDC BCCTP during the time period 1991–1995 (median time to diagnosis 32 days, 22% of women longer than 60 days). It is important to note that many of these studies examined women diagnosed with breast cancer, rather than non-cancer abnormalities as in our study. Additionally, the CDC program guarantees that women screened are eligible for follow-up care and programs have defined resources to help facilitate timely follow-up, resources that are not routinely available at all CHCs.

For 23% of our sample, we could find no evidence in the medical record that cancer-related abnormalities had been definitively evaluated, despite follow-up that averaged more than one year. Studies comparable to ours, however, have also documented sizeable percentages of women (9% to 30%) having breast-related abnormalities that had no medical record evidence of completing diagnostic evaluation.^{11, 12, 26–28} For those people who did achieve a definitive diagnosis, our study found a median time to diagnosis of 37 days, which is again well within the range reported by other studies examining care of disadvantaged populations.^{13, 17, 21, 23, 26, 29} Diagnostic delays greater than six months have been associated with worse survival for women diagnosed with breast cancer.³⁰

Previous studies have reported a number of characteristics that were predictive of more timely diagnosis of breast abnormalities. These characteristics include having breast symptoms,^{29, 31, 32} having an abnormal mammogram,^{11, 22, 31} having higher socioeconomic status,^{12, 33} being in better health,¹² having a family history of cancer,^{12, 16, 32} having

adequate health insurance,^{13, 15, 34} and being English-speaking.²⁶ African American and Hispanic women are more likely to have diagnostic delays.^{14–17, 21, 25, 29, 35, 36}

It is noteworthy that our study found very few patient-level predictors of diagnostic resolution or timeliness of diagnosis. There are a number of possible reasons for the lack of patient-level predictors of delay. First, the study population was, for the most part, uniformly disadvantaged in regard to socioeconomic status and other demographic characteristics. This may have limited our ability to assess outcomes across the entire spectrum of these factors by restricting variability. In addition, all patients evaluated were being seen in community health centers and may have been homogeneous in their ability to effectively access and navigate the health care system. Disparities may have been absent within CHCs because clinics were able to provide uniform care to all patients served. It is likely that disparities result more from having differing access to sources of care like CHCs, rather than differential care with a clinic. A similar study conducted in Boston community health centers also found few patient-level predictors of timely follow-up after abnormal mammogram or Pap tests.²³

We found that diagnostic evaluations were more likely to be incomplete for colorectal-related abnormalities compared to breast abnormalities. This may be the result of greater difficulty obtaining diagnostic colonoscopy than encountered when obtaining diagnostic breast imaging. Colonoscopy is much more expensive than most breast imaging tests, which poses a significant financial barrier for those who are uninsured or underinsured. Fewer studies have examined appropriate follow-up of colorectal cancer-related abnormalities. Studies have found that almost 50% of people do not receive appropriate diagnostic evaluation after an abnormal FOBT screening test.^{37–39}

Our study focused primarily on patient characteristics, but there are a number of reasons that diagnostic evaluation can be delayed or not completed. Patient, provider, and health care system factors can all contribute to delays.⁴⁰ Patients can contribute to delays because of fear, denial, or other health beliefs.^{24, 41, 42} Providers can contribute to delays if patients are falsely reassured about findings,⁴³ or if they fail to pursue appropriate diagnostic testing.^{37, 38, 44} Uncertainty about how and where to receive diagnostic care can also contribute to delays,¹⁶ while the presence of a usual health care provider or primary care provider helps minimize delays.^{13, 14} Health care system factors, such as inadequate health insurance or access to care also contribute to diagnostic delays.³⁴

This study had a number of limitations that should be considered when interpreting our findings. First, the sampling strategy of the study was clustered by clinic. Our analysis method appropriately took into account the clustered design but resulted in reduced statistical power to assess relationships. In addition, outcomes were determined solely by chart review, and it is possible that some subjects had completed evaluations that were not documented in the chart. We found that patient information relevant to this study (education and income) was not routinely recorded in the medical record. As this study was retrospective, we did not attempt to get additional data directly from patients or providers to shed light on why diagnostic tests were not performed or delayed. Finally this study was conducted among community health center patients in the Tampa Bay region and may not be representative of other populations or settings of care.

In conclusion, we found that diagnostic evaluations were often either not completed or were delayed after a cancer-related abnormality was discovered. This issue was more pronounced for colorectal-related abnormalities, perhaps because of the difficulty obtaining a colonoscopy. We found no evidence of disparities in these outcomes, however, due to patient race/ethnicity, insurance status, or spoken language. Further research is needed to

understand the patient, provider, and health care system factors that contribute to diagnostic delays. Whether patient navigators can eliminate or reduce these delays is uncertain but is the focus of future studies.

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Table 1

Demographic and Clinical Characteristics N = 317

	N	Percentage
Age, years		
Mean (SD)	47	(13.2)
Min - Max	18–79	
Gender		
Female	282	89.0
Male	35	11.0
Race/Ethnicity		
Black, non-Hispanic	64	20.6
White, non-Hispanic	130	41.9
Hispanic/Latina	108	34.8
Mixed/Other, non-Hispanic	8	2.6
Language		
English	224	71.3
Non-English	90	28.7
Marital status		
Married	113	38.6
Non married	180	61.4
Education level		
8th grade or less	31	25.6
Some high school	19	15.7
High School diploma (or equivalent)	50	41.3
Beyond High School [*]	21	17.4
Income		
Less than \$10,000	111	53.9
\$10,000 to \$19,999	67	32.5
\$20,000 to \$29,999	22	10.7
\$30,000 or more	6	2.9
Employment		
Employed full-time	51	24.5
Not employed full-time	157	75.5
Insurance status		
Private insurance	44	14.1
Medicaid (no private or Medicare)	72	23.2
Medicare (no private)	41	13.2
Other government insurance	66	21.2
Uninsured	88	28.3
Clinical abnormality		
Breast	237	74.8
Colorectal	80	25.2

	N	Percentage
Family history of breast or colorectal cancer		
Yes	56	17.7
No	261	82.3
Charlson Comorbidity Index		
0	256	80.8
1	41	12.9
2+	20	6.3

*
Some college/vocational after high school, Associate degree, or College graduate

Table 2

Association between Demographic and Clinical Factors and Diagnostic Resolution by 180 Days

	Cases Resolved	Total Cases	Percentage (95% CI)	P-value
Age Group				
18–39	50	88	56.8 (46.5–67.2)	0.10
40–49	56	93	60.2 (50.3–70.2)	
50–59	49	74	66.2 (55.4–77.0)	
60+	43	53	81.1 (70.6–91.7)	
Gender				
Female	185	278	66.5 (61.0–72.1)	0.15
Male	16	35	45.7 (29.2–62.2)	
Race/Ethnicity				
Black, non-Hispanic	41	62	66.1 (54.3–77.9)	0.11
White, non-Hispanic	79	128	61.7 (53.3–70.1)	
Hispanic/Latina	72	108	66.7 (57.8–75.6)	
Mixed/Other, non-Hispanic	2	8	25.0 (0 – 55.0)	
Language				
English	140	220	63.6 (57.3–70.0)	0.10
Non-English	58	90	64.4 (54.6–74.3)	
Marital Status				
Married	69	113	61.1 (52.1–70.1)	0.59
Non-married	115	176	65.3 (58.3–72.4)	
Education Level				
8 th grade or less	19	31	61.3 (44.1–78.4)	0.35
Some High School	15	19	78.9 (60.6–97.3)	
High School diploma	32	48	66.7 (53.3–80.0)	
Beyond High School*	14	20	70.0 (49.9–90.1)	
Income				
Less than \$10,000	74	110	67.3 (58.5–76.0)	0.55
\$10,000 – \$19,999	35	67	52.2 (40.3–64.2)	
\$20,000 – \$ 29,999	13	22	59.1 (38.5–79.6)	
\$30,000 or more	4	6	66.7 (28.9–100)	
Employment				
Employed full-time	28	51	54.9 (41.2–68.6)	0.57
Not Employed full-time	95	155	61.3 (53.6–69.0)	
Insurance Coverage				
Private Insurance	27	44	61.4 (47.0–75.8)	0.81
Medicaid (no private or Medicare)	38	69	55.1 (43.3–66.8)	
Medicare (no private)	27	40	67.5 (53.0–82.0)	
Other Government insurance	51	66	77.3 (67.2–87.4)	
Uninsured	55	88	62.5 (52.4–72.6)	
Clinical Abnormality				

	Cases Resolved	Total Cases	Percentage (95% CI)	P-value
Breast	166	234	70.9 (65.1–76.8)	0.002
Colorectal	35	79	44.3 (33.3–55.3)	
Family History of Breast or Colorectal Cancer				
No	168	257	65.4 (59.6–71.2)	0.59
Yes	33	56	58.9 (46.0–71.8)	
Charlson Comorbidity Index				
0	159	253	62.8 (56.9–68.8)	0.75
1	30	41	73.2 (59.6–86.7)	
2+	12	19	63.2 (41.5–84.8)	

* Some college/vocational after high school, Associate degree, or College graduate

Table 3

Multivariable Analysis of Diagnostic Resolution within 180 Days

	Adjusted Odds Ratio	95% Confidence Interval		P-value
Age (in years) *	1.01	0.99	1.03	0.30
Gender				
Male	1.00 (referent)			
Female	1.06	0.40	2.79	0.90
Race/Ethnicity				
White, non-Hispanic	1.00 (referent)			
Non-white	1.09	0.55	2.16	0.80
Language				
Non-English	1.00 (referent)			
English	1.79	0.76	4.19	0.18
Marital Status				
Non-married	1.00 (referent)			
Married	0.90	0.50	1.62	0.73
Insurance Status				
Insured	1.00 (referent)			
Uninsured	1.15	0.59	2.27	0.68
Clinical Abnormality				
Colorectal	1.00 (referent)			
Breast	2.84	1.38	5.86	0.005
Family History of Breast or Colorectal Cancer				
No	1.00 (referent)			
Yes	0.94	0.46	1.91	0.85
Charlson Comorbidity				
0	1.33	0.40	4.36	0.77
1	1.66	0.41	6.69	
2+	1.00 (referent)			

* Odds ratio reflects the change in odds of diagnostic resolution with each additional year of age.

Table 4

Factors Associated with Time to Diagnostic Resolution

Age Group	Median Time (days)	Minimum, Q1^{**}, Q3^{***}, Maximum (days)	P-value
18–39	18	0 6 55 590	0.02
40–49	62	0 26 103 699	
50–59	35	0 18 93 707	
60+	42	0 16 72 475	
Gender			
Male	25	0 8 44 136	0.42
Female	40	0 14 91 707	
Race/Ethnicity			
White, Non-Hispanic	35	0 14 92 707	0.75
Non-white	36	0 14 86 699	
Language			
Non-English	45	0 21 103 699	0.61
English	35	0 14 89 707	
Marital Status			
Non-married	43	0 14 97 707	0.43
Married	35	0 17 88 699	
Insurance Status			
Insured	36	0 15 94 707	0.73
Uninsured	41	0 12 82 699	
Clinical Abnormality			
Colorectal	67	0 21 125 699	0.13
Breast	35	0 13 82 707	
Family History of Breast or Colorectal Cancer			
No	35	0 14 89 699	0.19
Yes	55	1 28 89 707	
Charlson Comorbidity			
0	35	0 14 89 699	0.97

	Median Time (days)	Minimum, Q1** , Q3** , Maximum (days)	P-value
1	57	0 25 89 707	
2+	43	0 25 107 470	

* P-values for comparisons of log resolution times adjusted for clustering by clinics

** Q1 and Q3 refer to first and third quartiles respectively