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TO: Graham Barr, John Hankinson, and Diane Catellier

COPY Lisa Lavange, Gerardo Heiss, Franklyn Gonzalez

FROM: Marston Youngblood, HCHS/SOL Coordinating Center

DATE: February 9, 2009

RE: HCHS/SOL Management Report, January 2009 Spirometry Tables

Attached is an updated version of table 4.11 (page 1) from the last OSMB report that we have formatted so that you could monitor the performance of the HCHS/SOL field centers as they follow the spirometry protocol. The table breaks out information on airflow obstruction and bronchodilator response on the subset of the 1890 good quality studies that are now in the database. The trend seen since early in the study that there are more post-BD studies expected than performed is still true. Those differences between observed and expected studies are concentrated in two centers, the Bronx and Chicago.

In response to your request that we look at the refusals for the post-BD spirometry we tabulated the values for the bronchodilator status code (variable PRBA52) that is available from the data transfer file (see page 2). In the subset of 177 participants with a good quality spirometry and for whom a post-BD test was expected there were 37 refusals, 4 prior significant problems with a puffer, and 14 participants excluded from a post-BD test. We have also included a listing for your review of 19 cases where the status code indicator has a value of "exclude" or "refused" (see pages 4-5), but the FEV<sub>1</sub>/FVC ratio is above the study criteria for performing a post-BD test. Those 19 cases may need to be investigated for results inconsistent with the spirometry status code.

The disparity in number of participant refusals reported by field center appears to be driving the difference for observed vs. expected post-BD tests. There is an eightfold difference from the most to least compliant field centers. Perhaps the QC committee could find a way to work with technicians to overcome barriers to this procedure. Otherwise, we are going to permanently have a data acquisition bias introduced for these measurements in HCHS/SOL.

**HCHS/SOL Management Report, January 2009**

**Not for Publication or other Distribution**

**Table 4.11a Post-Bronchodilator Pulmonary Function Test Results by Center**

Pulmonary Function Measurement	Bronx (N=483)		Chicago (N=493)		Miami (N=417)		San Diego (N=533)		Overall (N=1926)	
	N	%	N	%	N	%	N	%	N	%
<b>Useable Studies</b>	466	96.5	484	98.2	415	99.5	525	98.5	1890	98.1
<b>Airflow Obstruction</b>	40	8.6	54	11.2	48	11.6	35	6.7	177	9.4
<b>Useable post-bronchodilator studies</b>	19	3.9	24	4.9	45	10.8	34	6.4	122	6.3
<b>COPD (FEV1/FEC &lt; 0.70 after BD)</b>	11	57.9	9	37.5	24	53.3	19	55.9	63	51.6
<b>Bronchodilator responsive</b>	3	15.8	2	8.3	4	8.9	3	8.8	12	9.8

Based on analysis files created on January 16, 2009.

## Broncholidator Response Codes (PRBA52) by Field Center Valid Spirometry Only

### The FREQ Procedure

Table of PRBA52 by center						
PRBA52(Bronchodilator Response Code (PRBA52))	center(Field Center)					
Frequency						
Percent						
Row Pct						
Col Pct	B	C	M	S	Total	
<b>PRB study Obtained</b>	413	434	368	482	1697	
	21.85	22.96	19.47	25.50	89.79	
	24.34	25.57	21.69	28.40		
	88.63	89.67	88.67	91.81		
<b>No, or don't know to significant problems with puffer</b>	19	27	38	35	119	
	1.01	1.43	2.01	1.85	6.30	
	15.97	22.69	31.93	29.41		
	4.08	5.58	9.16	6.67		
<b>Confirmed significant problems with puffer</b>	0	1	1	2	4	
	0.00	0.05	0.05	0.11	0.21	
	0.00	25.00	25.00	50.00		
	0.00	0.21	0.24	0.38		
<b>Exclude subject</b>	6	5	6	2	19	
	0.32	0.26	0.32	0.11	1.01	
	31.58	26.32	31.58	10.53		
	1.29	1.03	1.45	0.38		
<b>Refused test</b>	28	17	2	4	51	
	1.48	0.90	0.11	0.21	2.70	
	54.90	33.33	3.92	7.84		
	6.01	3.51	0.48	0.76		
<b>Total</b>	466	484	415	525	1890	
	24.66	25.61	21.96	27.78	100.00	

## Broncholidator Response Codes (PRBA52) by Field Center for Valid Spirometry and Airflow Obstruction

### The FREQ Procedure

Table of PRBA52 by center						
PRBA52(Bronchodilator Response Code (PRBA52))	center(Field Center)					
Frequency						
Percent						
Row Pct						
Col Pct	B	C	M	S	Total	
<b>PRB study Obtained</b>	4	8	6	1	19	
	2.26	4.52	3.39	0.56	10.73	
	21.05	42.11	31.58	5.26		
	10.00	14.81	12.50	2.86		
<b>No, or don't know to significant problems with puffer</b>	17	23	34	29	103	
	9.60	12.99	19.21	16.38	58.19	
	16.50	22.33	33.01	28.16		
	42.50	42.59	70.83	82.86		
<b>Confirmed significant problems with puffer</b>	0	1	1	2	4	
	0.00	0.56	0.56	1.13	2.26	
	0.00	25.00	25.00	50.00		
	0.00	1.85	2.08	5.71		
<b>Exclude subject</b>	3	5	5	1	14	
	1.69	2.82	2.82	0.56	7.91	
	21.43	35.71	35.71	7.14		
	7.50	9.26	10.42	2.86		
<b>Refused test</b>	16	17	2	2	37	
	9.04	9.60	1.13	1.13	20.90	
	43.24	45.95	5.41	5.41		
	40.00	31.48	4.17	5.71		
<b>Total</b>	40	54	48	35	177	
	22.60	30.51	27.12	19.77	100.00	

**Bronchodilator Response Codes (PRBA52) by Field Center  
Valid Spirometry and Excluded with Airflow\_obstruction^=1**

	FEV <sub>1</sub> (mL)	FVC(mL)	FEV <sub>1</sub> /FVC	LLN(%)
STUDY ID	PRBA29	PRBA25	prba29_prba25	prba46_
B5000084	3252	4391	0.74061	70.4
B5000844	2392	2680	0.89254	73.8
B5002540	1763	2151	0.81962	67.5
M7007804	2259	2953	0.76498	71.4
S8004732	2017	2443	0.82562	70.0

The IDs above have a bronchodilator status code suggesting that they should be excluded from the post-BD test, but **FEV<sub>1</sub>/FVC** is above criteria for the test.

**Bronchodilator Response Codes (PRBA52) by Field Center  
Valid Spirometry and Refused test with Airflow\_obstruction^=1**

STUDY ID	FEV <sub>1</sub> (mL)	FVC(mL)	FEV <sub>1</sub> /FVC	LLN(%)
	PRBA29	PRBA25	prba29_prba25	prba46_
B5000010	2897	3309	0.87549	75.6
B5000492	1543	1676	0.92064	67.5
B5001007	2322	2873	0.80821	72.5
B5001366	1450	1619	0.89561	73.2
B5001813	2679	2888	0.92763	79.0
B5002712	2808	3132	0.89655	71.8
B5004218	3758	4369	0.86015	71.1
B5004624	3459	4026	0.85917	70.0
B5005459	2838	3286	0.86366	66.9
B5005471	2297	3101	0.74073	67.2
B5010224	2117	2671	0.79259	71.8
B5012716	2120	2736	0.77485	71.1
S8002131	2740	3216	0.85199	72.5
S8010782	966	1202	0.80366	66.9

The IDs above have a bronchodilator status code suggesting that they refused the post-BD test, but FEV<sub>1</sub>/FVC is above criteria for the test.