TO: HCHS/SOL Quality Control Committee

CC: Kant Bangdiwala and Krista Perreira, SOL-Youth PI
   Yasmin Mossavar-Rahmani, SOLNAS PI
   Sanjay Patel, Sueño PI
   Carlos Rodriguez, ECHO-SOL PI

FROM: Daniela Sotres-Alvarez, HCHS/SOL Coordinating Center
DATE: November 27, 2012

RE: HCHS/SOL Quality Control Report, November 2012

MEMORANDUM

This report includes QC Status Reports for four HCHS/SOL Ancillary Studies:

- SOL-Youth

- Nutrition & Physical Activity Assessment Study (SOLNAS)

- Sueño Study (Sleep)

- ECHO-SOL

volumes, and diastolic function parameters). Greater than 85% of studies have 90% of all measures obtained. ECHO-SOL is currently ahead of schedule on its data acquisition and data analysis. Currently, 770 (82%) studies have been measured with full data interpretation.

B3. CERC QC Reproducibility Report
In blinded fashion, we assessed the CERC inter-reader reliability for the variables measured to derive our primary outcomes measures. Thirty-five echocardiograms were selected at random and measurements performed by the ECHO-SOL technician reader were compared to repeat measurements by an experienced echocardiographer for the same study. Intra-class correlations (ICC) and technical error of measurement (TEM) are summarized in Table 2. Every 3 months, we will repeat blinded reads of 5% of studies performed during that period.

B4. Clinical Alerts / Incidental Findings Report
All ECHO-SOL participants receive a summary report of their echocardiograms in both English and Spanish so that even mild abnormalities that are not significant enough to generate a clinical alert are communicated to the participant. Currently, 687 participant reports have been sent across all four sites. The remaining studies are currently under review. The mean length of time from routine study receipt by CERC to routine participant report sent to the site is 52 days. Twenty participants (2.1% of the overall cohort), were found to have a non-critical clinical alert findings (see Table 3). There have been no critical clinical alerts. All participants were offered and received an outpatient medical referral, and one could not be contacted for follow up. Fifty-percent of the non-critical alerts were first-line alerts at the FC level and full clinical echo reports were sent within 48 hours, per study protocol.

Table 1. Screening & Recruitment Breakdown by Site and Hispanic subgroup

Category	Bronx (N= 275)		Chicago (N= 346)		Miami (N= 245)		San Diego (N= 451)		Overall (N= 1317)	
	n	%	n	%	n	%	n	%	n	%
1. Recruitment										
a. Unable to Contact, status unknown	16	5.8	99	28.6	16	6.5	110	24.4	241	18.3
b. Ineligible	13	4.7	5	1.4	2	0.8	23	5.1	43	3.3
c. Refuses to Participate	9	3.3	21	6.1	4	1.6	61	13.5	95	7.2
d. Agrees to Participate	237	86.2	221	63.9	223	91	257	57	938	71.2
3. Age Distribution										
a. 45-54	93	40.6	87	41.2	87	39.4	116	45.3	383	41.8
b. 55-64	96	41.9	83	39.3	112	50.7	105	41	396	43.2
c. 65+	40	17.5	40	19	22	10	35	13.7	137	14.9
Missing	0	0	1	0.5	0	0	0	0	1	0.1
4. Hispanic/Latino Background										
a. Central/South American	28	12.2	65	30.8	77	34.8	0	0	170	18.5
b. Cuban	0	0	1	0.5	144	65.2	0	0	145	15.8
c. Dominican	111	48.5	0	0	0	0	0	0	111	12.1
d. Mexican	0	0	69	32.7	0	0	256	100	325	35.4
e. Puerto-Rican	90	39.3	73	34.6	0	0	0	0	163	17.8
h. Other	0	0	3	1.4	0	0	0	0	3	0.3
5. Gender										
a. Male	76	33.2	76	36	91	41.2	83	32.4	326	35.6
b. Female	153	66.8	135	64	130	58.8	173	67.6	591	64.4

Table 2. QC Inter-Reader Variability Breakdown

Measure	N	TEM Rel %		ICC		Pearson Correlation	
		Inter	Intra	Inter	Intra	Inter	Intra
EDV 2	35	4.4	4.0	0.98	0.99	0.98	0.99
EDV 4	35	5.0	2.2	0.98	1.00	0.98	1.00
EF 2	35	6.5	3.0	0.80	0.96	0.82	0.96
EF 4	35	7.2	3.1	0.75	0.95	0.77	0.96
ESV 2	35	6.1	5.8	0.99	0.99	0.98	0.99
ESV 4	35	6.9	4.8	0.98	0.99	0.98	0.99
IVSD	35	8.2	6.9	0.80	0.87	0.85	0.88
LADIM *	35	3.5	1.7	0.91	0.98	0.97	0.98
LAV 2	35	6.6	4.3	0.97	0.99	0.97	0.99
LAV 4 **	35	5.4	3.4	0.97	0.99	0.98	0.99
LVIDD	35	2.8	1.5	0.94	0.98	0.96	0.98
LV Mass	35	7.5	5.5	0.94	0.97	0.96	0.97
LVPWD	35	7.5	4.0	0.83	0.94	0.88	0.95
Notes:		* 33 cases available for inter and intra reader reliability					
		** 34 cases available for inter-reader reliability					

technical error of measurement (TEM) (standardized measurement variability) for continuous variables. "Agreement" between readings was defined as differences of <10%, "borderline" agreement as differences of 11-15%, and "disagreement" as differences >15%.

intraclass correlation (ICC). ICC was interpreted as follows: 0-0.2 indicates poor agreement: 0.3-0.4 indicates fair agreement; 0.5-0.6 indicates moderate agreement; 0.7-0.8 indicates strong agreement; and >0.8 indicates almost perfect agreement.

Table 3. Clinical Alerts by type

non_critical_Clinical Alert type	Frequency
1. Moderate or greater mitral regurgitation	4
2. Moderate or greater mitral stenosis	1
3. Moderate or greater obstructive lesions of the LVOT, including AS, HCOM	1
4. Moderate or greater aortic regurgitation	1
6. Severe left or right ventricular enlargement.	1
7. Low ejection fraction or wall motion abnormality	12

Figure. Image Study Quality