



TO: HCHS/SOL Quality Control Committee
CC: Jianwen Cai, Wayne D Rosamond, Laura Loehr

FROM: Daniela Sotres-Alvarez, HCHS/SOL Coordinating Center
DATE: August 22, 2012

RE: HCHS/SOL Quality Control Report, August 2012

MEMORANDUM

This QC report includes:

1. Physical Activity (Actical) update

Summary

Tables and Figures

August 2012 PA tables were generated with data from 14,327 participants for which Actical date is the day before the clinic or maximum 3 days after, and was processed using the revised version of the SAS program (details in appendix).

Table 3.3 Average number of hours physical monitor was worn

Table 3.3c Adherence to wearing of physical activity monitor

Table 3.3.1 Average number of hours physical monitor was worn, by number of times the device has been used

Figure Average number of hours physical monitor was worn, by year of recruitment and number of times the device has been used

Appendix. Description of major update on Actical Data Processing and Cleaning in HCHS/SOL

2. Progress report for the ongoing QC for abstraction and adjudication of events.

FROM November 2011 OSMB Report:

- **Since 2010, it was observed that the amount of time an Actical device was used per day (in hours) and days of adherence usage (more than 10 hours per day) were decreasing over time (Table 3.3).** Overall, the Actical was worn on average (\pm SD) 9.3 \pm 4.4, 8.6 \pm 4.6 and 7.4 \pm 5.0 hrs/day the 1st, 2nd and 3rd year of recruitment respectively. Similarly, in all field centers (FC) the number of days' adherent decreased over time, from 3.9 \pm 2.2 to 3.1 \pm 2.4 adherent days. Early on, when this trend was noticed, efforts were made to check that the FC were following the stated protocol. Then, in 2011 the CC investigated possible causes for this trend including the effect of Actical aging, battery life, and calibration.
- We further observed that these two key compliance variables decreased significantly as the number of Actical previous uses increased (Table 3.3.1 and Figure 3.3.2). **In other words, the Acticals that were used more times provided less number of hours/day and adherent days.**

March – August 2012

The Coordinating Center (CC) revised the SAS program being used in HSHC/SOL to process, clean and summarize physical activity which was originally developed for another study that used the Actigraph. Although the program was adapted for HCHS/SOL study protocol which measured physical activity using the Actical, in July 2012 we discovered that there were three modifications that still needed to be done:

1. Adjust protocol deviations for start date and start time
2. Keep data (counts per epoch) between midnight and 6:00am
3. Remove strong duplicate check needed for the ActiGraph but not for the Actical (details in the appendix)

In addition, currently, there is undergoing data cleaning for 875 discrepancies between clinic visit date (considered to be the "on date") and Actical date.

August 2012 QC report includes data for 14,327 participants for which Actical date is the day before the clinic or maximum 3 days after, and has been processed using the revised version of the SAS program.

HCHS/SOL participants with Actical data

	Freq	%
HCHS/SOL cohort	16,415	100
Actical returned (valid ID)	15,202*	92.61
AUGUST 2012 QC REPORT*		
Actical date is the day before the clinic or maximum 3 days after	14,327	

*The CC is cleaning 875 dates

In conclusion, there are no trends over time in the amount of time an Actical device was used per day (in hours) and days of adherence usage (more than 10 hours per day) (Table 3.3). Furthermore, these key compliance variables did not decreased significantly as the number of Actical previous uses increased.

HCHS/SOL Report, August 2012 (PA_CNTS4)

**Table 3.3 Average number of hours physical monitor was worn
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		<u>Bronx</u> (N=3491)			<u>Chicago</u> (N=3374)			<u>Miami</u> (N=3677)			<u>San Diego</u> (N=3785)			<u>Overall</u> (N=14327)		
		<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>
<i>Daily hours of monitoring</i>	<i>Mar 08-Feb 09</i>	559	14.6	6.07	574	11.6	4.61	467	10.9	4.66	761	10.8	3.99	2361	12.0	5.06
	<i>Mar 09-Feb 10</i>	1081	15.7	5.12	1090	12.9	4.95	1167	10.7	4.31	1322	11.0	4.06	4660	12.5	5.00
	<i>Mar 10-Feb 11</i>	1400	16.2	5.07	1157	15.5	4.36	1541	11.0	4.28	1281	11.5	4.00	5379	13.4	5.04
	<i>Mar 11-June 11</i>	451	16.3	4.61	553	14.6	4.41	502	11.2	3.82	421	12.4	4.24	1927	13.6	4.69
	<i>Overall</i>	3491	15.8	5.23	3374	13.9	4.83	3677	10.9	4.28	3785	11.3	4.07	14327	12.9	5.02
<i>Days adherent*</i>	<i>Mar 08-Feb 09</i>	559	5.1	2.05	574	4.7	2.00	467	4.5	2.19	761	4.6	1.98	2361	4.7	2.06
	<i>Mar 09-Feb 10</i>	1081	5.6	1.83	1090	5.1	1.90	1167	4.4	2.15	1322	4.8	2.10	4660	4.9	2.05
	<i>Mar 10-Feb 11</i>	1400	5.8	1.82	1157	5.8	1.54	1541	4.5	2.11	1281	5.0	2.03	5379	5.2	1.98
	<i>Mar 11-June 11</i>	451	5.8	1.67	553	5.6	1.56	502	4.8	1.95	421	5.3	1.88	1927	5.4	1.80
	<i>Overall</i>	3491	5.6	1.86	3374	5.4	1.80	3677	4.5	2.11	3785	4.8	2.04	14327	5.1	2.01

*Days adherent defined as days with 10 or more hours of data collected
 Non compliance defined as 60 min of consecutive zero counts
 Created by HC058905 (AGH) on 14AUG12 12:39
 Based on data retrieved at the CC on August 13, 2012 (PA_CNTS4)

HCHS/SOL Report, August 2012 (PA_CNTS4)

Table 3.3c Adherence to wearing of physical activity monitor
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	<i>Bronx</i> <i>(N=3491)</i>		<i>Chicago</i> <i>(N=3374)</i>		<i>Miami</i> <i>(N=3677)</i>		<i>San Diego</i> <i>(N=3785)</i>		<i>Overall</i> <i>(N=14327)</i>	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
<i>Less than 1 day with 10 hrs of PA data</i>										
<i>Mar 08-Feb 09</i>	24	4.3	28	4.9	37	7.9	37	4.9	126	5.3
<i>Mar 09-Feb 10</i>	32	3.0	42	3.9	89	7.6	71	5.4	234	5.0
<i>Mar 10-Feb 11</i>	48	3.4	19	1.6	95	6.2	58	4.5	220	4.1
<i>Mar 11-June 11</i>	9	2.0	10	1.8	16	3.2	8	1.9	43	2.2
<i>Overall</i>	113	3.2	99	2.9	237	6.5	174	4.6	623	4.4
<i>1-3 days with 10 hrs of PA data</i>										
<i>Mar 08-Feb 09</i>	91	16.3	117	20.4	103	22.1	161	21.2	472	20.0
<i>Mar 09-Feb 10</i>	126	11.7	161	14.8	278	23.8	260	19.7	825	17.7
<i>Mar 10-Feb 11</i>	124	8.9	90	7.8	365	23.7	229	17.9	808	15.0
<i>Mar 11-June 11</i>	40	8.9	41	7.4	110	21.9	71	16.9	262	13.6
<i>Overall</i>	381	10.9	409	12.1	856	23.3	721	19.1	2367	16.5
<i>4 or more days with 10 hrs of PA data</i>										
<i>Mar 08-Feb 09</i>	444	79.4	429	74.7	327	70.0	563	74.0	1763	74.7
<i>Mar 09-Feb 10</i>	923	85.4	887	81.4	800	68.6	991	75.0	3601	77.3
<i>Mar 10-Feb 11</i>	1228	87.7	1048	90.6	1081	70.2	994	77.6	4351	80.9
<i>Mar 11-June 11</i>	402	89.1	502	90.8	376	74.9	342	81.2	1622	84.2
<i>Overall</i>	2997	85.9	2866	84.9	2584	70.3	2890	76.4	11337	79.1

Non compliance defined as 60 min of consecutive zero counts

Created by HC058906 (AGH) on 14AUG12 12:39

Based on data retrieved at the CC on August 13, 2012 (PA_CNTS4)

HCHS/SOL Report, August 2012 (PA_CNTS4)

Table 3.3.1 Average number of days adherent and hours physical monitor was worn, by number of times the device has been used

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		<u>Bronx</u> (N=3491)			<u>Chicago</u> (N=3374)			<u>Miami</u> (N=3677)			<u>San Diego</u> (N=3785)			<u>Overall</u> (N=14327)		
		<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>	<i>N</i>	<i>Mean</i>	<i>SD</i>
<i>Number of times actual is used</i>																
<i>Days adherent*</i>	<i>1-5</i>	1231	5.5	1.97	1156	4.9	1.96	1289	4.4	2.15	1343	4.8	2.03	5019	4.9	2.07
	<i>6-10</i>	887	5.6	1.80	877	5.4	1.76	881	4.6	2.08	969	4.8	2.06	3614	5.1	1.98
	<i>11-15</i>	589	5.8	1.70	544	5.7	1.53	625	4.5	2.18	688	4.8	2.05	2446	5.2	1.98
	<i>16-20</i>	380	5.6	1.91	414	5.6	1.62	472	4.6	2.03	486	4.9	2.06	1752	5.1	1.97
	<i>21-25</i>	225	5.7	1.86	267	5.7	1.62	285	4.5	2.02	223	5.0	1.96	1000	5.2	1.94
	<i>26-30</i>	131	5.8	1.79	96	5.5	1.69	97	4.7	2.09	66	5.0	1.95	390	5.3	1.92
	<i>31-35</i>	45	6.2	1.08	16	5.3	1.48	14	4.4	2.21	10	5.0	1.94	85	5.6	1.63
	<i>36-40</i>	3	6.7	0.58	4	6.3	0.50	14	4.7	2.27	-	-	-	21	5.3	2.03
<i>Daily hours of monitoring</i>	<i>1-5</i>	1231	15.2	5.50	1156	12.7	4.95	1289	10.8	4.38	1343	11.4	4.22	5019	12.5	5.06
	<i>6-10</i>	887	16.0	5.12	877	14.0	4.81	881	11.1	4.18	969	11.1	4.10	3614	13.0	5.01
	<i>11-15</i>	589	16.3	4.81	544	15.1	4.44	625	10.7	4.39	688	11.4	4.08	2446	13.2	5.01
	<i>16-20</i>	380	15.9	5.27	414	14.6	4.38	472	11.0	4.20	486	11.4	3.87	1752	13.0	4.86
	<i>21-25</i>	225	16.1	5.30	267	14.9	4.72	285	10.9	4.02	223	11.3	3.62	1000	13.2	4.98
	<i>26-30</i>	131	16.6	4.91	96	14.3	4.88	97	11.1	4.23	66	11.6	3.38	390	13.8	5.06
	<i>31-35</i>	45	17.4	3.58	16	14.1	4.57	14	11.6	4.73	10	11.6	4.69	85	15.2	4.79
	<i>36-40</i>	3	18.7	2.46	4	17.1	2.67	14	12.0	5.34	-	-	-	21	13.9	5.31

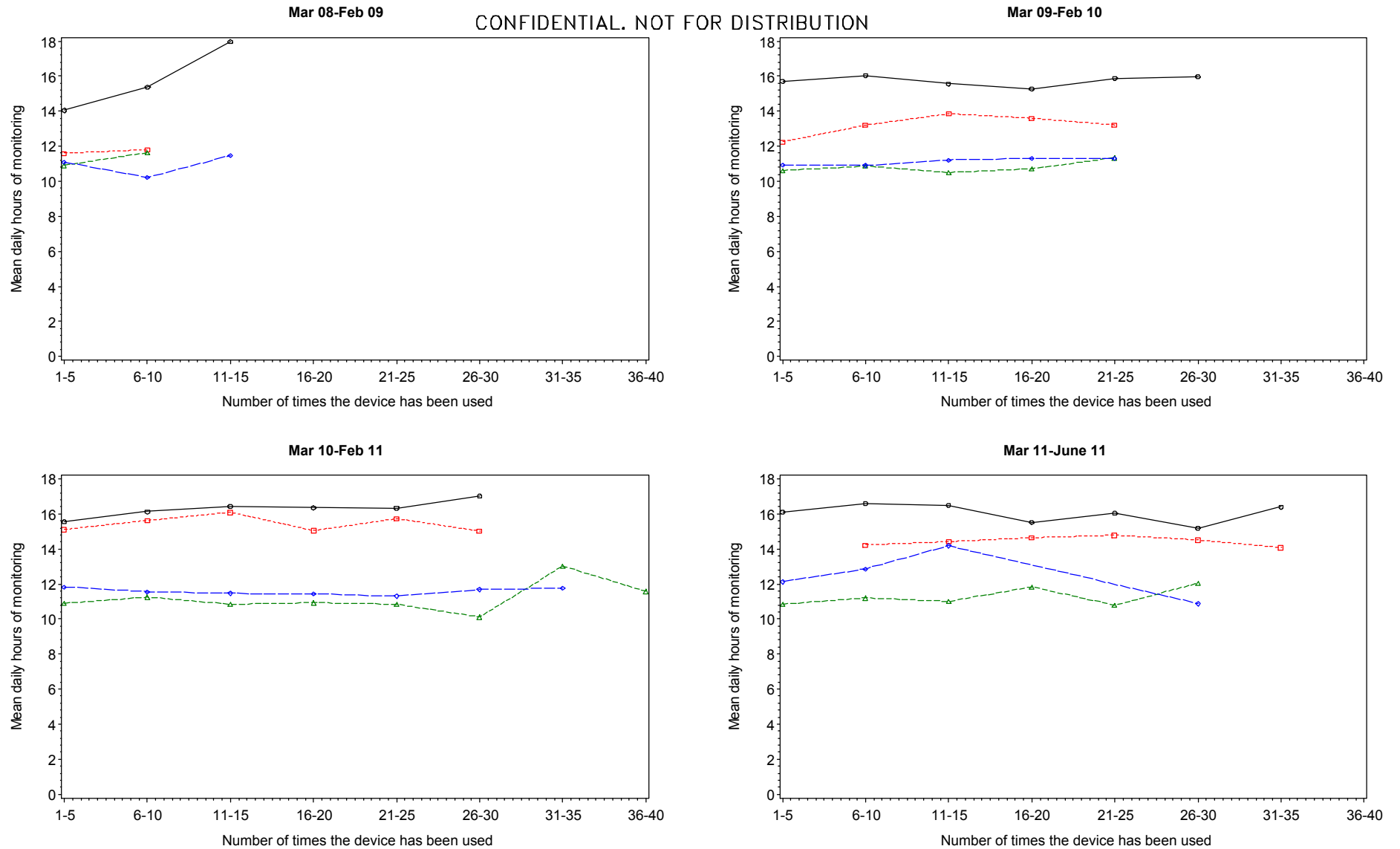
*Days adherent defined as days with 10 or more hours of data collected

Non compliance defined as 20 min of consecutive zero counts

Created by HC058907 (AGH) on 14AUG12 13:15

Based on data retrieved at the CC on August 13, 2012 (PA_CNTS4)

Average daily hours physical activity monitor worn, by center, year and number of times the device has been used*



Bronx=BLACK CIRCLE, Chicago=RED SQUARE, Miami=GREEN TRIANGLE, San Diego=BLUE DIAMOND

Created by HC058908 (AGH) on 14AUG12 13:17
 Based on data retrieved at the CC on August 13, 2012
 *Means were omitted which were calculated using <=5 participants
 *Days adherent defined as days with 10 or more hours of data collected
 Non compliance defined as 60 min of consecutive zero counts

**Appendix. MAJOR UPDATE on
Actical Data Processing and Cleaning in HCHS/SOL
August 2012**

The CSCC developed a SAS program to data process, clean and summarize physical activity measured by the ActiGraph. This program was adapted for HCHS/SOL study protocol which measured physical activity using the Actical. However, in July 2012 we discovered that there were three modifications to the SAS program that still needed to be done:

1. Adjust protocol deviations to start date and start time
2. Keep data (counts per epoch) between midnight and 6:00am
3. Remove strong duplicate check done for the Actigraph but not needed for the Actical

Below we explain the need for the duplicate check when using the ActiGraph #7164 and its algorithm, and the implications when dealing with physical activity data from Actical in HCHS/SOL.

Early versions of the ActiGraph (#7164) had a small bug in the software that occasionally did not properly initialize the data files that the accelerometer software created with each new use. The nature of the bug was that if an accelerometer was worn by a participant for several days, this data would remain on the file even after the accelerometer was re-initialized and given to a new participant. The accelerometer would begin laying down new data for the new participant at the top of the text file, over-writing the old values as it laid down new data. If, however, the later participant did not wear the accelerometer for as long a period of time as the previous person, then the previous person's data would remain at the end of the text file.

For example, if person 1 accumulated the following 6 lines of data:

105	108	105	105	105	108	106	103	104	104
104	108	107	104	106	103	106	105	108	104
107	108	108	108	105	105	103	103	105	107
107	104	106	105	104	104	106	104	104	105
106	103	108	106	108	104	103	104	104	106
103	108	106	106	107	107	103	103	107	103

and person 2 accumulated the following 4 lines of data:

253	254	257	256	255	258	257	257	255	255
255	253	255	253	254	258	258	257	257	255
256	256	255	255	257	253	255	256	256	255
257	255	257	256	255	255	254	254	253	255

the resulting file would look fine for person 1, but person 2 would have the following data file:

253	254	257	256	255	258	257	257	255	255
255	253	255	253	254	258	258	257	257	255
256	256	255	255	257	253	255	256	256	255
257	255	257	256	255	255	254	254	253	255
106	103	108	106	108	104	103	104	104	106
103	108	106	106	107	107	103	103	107	103

**Appendix. MAJOR UPDATE on
Actical Data Processing and Cleaning in HCHS/SOL
August 2012**

In order to deal with this possibility, the original version of the SAS program compared the data of each participant who wore a specific accelerometer to all previously collected data for participants who wore the same accelerometer. The program compared each line of data (each line containing 60 data points corresponding to an hour data with epoch of one minute) to the same row of data for all previous wears of the same accelerometer. If the same row of data from a previous wear shared the same mean and the same standard deviation, and the mean was greater than zero, then the program assumed the data for the current participant was duplicated data. The program would then set all data beyond this point to missing, assuming that the data was left-over from a previous participant. **This algorithm was checked extensively in the Study that was developed for, and caused no problems.**

However, when the HCHS/SOL study implemented this same check for duplicate data, at least two differences in the HCHS/SOL data likely caused this data check to be too sensitive to duplicate data, over-classifying data as duplicate when in fact it wasn't. These differences include:

1. The accelerometers were worn numerous times by participants in the HCHS/SOL study. Acticals were worn on average 13 ± 8.6 times (Inter quartile (Q1-Q3): 6-20 wears; range 1-48 uses). This generates many, many comparisons to previous data. Thirty wears would generate $\sum (n-1)$ comparisons = 435 comparisons, whereas 10 wears would generate $\sum (n-1)$ comparisons = 45 comparisons. So the number of comparisons grows non-linearly as the number of wears increases.
2. Also, the number of participants in HCHS/SOL study was so big that by itself created many comparisons.

These two differences greatly increased the probability that data would be classified as duplicate even when it wasn't. **This meant that a significant proportion of data were being cleaned out, when it should have been retained for analysis.**

Point number 1 above was the root cause of why the number of hours of physical activity data and the adherent days decreased over time. As the number of wears increased, the number of comparisons to previous data increased at an ever increasing rate. This increased the probability of falsely classifying the data as duplicate when it was not, at which point the data would be set to missing. Point number 2 abetted the problem by also increasing the probability that the increasing number of comparisons would falsely classify data as duplicate.

Because Acticals do not exhibit the same software bug (this has been investigated and verified), there is no need to check for duplicate leftover data. Once this check was removed, the data was no longer set to missing. This changed removed the trend over time which had (falsely) indicated that the accelerometers were becoming less reliable.

QC Report on Abstraction and Adjudication of Events
August 22, 2012

- 1 Medical records acquisition phase (FC staff)
 - Success in obtaining records (monthly)
 - **Currently, we aren't having many problems obtaining records. This has improved. However, the few problems we've had include facilities requesting their own ROIs and the occasional out of country hospitalization. Even these issues have been overcome in almost all cases though.**
 - **We continue to have monthly conference calls we have with the field centers. Jeremy is also working on making individual calls to each field center in between our monthly calls.**
 - **One site visit was conducted (Chicago) and another one is being scheduled (Miami).**
 - Re-certification of records acquisition staff (annually)
 - **We conducted an annual face to face meeting and now monthly calls, as above.**
 - Completeness of records sent to CC (weekly)
 - **Currently, the records we are receiving are generally quite complete.**
 - **We now confirm receipt of all records by weekly email and include our requests for additional materials.**

- 2 Medical record abstraction (CC)
 - 2 certified RN abstractors
 - **Jeremy and Jan have continued working with SOL events**
 - Double abstraction (first 50), thereafter 5% re-abstraction
 - **We just double abstracted the first 10 pulmonary cases. This should pick up in the beginning of next month.**
 - **As of this week, the heart failure abstraction forms are now available on the DMS recently, so we will start double abstracting these records as well.**
 - Summarize item by item disagreement
 - **We will begin this within next 2 week for double abstracted pulmonary events then HF will follow**
 - Annual re-certification exams
 - **We held annual face to face recertification and will plan re-certification annually.**

- 3 Reviewer teams (FC, CC) – **A Pulmonary reviewer call is scheduled for 8/28 to discuss the impending reviews that will be sent out. We hope to have events ready to send to pulmonary reviewers by the end of Oct 1st. No reviews have been performed yet for any of the endpoints.**
 - Pulmonary, Cardiac, Stroke
 - Double reviews (first 500), disagreements adjudicated
 - **As mentioned the first 100 Pulmonary reviews will all be sent for double review. Adjudicator, Graham Barr will settle disagreements. Once we have reviewed the first 20-40 events, a reviewers call will be scheduled to discuss controversial cases.**
 - Monitor inter-reviewer disagreement rates
 - Intra-reviewer agreement for pulmonary events