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

FROM: Daniela Sotres-Alvarez, HCHS/SOL Coordinating Center
DATE: May 23, 2013

RE: HCHS/SOL Quality Control Report, May 2013

MEMORANDUM

This quality control (QC) report includes a progress report for the ongoing QC for HCHS/SOL abstraction and adjudication of events. Attached also Tables 3.1, 3.2 and 3.6 from April 2013 HCHS/SOL Management Report.

HCHS/SOL Endpoints Summary Report for QC call on 5/23/2013

Tables below refer to the April 23, 2013 HCHS/SOL Data Management report. **We bolded below what is new from previous report.**

Medical Records Acquisition

Success in obtaining records.

- **Compared to the initial efforts, field center staff have now developed the necessary relationships and clearances with medical records departments in their local hospitals to routinely not have requests for materials obstructed. If records exist for an admission they can usually be obtained.**
- **See TABLE 3.2 in HCHS/SOL Management Report, Last Reported Stage for Endpoints Investigation by Event Year. 99% of 2008-2009 events are in DMS, and being tracked. 97% are closed for 2008-2009.**
- **One quality measure of medical records is getting charts with ICD-9 codes. TABLE 3.2 shows that we are holding steady at about 4% of verification forms without codes, a little improvement from 6% in the first 2 years of events. There is however still some center differences with Bronx at 1.4% and Chicago at 6.7% (Table 3.1).**

Completeness of records sent to CC.

- **Completeness of records is defined by the endpoints protocol which is programmed in the DMS to expect certain materials based on the ICD-9 codes on the discharge summary. A cover sheet (the VER form) provides a checklist for the abstractors in Chapel Hill to use in evaluating completeness.**
- **Also in Table 3.2, 94% of 2008-2009 records with ICD codes on verification forms, which increases to 96% for the following years.**

Death Certificate acquisition and abstraction

We recently abstracted 64 death certificates that were in-house at the CSCC. Issues that arose from this process include:

- **Listed diagnoses were not ICD coded on any of the death certificates, and there was not underlying cause of death (UCOD) thus we are planning to send them to a nosologist for coding. Only 1 death certificate was completely missing diagnoses.**
- **Some death certificates were blinded to informant, address, physician name, address at the level of the state.**
- **Very few death certificates were available from the Bronx. Only about 5 of the death certificates available are at the CSCC for the over 40 or more deaths reported from Bronx. The field center is in the process of trying to obtain permission for these from NY.**

Loehr and Rosamond are moving forward to define the mortality review form, and process to validate underlying cause of death for endpoints of interest

Medical record abstraction (CC)

Two certified RN abstractors are **currently focused on entering Event eligibility forms for 2010 events.**

-Double abstraction (first 50), thereafter 5% re-abstraction

- **See TABLE 3.6 Event Processing and Abstraction Status by Year**
- The first 13 pulmonary cases were double abstracted as discussed on prior call, **and now a total of 27 pulmonary records abstracted. From the table, this is 27/35 (77%) of the 2008-2009 PUL eligible records.**
- **The first 12 MI records were double abstracted. This is 12/33 (36%) of the MI eligible charts for 2008-2009.**
- **The first 6 heart failure charts have been single abstracted, plan double abstraction these and at least 5 more, then assess for agreement. This is 6/15 of eligible HF charts for 2008-2009.**

-Summarize item by item disagreement

- PUL abstraction form: 91% agreement between the 2 abstractors. Disagreements were reviewed, adjudicated and discussed with abstractors.
- **MI abstraction form: 95% agreement between abstractors for total item agreement (525 items*12 charts-302/(525*12). Plan to review with abstractors and adjudicate these answers. Also identify items for which there was disagreement to clarify QXQ as needed.**

Reviewer teams (FC, CC)

Pulmonary – 27 pulmonary events have been reviewed, classified, and entered into DMS. These records were reviewed by all reviewers and then discussed on call, and classified by consensus. Therefore, agreement between reviewers cannot be assessed. Next call when next set of 10 records have been abstracted and are ready to go to reviewers. Plan DMS training for reviewers at the point of the next cycle of reviews.

- Double reviews (first 500), disagreements to be adjudicated. Reviewer calls to discuss cases.
- Will measure agreement between reviewers and with adjudicator

Myocardial Infarction – 12 records ready to go to reviewers once disagreement between reviewers adjudicated and event summary forms created.

Heart Failure - Await completion of double abstraction of at least 10 charts.

Death – DTH Abstractions ready and entered into DMS, Death reviewer form in process.

Stroke – Forms in process

SOL/HCHS Endpoints Progress – Forms creation in the data management system (DMS), and processing of events with abstraction and review							
	Abstraction Form	Abstraction QXQ	Reviewer Form	Reviewer QXQ	ESF	Abstracted	Reviewed
PUL	In DMS	complete	In DMS	complete	electronic	27	27
HTF	In DMS	complete	In DMS	complete	paper only	6	0
AMI	in DMS	complete	In DMS	complete	Paper only	12	0
STROKE	In process	-	In process	-	-	-	-
DEATH	complete	-	In process	-	-	64	-

HCHS/SOL Management Report, April 2013
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Table 3.1 Last Reported Stage for Endpoints Investigation by Center

Event Materials Status	<u>Bronx</u>		<u>Chicago</u>		<u>Miami</u>		<u>San Diego</u>		<u>Overall</u>	
	N	%	N	%	N	%	N	%	N	%
Hosp + ED visits on AFU¹	2724		2099		1859		1695		8377	
Total eligible events for investigation	1246		939		1001		763		3949	
Total reported events w/tracking information	1232	98.9	930	99.0	890	88.9	751	98.4	3803	96.3
Pending records request	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Release of Information requested	14	1.1	0	0.0	1	0.1	1	0.1	16	0.4
Release of Information obtained	0	0.0	7	0.7	0	0.0	0	0.0	7	0.2
Event Record requested	93	7.5	52	5.5	18	1.8	8	1.0	171	4.3
Ineligible	305	24.5	215	22.9	220	22.0	206	27.0	946	24.0
Records Not Available	34	2.7	29	3.1	2	0.2	92	12.1	157	4.0
Medical records received for event	0	0.0	9	1.0	0	0.0	0	0.0	9	0.2
Supplemental records requested	0	0.0	48	5.1	5	0.5	0	0.0	53	1.3
Verification of medical records	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Verification forms with ICD-9 Codes²	772	98.6	532	93.3	613	95.2	420	94.8	2337	95.8
Verification forms Missing ICD-9 Codes²	11	1.4	38	6.7	31	4.8	23	5.2	103	4.2
Shipping Medical records to CC	783	62.8	570	60.7	644	64.3	443	58.1	2440	61.8
Closed Event	1122	90.0	814	86.7	866	86.5	741	97.1	3543	89.7
Pending Event	107	8.6	116	12.4	24	2.4	9	1.2	256	6.5

Based on analysis files created on April 23, 2013.

Source Files: ETRA forms and AFU interview.

¹For reported Hosp/ED visits with a non-missing event date. Participants may report more than one hospitalization or ED visit per AFU interview.

²Percents for presence of ICD-9 codes is calculated using number of eligible events shipped to CC.

Other Notes: *Percents are calculated using the number of eligible events from DMS.

*Closed events have either had medical records shipped to the CC, or have been confirmed locally as having no existing records and or not being an event for investigation.

Pending events are at an intermediate stage of investigation. Ineligible cases included, AFU reported hospitalizations of ED visits which after investigation are determined to be ineligible for endpoint classification (e.g. outpatient visits, ED visit for non-qualifying condition).

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Table 3.2 Last Reported Stage for Endpoints Investigation by Event Year

Event Materials Status	2008-9		2010		2011		2012		2013		Overall	
	N	%	N	%	N	%	N	%	N	%	N	%
Hosp + ED visits on AFU¹	961		1906		3014		2246		250		8377	
Total eligible events for investigation	453		943		1466		988		99		3949	
Total reported events w/tracking information	450	99.3	938	99.5	1451	99.0	893	90.4	71	71.7	3803	96.3
Pending records request	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Release of Information requested	0	0.0	0	0.0	4	0.3	12	1.2	0	0.0	16	0.4
Release of Information obtained	0	0.0	0	0.0	1	0.1	2	0.2	4	4.0	7	0.2
Event Record requested	2	0.4	5	0.5	33	2.3	100	10.1	31	31.3	171	4.3
Ineligible	118	26.0	257	27.3	376	25.6	187	18.9	8	8.1	946	24.0
Records Not Available	23	5.1	51	5.4	60	4.1	23	2.3	0	0.0	157	4.0
Medical records received for event	1	0.2	0	0.0	3	0.2	5	0.5	0	0.0	9	0.2
Supplemental records requested	9	2.0	9	1.0	18	1.2	17	1.7	0	0.0	53	1.3
Verification of medical records	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Verification forms with ICD-9 Codes²	279	93.9	591	95.9	915	95.9	525	96.3	27	96.4	2337	95.8
Verification forms Missing ICD-9 Codes²	18	6.1	25	4.1	39	4.1	20	3.7	1	3.6	103	4.2
Shipping Medical records to CC	297	65.6	616	65.3	954	65.1	545	55.2	28	28.3	2440	61.8
Closed Event	438	96.7	924	98.0	1390	94.8	755	76.4	36	36.4	3543	89.7
Pending Event	12	2.6	14	1.5	59	4.0	136	13.8	35	35.4	256	6.5

Based on analysis files created on April 23, 2013.

Source Files: ETRA forms and AFU interview.

¹For reported Hosp/ED visits with a non-missing event date. Participants may report more than one hospitalization or ED visit per AFU interview.

²Percents for presence of ICD-9 codes is calculated using number of eligible events shipped to CC.

Other Notes: *Percents are calculated using the number of eligible events from DMS.

*Closed events have either had medical records shipped to the CC, or have been confirmed locally as having no existing records and/or not being an event for investigation.

Pending events are at an intermediate stage of investigation. Ineligible cases include, AFU reported hospitalizations of ED visits which after investigation are determined to be ineligible for endpoint classification (e.g. outpatient visits, ED visit for non-qualifying condition).

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Table 3.6 Event Processing and Abstraction Status by Year

Event Abstraction Status	<u>2008-9</u>		<u>2010</u>		<u>2011</u>		<u>2012</u>		<u>2013</u>		<u>Overall</u>	
	N	%	N	%	N	%	N	%	N	%	N	%
Events with records at CC	297		616		954		545		28		2440	
Event records inventoried	280	94.3	593	96.3	908	95.2	458	84.0	11	39.3	2250	92.2
Inventoried pending processing ¹	16	5.7	443	74.7	612	67.4	259	56.6	0	0.0	1330	59.1
Pending query resolution	38	13.6	48	8.1	136	15.0	118	25.8	11	100.0	351	15.6
Processing complete, not scanned	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0	1	0.0
Abstraction eligibility pending	57	20.4	83	14.0	152	16.7	73	15.9	0	0.0	365	16.2
Abstraction eligibility determined	168	60.0	19	3.2	8	0.9	8	1.8	0	0.0	203	9.0
No abstraction required ²	97	57.7	10	52.6	3	37.5	6	75.0	0	0.0	116	57.1
MI eligible	33	19.6	2	10.5	1	12.5	0	0.0	0	0.0	36	17.7
Stroke eligible	13	7.7	0	0.0	3	37.5	1	12.5	0	0.0	17	8.4
HF eligible	15	8.9	3	15.8	0	0.0	0	0.0	0	0.0	18	8.9
Pulmonary eligible	35	20.8	5	26.3	0	0.0	1	12.5	0	0.0	41	20.2

Based on analysis files created on April 23, 2013.

Note: Participants are screened for more than one outcome per event reported date.

(1) Denominator is number of events with event records inventoried.

(2) Denominator is number of events with eligibility determined.