



UNC
GILLINGS SCHOOL OF
GLOBAL PUBLIC HEALTH

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at CHAPEL HILL

COLLABORATIVE STUDIES COORDINATING CENTER
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TO: HCHS/SOL Quality Control Committee
CC: Jianwen Cai, Gerardo Heiss, Wayne D Rosamond

FROM: Daniela Sotres-Alvarez and Laura Loehr, HCHS/SOL Coordinating Center
DATE: Jan 22, 2014

RE: HCHS/SOL Quality Control Report, January 2014

MEMORANDUM

This quality control (QC) report includes a progress report for the ongoing QC for HCHS/SOL abstraction and adjudication of events. We also include:

- Tables 3.1, 3.2, 3.6 and 3.9 from Dec 2013 HCHS/SOL Management Report.
- PLD-Pulmonary Reviewer Form

HCHS/SOL Endpoints Summary Report for QC call on 1/22/2014

Reviewer teams (FC, CC)

See Table 3.9 “Event Processing, Abstraction and Review Status by Event Type” from December 2013 HCHS/SOL Data Management report

*Pulmonary – 14 Pulmonary classifications complete. 40 additional records were abstracted and sent to reviewers, 40 paired reviews have been completed, and 2 of these records are pending with the adjudicator. Agreement between reviewers is shown for 38 of these records. 18 Pulmonary records are ready for abstraction.

*Myocardial Infarction – 61 abstracted, and ready to go to reviewers. 27 ready for abstraction.

*Heart Failure - 26 abstracted, and ready to go to reviewers. 5 are ready for abstraction.

*Stroke – 27 ready for abstraction

Item by item analysis of disagreement between paired physician reviewers for 38 Pulmonary events in the HCHS/SOL

<u>Variable</u>	<u>Label</u>	<u>Disagreement</u>
PD1A1	SOL criteria for CLRD	5/38 (13%)
PD1A1_RC	SOL criteria for CLRD, 3 RC to 2	4/38 (11%)
PD1A2A	Asthma	9/38 (24%)
PD1A2A_RC	Asthma, 3 and 2, 5 and 4 recoded	5/38 (11%)
PD1A2B	COPD	2/38 (5%)
PD1A2B_RC	COPD, 3 and 2, 5 and 4 recoded	2/38 (5%)
PD1A2C	Emphysema	2/38 (5%)
PD1A2C_RC	Emphysema, 3 and 2, 5 and 4 recoded	2/38 (5%)
PD1A2D	Chronic Bronchitis	3/38 (5%)
PD1A2D_RC	Chronic Bronchitis	3/38 (5%)
PD1A3	Predominant CLRD subtype	5/38 (13%)
PD1A4	Evidence of other lung disease	5/38 (13%)
PD1A5	Exacerbation of CLRD	13/38 (34%)
PD1A5_RC	Exac of CLRD, 3 RECODED TO 2	8/38 (21%)
PD1A5B1	Pneumonia	2/38 (5%)
PD1A5B2	Pulmonary embolus	3/38 (8%)
PD1A5B3	Pneumothorax	3/38 (8%)
PD1A5B4	Acute myocardial infarction	3/38 (8%)
PD1A5B5	Acute decompensated heart failure	3/38 (8%)
PD1A5B6	Other condition	2/38 (5%)
PD1A5B5A	Type of ADHF	1/38 (3%)

Recoding:

For PD1A1, choices were Def/HP/P/PN/Unknown, so regrouped 3=probable with 2=highly probable

For PD1A2A-D, choices were Def/HP/P/PN/Unknown, 3=probable was grouped with 2=highly probable and 5=probably not/unknown was grouped with 4=definitely not.

For PD1A5, choices were Def/HP/P/PN/Unknown, so regrouped 3=probable with 2=highly probable



HCHS/SOL PULMONARY DIAGNOSIS (PLD) FORM

ID NUMBER:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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FORM CODE: PLD
VERSION: A 1/9/13

Contact Occasion

<input type="text"/>	<input type="text"/>
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SEQ #

<input type="text"/>	<input type="text"/>
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Administrative Information

0A. Completion Date: //
Month /Day /Year

0B. Reviewer ID:

0C. Event ID:

0D.Event Date: //
Month / Day/Year

1. Does this patient meet SOL criteria for chronic lower respiratory disease (CLRD)?

<u>Definite</u> 1 <input type="checkbox"/>	<u>Highly Probable</u> 2 <input type="checkbox"/>	<u>Probable</u> 3 <input type="checkbox"/>	<u>NO/unknown</u> 4 <input type="checkbox"/>
<i>if 4 then STOP</i>			

2. If YES (definite, highly probable, or probable) CLRD, which sub-type(s) of CLRD does this patient have?

	<u>Definite</u>	<u>Highly Probable</u>	<u>Probable</u>	<u>Definitely Not</u>	<u>Probably not/Unknown</u>
a. Asthma	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
b. COPD	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
c. Emphysema	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
d. Chronic Bronchitis	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>

3. In your opinion, which CLRD subtype do you think is predominant?

1 Asthma 2 COPD 3 Emphysema 4 Chronic Bronchitis 5 Unsure

4. Is there evidence of other lung disease? No=0 Yes=1

a. If yes, specify lung disease _____

5. Does this patient have an exacerbation of CLRD?

<u>Definite</u> 1 <input type="checkbox"/>	<u>Highly Probable</u> 2 <input type="checkbox"/>	<u>Probable</u> 3 <input type="checkbox"/>	<u>No/Unknown</u> 4 <input type="checkbox"/>
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a. If YES to #5 (definite, highly probable, or probable), then was there evidence for another cardiopulmonary diagnosis concomitant with the event?

1 No, "LONE" CLRD exacerbation 2 Yes, "COMORBID" CLRD
*if 1 for Lone CLRD then **STOP***

b. If YES to #5a (Comorbid CLRD exacerbation), then indicate evidence for any of the following:

	<u>Yes</u>	<u>No/unknown</u>
b1. Pneumonia	1 <input type="checkbox"/>	2 <input type="checkbox"/>
b2. Pulmonary embolus	1 <input type="checkbox"/>	2 <input type="checkbox"/>
b3. Pneumothorax	1 <input type="checkbox"/>	2 <input type="checkbox"/>
b4. Acute myocardial infarction	1 <input type="checkbox"/>	2 <input type="checkbox"/>
b5. Acute decompensated heart failure (ADHF)	1 <input type="checkbox"/>	2 <input type="checkbox"/>
b5.a. IF YES to ADHF (b5), then what type?		
1 <input type="checkbox"/> Left-sided 2 <input type="checkbox"/> Right-sided 3 <input type="checkbox"/> Unknown		
b6. Other	1 <input type="checkbox"/>	2 <input type="checkbox"/>
b6.a. IF YES to Other (b6), then what OTHER condition is comorbid?	_____	

6. Comments: _____

HCHS/SOL Management Report, December 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	3396		2552		2399		2188		10535	
Total eligible events for investigation	1560		1032		1333		992		4917	
Total reported events w/tracking information	1558	99.9	1003	97.2	1207	90.5	933	94.1	4701	95.6
Pending Event	73	4.7	83	8.0	9	0.7	19	1.9	184	3.7
Pending records request	1	0.1	0	0.0	5	0.4	0	0.0	6	0.1
Release of Information requested	5	0.3	0	0.0	0	0.0	0	0.0	5	0.1
Release of Information obtained	1	0.1	0	0.0	0	0.0	0	0.0	1	0.0
Event Record requested	66	4.2	29	2.8	1	0.1	19	1.9	115	2.3
Medical records received for event	0	0.0	15	1.5	0	0.0	0	0.0	15	0.3
Supplemental records requested	0	0.0	39	3.8	3	0.2	0	0.0	42	0.9
Verification of medical records	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Closed Event	1485	95.2	920	89.1	1198	89.9	914	92.1	4517	91.9
Ineligible	431	27.6	211	20.4	328	24.6	254	25.6	1224	24.9
Records Not Available	48	3.1	28	2.7	9	0.7	118	11.9	203	4.1
Shipping Medical records to CC	1006	64.5	681	66.0	861	64.6	542	54.6	3090	62.8
Verification forms with ICD-9 Codes²	995	98.9	651	95.6	813	94.4	502	92.6	2961	95.8
Verification forms Missing ICD-9 Codes²	11	1.1	30	4.4	48	5.6	40	7.4	129	4.2

Based on analysis files created on January 8, 2014.

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		2013-14		Overall	
	N	%	N	%	N	%	N	%	N	%	N	%
Hosp + ED visits on AFU¹	969		1913		3066		2826		1761		10535	
Total eligible events for investigation	454		926		1493		1300		744		4917	
Total reported events w/tracking information	450	99.1	922	99.6	1486	99.5	1256	96.6	587	78.9	4701	95.6
Pending Event	1	0.2	1	0.1	23	1.5	53	4.1	106	14.2	184	3.7
Pending records request	1	0.2	1	0.1	0	0.0	2	0.2	2	0.3	6	0.1
Release of Information requested	0	0.0	0	0.0	0	0.0	4	0.3	1	0.1	5	0.1
Release of Information obtained	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1	1	0.0
Event Record requested	0	0.0	0	0.0	12	0.8	28	2.2	75	10.1	115	2.3
Medical records received for event	0	0.0	0	0.0	3	0.2	7	0.5	5	0.7	15	0.3
Supplemental records requested	0	0.0	0	0.0	8	0.5	12	0.9	22	3.0	42	0.9
Verification of medical records	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Closed Event	449	98.9	921	99.5	1463	98.0	1203	92.5	481	64.7	4517	91.9
Ineligible	120	26.4	253	27.3	395	26.5	312	24.0	144	19.4	1224	24.9
Records Not Available	25	5.5	51	5.5	70	4.7	42	3.2	15	2.0	203	4.1
Shipping Medical records to CC	304	67.0	617	66.6	998	66.8	849	65.3	322	43.3	3090	62.8
Verification forms with ICD-9 Codes²	294	96.7	594	96.3	956	95.8	809	95.3	308	95.7	2961	95.8
Verification forms Missing ICD-9 Codes²	10	3.3	23	3.7	42	4.2	40	4.7	14	4.3	129	4.2

Based on analysis files created on January 8, 2014.

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>2013-14</u>		<u>Overall</u>	
	N	%	N	%	N	%	N	%	N	%	N	%
Events with records at CC	304		616		997		849		322		3088	
Event records inventoried	301	99.0	596	96.8	961	96.4	755	88.9	243	75.5	2856	92.5
Inventoried pending processing¹	5	1.7	23	3.9	466	48.5	290	38.4	72	29.6	856	30.0
Pending query resolution	5	1.7	169	28.4	206	21.4	332	44.0	148	60.9	860	30.1
Processing complete, not scanned	0	0.0	12	2.0	4	0.4	5	0.7	2	0.8	23	0.8
Abstraction eligibility pending	7	2.3	259	43.5	270	28.1	119	15.8	20	8.2	675	23.6
Abstraction eligibility determined	284	94.4	133	22.3	15	1.6	9	1.2	1	0.4	442	15.5
No abstraction required²	163	57.4	81	60.9	8	53.3	7	77.8	1	100.0	260	58.8
MI eligible	59	20.8	26	19.6	2	13.3	0	0.0	0	0.0	87	19.7
Stroke eligible	19	6.7	4	3.0	3	20.0	1	11.1	0	0.0	27	6.1
HF eligible	24	8.5	7	5.3	0	0.0	0	0.0	0	0.0	31	7.0
Pulmonary eligible	54	19.0	26	19.6	1	6.7	1	11.1	0	0.0	82	18.6

Based on analysis files created on January 8, 2014.

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.

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Table 3.9 Event Processing, Abstraction and Review Status by Event Type

Event Abstraction and Review Status	<u>MI</u>		<u>Stroke</u>		<u>HTF</u>		<u>Pulmonary</u>	
	N	%	N	%	N	%	N	%
All eligible cases¹	88		27		31		82	
Abstraction pending	27	30.7	27	100.0	5	16.1	18	22.0
Abstraction complete, pending review	61	69.3	0	0.0	26	83.9	5	6.1
Assigned to review	0	0.0	0	0.0	0	0.0	3	3.7
Review complete	0	0.0	0	0.0	0	0.0	40	48.8
Assigned for adjudication	0	0.0	0	0.0	0	0.0	2	2.4
Classification complete	0	0.0	0	0.0	0	0.0	14	17.1

Based on analysis files created on January 8, 2014.

Source Files: EVTA,EEFA,PULA,PD1A-PD3A,HTFA, and MIFA

(1) Number of cases eligible for abstraction for MI,stroke,heart failure and pulmonary, respectively.