February 25, 2014

WHI Heart Failure Data Summary

A. Original WHI outcome (referred to as CHF)

Sample: Collected and centrally adjudicated for HT participants and locally adjudicated on all non-HT CT and OS participants enrolled in WHI
N=161,808

Timeframe: Adjudicated throughout WHI (through April 8 2005)

Process:

Congestive heart failure (fatal and nonfatal) requiring hospitalization, was monitored during the WHI. All self-reports of cardiovascular (CVD) events and heart failure were evaluated until the first post-MI congestive heart failure (CHF) event. Any subsequent heart failure self-report was not adjudicated. Only the first adjudicated event is reported.

All WHI participants (CT and OS) were asked to self-report any hospitalized CVD event and non-hospitalized PTCA, coronary stent or coronary atherectomy. Non-hospitalized CVD events, excluding outpatient revascularization procedures, remained as self-reported outcomes.

After the self-reported event was entered into the study database, the outcomes coordinators requested documents from the admitting hospital to support the diagnosis. The required document set was chosen to allow the WHI Physician Adjudicator to make the most accurate diagnosis of the event. The document set included the following:
discharge summary, hospital face sheet with ICD-9-CM coded and/or physician attestation sheet with ICD-9-CM codes.
In addition to these three documents, other documents requested (if available) for CHF events were:
All ECGs from that hospitalization; cardiac enzyme and troponin data; and reports of any cardiac procedures (if done) including coronary angiograms, exercise stress testing, nuclear cardiac imaging, echocardiogram, angioplasty, and any cardiovascular surgical procedures. Cases were evaluated based on all available documents, which included many cases without one or more of the requested items.

Outcome Definition:

Congestive heart failure in WHI was defined as a constellation of symptoms (such as shortness of breath, fatigue, orthopnea, and paroxysmal nocturnal dyspnea) and physical signs (such as edema, rales, tachycardia, a gallop rhythm, and a displaced point of maximum intensity [PMI]) that occurred in a participant whose cardiac output could not match metabolic needs despite adequate filling pressures.
Only a hospitalization involving new or worsening CHF was a WHI outcome. Thus, diagnosis and treatment of CHF by a physician or other provider in the office or clinic setting or emergency room without hospital admission was not considered a WHI outcome. The diagnosis of CHF was based on one or more of the following:

- Diagnosis of CHF by a physician and receiving medical treatment (diuretic, digitalis, vasodilator, or angiotension-converting enzyme inhibitor) on the admission.
- On the admission, dilated ventricle or poor left (or right-side) ventricle function (e.g., wall-motion abnormalities) by echocardiography, radionuclide ventriculogram, contrast ventriculography or multigated acquisition (MUGA) scan, or evidence of left ventricular diastolic dysfunction.
- Diagnosis of CHF by a physician and receiving medical treatment plus the current medical record documented a history of an imaging procedure showing impaired systolic or diastolic LV dysfunction.

- Pulmonary edema/congestion by chest X-ray on the admission.

Note: The differential diagnoses of the symptoms that might produce the clinical picture and physician diagnosis CHF include chronic obstructive pulmonary disease (COPD), pneumonia, or other lung disease, volume overload states (e.g. renal failure), valvular heart disease and others.

Use of WHI CHF outcome for analyses

Pros:	Available on a large sample
Cons:	Definition is not contemporary; details such as ejection fraction not recorded; not all self-reports were adjudicated; only the first adjudicated event was reported; not adjudicated prospectively after April 8 2005

Data available for analysis:

In CT+OS dataset (outc_ct_os_inv): CHF=event indicator, CHFDY=days from enrollment to first confirmed CHF diagnosis, ENDWHIDY=days from enrollment to end of WHI follow-up (use for censoring when no event); Form 121 questions relevant to CHF event (#1, #2, #6.2 and #6.3) in outc_cardio_inv. (# 8.1 and 8.2 in Extension 2)
In CaD trial only dataset (outc_cad_inv): CHF=event indicator, CHFDY=days from enrollment to first confirmed CHF diagnosis, ENDWHICADDY=days from CaD randomization to CaD study close-out (use for censoring when no event); Form 121 questions relevant to CHF event (#1, #2, #6.2 and #6.3) in outc_cardio_cad_inv dataset. (#8.1 and 8.2 in Extension 2)

Table 1.1

WHI Congestive Heart Failure Confirmed Outcomes (Annualized Percentages) Overall and by Age

Data as of: September 20, 2013; Events through April 8, 2005

		Age			
Outcomes	**Total**	**50-54**	**55-59**	**60-69**	**70-79**
Overall					
Number enrolled	161808	21569	31990	72589	35660
Mean follow-up (months)	96.4	102.2	99.8	95.4	92.0
Congestive heart failure	4043 (0.31%)	162 (0.09%)	346 (0.13%)	1627 (0.28%)	1908 (0.70%)
By study component					
Observational Study					
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	136.7	99.6	98.0	93.9	90.6
Congestive heart failure	2295 (0.31%)	81 (0.08%)	174 (0.12%)	882 (0.27%)	1158 (0.67%)
Clinical Trial					
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	146.5	105.7	102.0	97.3	94.5
Congestive heart failure	1748 (0.31%)	81 (0.10%)	172 (0.14%)	745 (0.29%)	750 (0.74%)
Hormone Therapy					
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	97.2	103.0	100.1	96.4	93.2
Congestive heart failure	806 (0.36%)	41 (0.14%)	75 (0.17%)	333 (0.34%)	357 (0.75%)
Dietary Modification					
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	99.9	106.8	102.8	97.9	95.4
Congestive heart failure	1170 (0.29%)	52 (0.08%)	120 (0.13%)	526 (0.28%)	472 (0.73%)
Calcium and Vitamin D					
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	84.8	90.9	87.4	83.0	80.9
Congestive heart failure	806 (0.31%)	33 (0.08%)	84 (0.14%)	376 (0.33%)	313 (0.73%)

Table 1.2

WHI Congestive Heart Failure Confirmed Outcomes (Annualized Percentages) Overall and by Race/Ethnicity

Data as of: September 20, 2013; Events through April 8, 2005

Outcomes	Race/Ethnicity					
	American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Overall						
Number enrolled	713	4190	14618	6484	133541	2262
Mean follow-up (months)	91.4	92.8	93.0	89.5	97.3	92.7
Congestive heart failure	21 (0.39%)	39 (0.12%)	477 (0.42%)	91 (0.19%)	3357 (0.31%)	58 (0.33%)
By study component						
Observational Study						
Number enrolled	421	2671	7635	3609	78106	1324
Mean follow-up (months)	88.2	91.4	89.1	85.9	95.7	91.4
Congestive heart failure	16 (0.52%)	22 (0.11%)	233 (0.41%)	42 (0.16%)	1948 (0.31%)	34 (0.34%)
Clinical Trial						
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	96.1	95.3	97.3	93.9	99.5	94.6
Congestive heart failure	5 (0.21%)	17 (0.14%)	244 (0.43%)	49 (0.22%)	1409 (0.31%)	24 (0.32%)
Hormone Therapy						
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	93.6	527	96.3	94.0	97.8	93.3
Congestive heart failure	3 (0.30%)	9 (0.22%)	99 (0.45%)	29 (0.24%)	655 (0.36%)	11 (0.37%)
Dietary Modification						
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	97.8	96.5	98.0	94.3	100.6	95.4
Congestive heart failure	2 (0.12%)	10 (0.11%)	178 (0.41%)	31 (0.21%)	933 (0.28%)	16 (0.31%)
Calcium and Vitamin D						
Number randomized	149	721	3315	1502	30155	128.8
Mean follow-up (months)	84.7	80.9	83.6	82.8	85.1	81.2
Congestive heart failure	2 (0.19%)	7 (0.14%)	103 (0.45%)	29 (0.28%)	656 (0.31%)	9 (0.30%)

B. New UNC adjudicated outcomes (referred to as HF)

Sample: Adjudicated on all participants randomized to the Hormone Trial (HT) and all Black and Hispanic participants enrolled in WHI (HAH)
N=44,174

Note: the MRC is a subset of HAH consisting of all HT and all Black and Hispanic participants enrolled in the Extension 2 study (N=22,315)

Timeframe: Adjudicated for this cohort throughout WHI, Extension 1 and Extension 2 (1998-present)

Process:

All locally or centrally confirmed WHI CHF cases were sent to UNC for adjudication, regardless of what outcome was self-reported by the participant. In addition, if neither a local or central adjudication confirmed a CHF diagnosis, and the participant self-reported CHF, angina or "other" CVD on Form 33 or 33D, and their outcomes case packet included 2 or more essential documents (discharge summary, operative/procedure report, Emergency Department records, 12-lead ECG, cardiac enzymes, RVG/MUGA, CXR, or echocardiography reports), the case was also sent to UNC. Of the total number of eligible cases, approximately 2% were not sent because of lack of essential documentation.

All cases during the main WHI trial and Extension 1 were restrospectively sent to UNC for adjudication and all medical records for events during Extension 1 were collected retrospectively. Extension 2 cases are being sent to UNC on an ongoing basis as they are reported.

All cases meeting the above criteria were sent, not just the first occurrence. Cases were electronically sent from the CCC to UNC for a two-step review process.

- Step 1 – Abstraction: Available medical records for each case was abstracted by a professional medical record abstractor who completed and data-entered the Heart Failure Hospital Record Abstraction Form (HTF). The abstraction form includes 65 questions covering the following: 1) screening for decompensation, 2) history of heart failure, 3) medical history, 4) physical exam (vital signs), 5) physical exam (findings), 6) diagnostic tests, 7) interventions, 8) medications, 9) complications following events, and 10) administrative information. It is from the HTF that an Event Summary Form (ESF), a synopsis of the critical variables (e.g. screening for decompensation at time of event, medical history, ejection fraction, diagnostic findings, etc.) was created. The abstractor also copied relevant sections of the medical records (e.g. echocardiograms, ECGs, cardiac catheterization reports, chest x-rays, lab results (e.g., BNP and proBNP – worst, last and upper limit of normal values) to create a diagnostic PDF. A combined file, ESF and diagnostic PDF, was uploaded into a secure data management system to which the physician heart failure reviewer had access.
- Step 2 – Heart Failure Diagnosis: the combined file was viewed by a physician trained in heart failure review who classified each case using the Heart Failure diagnosis form (Form 135). Following ARIC classification guidelines, the reviewer selected a HF diagnosis on Form 135 as one of the five classifications (see below). A case can be further sub-classified as preserved ejection fraction or reduced ejection fraction HF using data captured on Forms 135 and 136 (see Appendix 1 for link to copies of the forms). A computer algorithm was not used to assist with the diagnoses on the cases reviewed.

Heart Failure Outcome Definitions (every case receives one designation):

Definite decompensated heart failure, i.e., decompensation clearly present based on available data (satisfies criteria for decompensation).

Possible decompensated heart failure, i.e., decompensation possibly but not definitively present. A typical case of "possible" rather than "definite" would be due to the presence of co-morbidity that could account for the acute symptoms (COPD exacerbation, for example). In some cases of chronic CHF, it may be difficult to tell whether the patient's status matches the baseline CHF status or indicates some deterioration. If in doubt, reviewers record "possible decompensated HF". In general, reviewers prefer "possible" whenever the evidence for decompensation (symptoms, signs, imaging) is subtle. For example, a case of possible decompensated HF may be one that has a known history of CHF who has chest x-rays showing "active CHF", description of diuretic therapy, and an ICD-9 codes of 428, but there is no statement about decompensated heart failure in the discharge summary. (However, if a patient has such documentation with no known history of CHF, then the patient most likely has "definite decompensated heart failure"). If there is scant documentation and a decision "definite decompensated heart failure" and "possible decompensated heart failure" is required, reviewers rely more on the ESF than the provided records; e.g., records do not confirm definite decompensated heart failure but "MD notes suggest reason for hospitalization is HF = yes", then choose "definite decompensated heart failure".

Chronic stable heart failure, i.e., no decompensation but patient has chronic heart failure. "Stable" also denotes "compensated" heart failure (not necessarily asymptomatic, but that patient's chronic HF symptoms are controlled with therapy and there is no evidence in augmentation of therapy for worsening HF during the hospitalization.) Note: This includes patients with asymptomatic heart failure (evidence of LV systolic dysfunction, i.e., EF < 50%, and no heart failure symptoms). NOT included are: a history of transient LV/RV dysfunction if heart function is currently normal; or asymptomatic diastolic dysfunction alone.

Heart failure unlikely**,** i.e., there is no HF, heart function is normal based on available documentation. Ideally, for these cases there is some mention of normal heart function, but "heart failure unlikely" may be selected if there is sufficient data to make that inference in the absence of clear documentation.

Unclassifiable, i.e., medical record documentation is missing; or there is no decompensated HF AND cannot differentiate between "chronic stable heart failure" and "heart failure unlikely".

Note: If there are symptoms of heart failure only in the setting of a fatal cardiac arrest not due to an acute myocardial infarction, and the patient otherwise was not hospitalized for a heart failure exacerbation, reviewers do not count these as "decompensated heart failure" or "possible decompensated heart failure". Instead, these are classified as "chronic stable heart failure" *if* the patient had known history of heart failure but was not hospitalized with decompensated heart failure except at time of arrest (e.g., patient with metastatic cancer who had known LVEF 15% from ischemic cardiomyopathy, but had an arrest while being evaluated for failure to thrive because of the cancer).

Use of UNC HF outcome for analyses:

Pros: uses contemporary definitions of HF; detailed chart abstraction; ejection fraction and echo results are available so that reduced/preserved ejection fraction can be determined; subsequent events are adjudicated

Cons: not adjudicated on all WHI participants, and therefore there is some potential selection bias and differential drop-out of this HAH cohort that had UNC HF adjudications. Also, some cases have resulted in unknown status as a result of limited documentation. Therefore, care should be taken in creating an appropriate censoring time variable, taking into consideration cases with unknown status. Use of inverse probability weighting or other statistical techniques to account for potential selection bias should be considered.

Data available for analysis:

In the new dataset (unc_hf_inv.dat): UNCHF=event indicator, CASEDY=days from enrollment to HF diagnosis, variables for all items collected on Forms 135 and 136, and a computed variable indicating type of HF (ADHFTYPE). The definition for ADHFTYPE follows that of the ARIC study, and classifies the HF events as decompensated heart failure with preserved ejection fraction, systolic heart failure or recovered. See Appendix 2 for the algorithm used in computation.
Note: this dataset will include multiple records for participants with more than one case sent to UNC for adjudication.

Table 2.1

UNC Heart Failure Confirmed Outcomes (Annualized Percentages) Overall and by Age at Screening

Data as of: September 20, 2013; Events through September 30, 2010 (RR)

		Age			
Outcomes	**Total**	**50-54**	**55-59**	**60-69**	**70-79**
Overall HAH[1]					
Number enrolled	43901	6767	9326	19296	8512
Mean follow-up (months)	135.8	140.5	140.5	136.1	126.3
Heart failure	1742 (0.35%)	98 (0.12%)	171 (0.16%)	768 (0.35%)	705 (0.79%)
By study component					
Hormone Therapy					
Number randomized	27169	3410	5397	12275	6087
Mean follow-up (months)	143.2	151.6	148.9	143.6	132.6
Heart failure	1293 (0.40%)	51 (0.12%)	109 (0.16%)	554 (0.38%)	579 (0.86%)
MRC[2]					
Number randomized	22219	3716	5279	10068	3156
Mean follow-up (months)	167.3	171.9	169.3	165.7	163.6
Heart failure	574 (0.19%)	43 (0.08%)	64 (0.09%)	298 (0.21%)	169 (0.39%)

Table 2.2

UNC Heart Failure Confirmed Outcomes (Annualized Percentages) by Race/Ethnicity

Data as of: September 20, 2013; Events through September 30, 2010 (RR)

	Race/Ethnicity					
Outcomes	**American Indian/ Alaskan Native**	**Asian/ Pacific Islander**	**Black/ African American**	**Hispanic/ Latino**	**White**	**Other/ Unspecified**
Overall HAH[1]						
Number enrolled	130	525	14522	6466	21874	384
Mean follow-up (months)	131.2	133.5	128.2	121.4	145.2	135.8
Heart failure	6 (0.42%)	17 (0.29%)	526 (0.34%)	91 (0.14%)	1089 (0.41%)	13 (0.30%)
By study component						
Hormone Therapy						
Number enrolled	130	525	2721	1535	21874	384
Mean follow-up (months)	131.2	133.5	138.3	129.5	145.2	135.8
Heart failure	6 (0.42%)	17 (0.29%)	136 (0.43%)	32 (0.19%)	1089 (0.41%)	13 (0.30%)
MRC[2]						
Number randomized	64	239	6107	2463	13146	200
Mean follow-up (months)	167.7	164.9	166.6	165.0	168.1	163.9
Heart failure	3 (0.34%)	4 (0.12%)	156 (0.18%)	22 (0.06%)	386 (0.21%)	3 (0.11%)

[1] All Hormone Trial (HT), African American and Hispanic participants

[2] Medical Record Cohort (MRC) consists of all HAH participants enrolled in the Extension 2010-2015 study

Table 2.3

Number of UNC Cases Per Participant Adjudicated as Definite or Possible Decompensated HF by Cohort

Data as of: September 20, 2013; Events through September 30, 2010

	HAH participants[1]		HT participants		MRC participants	
	N	%	N	%	N	%
Total number of cases per participant sent to UNC						
1	1649	64.1	1164	62.3	600	65.4
2	473	18.4	357	19.1	182	19.8
3	222	8.6	173	9.3	68	7.4
4	104	4.0	78	4.2	31	3.4
≥5	126	4.9	96	5.1	37	4.0
Number of HF[2] cases per participant						
0	829	32.2	572	30.6	344	37.5
1	1266	49.2	925	49.5	443	48.3
2	288	11.2	224	12.0	81	8.8
3	116	4.5	82	4.4	32	3.5
≥4	75	2.9	65	3.5	18	2.0

[1] HT, African American and Hispanic Participants.

[2] Definite or possible decompensated heart failure.

Table 2.4
Comparison of WHI CHF vs. UNC HF[1] for HT, African American and Hispanic (HAH) Participants

Data as of: September 20, 2013; Events through April 8, 2005

	Congestive Heart Failure, WHI			
	No		Yes	
	# of Participants	%	# of Participants	%
All HAH participants				
Heart failure, UNC				
No	42571	99.2	254	20.4
Yes[2]	158	0.4	918	73.7
Unclassifiable[3]	141	0.3	64	5.1
Insufficient documentation[4]	58	0.1	10	0.8
HT participants				
Heart failure, UNC				
No	26283	99.0	77	9.6
Yes6	127	0.5	682	84.6
Unclassifiable7	94	0.4	41	5.1
Insufficient documentation8	37	0.1	6	0.7
MRC participants				
Heart failure, UNC				
No	21905	99.5	69	22.5
Yes6	32	0.1	213	69.4
Unclassifiable7	55	0.2	21	6.8
Insufficient documentation8	16	0.1	4	1.3

[1] UNC heart failure is counted as yes if the participant had any case adjudicated as heart failure. It is counted as no if all cases were adjudicated as no heart failure or the participant had no possible heart failure cases. It is counted as unclassifiable or insufficient documentation if any case was coded unclassifiable or if a possible case was not forwarded to UNC and any other case is classified as no heart failure.

[2] UNC heart failure includes definite or possible decompensated heart failure.

[3] Coded by UNC as unclassifiable.

[4] Insufficient documentation to forward the case to UNC.

Table 2.5. Baseline Characteristics of HAH Sample (All HT, Black/African American and Hispanic/Latino participants)

	Total HAH		HT		Black/ African American		Hispanic/ Latino	
	N	%	N	%	N	%	N	%
Number of participants	**44174**		**27347**		**14618**		**6484**	
Age group at screening								
65-69	16140	36.54	8833	32.30	6070	41.52	3264	50.34
70-74	19418	43.96	12360	45.20	6251	42.76	2527	38.97
75+	8616	19.50	6154	22.50	2297	15.71	693	10.69
BMI (kg/m^2)								
Underweight (< 18.5)	234	0.53	158	0.58	72	0.50	23	0.36
Normal (18.5 - 24.9)	10287	23.46	7106	26.13	2255	15.57	1572	24.51
Overweight (25.0 - 29.9)	15268	34.82	9540	35.07	4711	32.52	2443	38.09
Obese (≥30.0)	18061	41.19	10396	38.22	7447	51.41	2376	37.05
Race/ethnicity								
White	22030	49.87	22030	80.56				
Black/African American	14618	33.09	2738	10.01	14618	100.00		
Hispanic/Latino	6484	14.68	1537	5.62			6484	100.00
American Indian	130	0.29	130	0.48				
Asian/Pacific Islander	527	1.19	527	1.93				
Unknown	385	0.87	385	1.41				
Education								
0-8 years	1850	4.23	710	2.62	444	3.08	1168	18.34
Some high school	2888	6.60	1459	5.37	1305	9.04	603	9.47
High school diploma or GED	8010	18.31	5645	20.79	2017	13.97	1036	16.27
School after high school	17274	39.49	11039	40.66	5621	38.95	2232	35.05
College degree or higher	13725	31.37	8298	30.56	5046	34.96	1329	20.87
Income								
< $20,000	10791	26.23	6058	23.47	4124	30.58	2238	38.94
$20,000 - $34,999	10966	26.66	7315	28.34	3280	24.33	1355	23.58
$35,000 - $49,999	8040	19.55	5277	20.44	2431	18.03	932	16.22
$50,000 - $74,999	6747	16.40	4220	16.35	2247	16.67	732	12.74
≥ &75,000	4591	11.16	2943	11.40	1401	10.39	490	8.53
Smoking								
Never	22433	51.58	13605	50.33	7082	49.48	4006	63.07
Past	16653	38.29	10595	39.20	5594	39.08	1886	29.69
Current	4409	10.14	2831	10.47	1637	11.44	460	7.24
Moderate/strenuous physical activity (episodes/wk of at least 20 mins)								
None	8535	20.68	4907	19.59	3295	23.37	1342	21.97
<2 episodes/wk	18270	44.26	11043	44.08	6331	44.91	2783	45.56
2- <4 episodes/wk	6254	15.15	3843	15.34	2085	14.79	840	13.75
≥ 4 episodes/wk	8219	19.91	5259	20.99	2387	16.93	1143	18.71
Hysterectomy	19497	44.15	10739	39.27	8125	55.60	2900	44.76
Systolic blood pressure (mm Hg)								
≤ 120	15173	34.35	9664	35.34	4056	27.75	2767	42.70
>120 – 140	18656	42.24	11514	42.10	6444	44.09	2537	39.15
>140	10337	23.40	6169	22.56	4114	28.15	1176	18.15
Diastolic blood pressure (mm Hg)								
< 90	40159	90.94	25184	92.10	12705	86.98	6049	93.35
≥ 90	3999	9.06	2161	7.90	1902	13.02	431	6.65
Hypertension (Self report of treated disease or taking medication)	15639	35.40	8162	29.85	7547	51.63	1634	25.20
Treated diabetes (pills or shots)	3323	7.53	1556	5.69	1775	12.16	468	7.23

High cholesterol requiring medication	5878	14.51	3366	13.67	2195	15.92	906	15.28
History of heart failure	471	1.16	198	0.80	273	1.98	42	0.71
History of atrial fibrillation	1723	3.98	959	3.57	741	5.21	195	3.10
History of CHD (MI, angina, PCI, CABG)	3431	7.77	1802	6.59	1570	10.74	411	6.34
Has biomarker data (CRP, creatinine, glucose, insulin or lipids)[1]	27326	61.86	15742	57.56	10550	72.17	4345	67.01
Has GWAS data on dbGaP (imputed)	23421	53.02	14216	51.98	8596	58.80	3641	56.15
Has both biomarker and GWAS	22332	50.55	13239	48.41	8444	57.76	3597	55.48

[1] Actual number with each biomarker result may be slightly less than the total.

Appendix 1:

Copies of the following forms are available on the WHI website:
https://www.whi.org/researchers/studydoc/WHI%20Forms/Forms/Adjudication.aspx

Form 121 – Report of cardiovascular outcome (WHI CHF).
Form 135 – Heart failure diagnosis form (UNC HF)
Form 136 – Heart failure record abstraction form (UNC HF)

Appendix 2:

Algorithm used to create the UNC HF variable: ADHFTYPE
Variable names refer to data items in the UNC HF dataset. Please note that the algorithm uses actual dates that are not available in the investigator data file.

```
IF ARRIVEDT - 90 <= TTEDT <= DSCHDT THEN TTEEF = TTEEJECT;
IF ARRIVEDT - 90 <= CARDMRIDT <= DSCHDT THEN CARDMRIEF = CARDMRIEJECT;
IF ARRIVEDT - 90 <= CARDCTDT <= DSCHDT THEN CARDCTEF = CARDCTEJECT;
IF ARRIVEDT - 90 <= CARDRADVENTDT <= DSCHDT THEN CARDRADVENTEF = CARDRADVENTEJECT;
IF ARRIVEDT - 90 <= COROANGIODT <= DSCHDT THEN COROANGIOEF = COROANGIOEJECT;
IF ARRIVEDT - 90 <= STRESSTESTDT <= DSCHDT THEN STRESSTESTEF = STRESSTESTEJECT;
IF ARRIVEDT - 90 <= TEEDT <= DSCHDT THEN TEEEF = TEEEJECT;
IF ARRIVEDT - 90 <= TTEDT <= DSCHDT THEN TTELVSYST = TTEIMPLVSYST;
IF ARRIVEDT - 90 <= TEEDT <= DSCHDT THEN TEELVSYST = TEEIMPLVSYST;

IF TTEEF ne . THEN LVEF_CUR = TTEEF;
  ELSE IF CARDMRIEF ne . THEN LVEF_CUR = CARDMRIEF;
  ELSE IF CARDCTEF ne . THEN LVEF_CUR = CARDCTEF;
  ELSE IF CARDRADVENTEF ne . THEN LVEF_CUR = CARDRADVENTEF;
  ELSE IF COROANGIOEF ne . THEN LVEF_CUR = COROANGIOEF;
  ELSE IF STRESSTESTEF ne . THEN LVEF_CUR = STRESSTESTEF;
  ELSE IF TEEEF ne . THEN LVEF_CUR = TEEEF;

IF ESTLVEF = 1 THEN LVEF_CUR_LOW = 0;
  ELSE IF ESTLVEF IN(2,3) THEN LVEF_CUR_LOW = 1;
  ELSE IF LVEF_CUR >= 50.0 THEN LVEF_CUR_LOW = 0;
  ELSE IF . < LVEF_CUR < 50.0 THEN LVEF_CUR_LOW = 1;
  ELSE IF TTELVSYST = 4 THEN LVEF_CUR_LOW = 0;
  ELSE IF TTELVSYST IN(1,2,3,5) THEN LVEF_CUR_LOW = 1;
  ELSE IF TEELVSYST = 4 THEN LVEF_CUR_LOW = 0;
  ELSE IF TEELVSYST IN(1,2,3,5) THEN LVEF_CUR_LOW = 1;


IF ARRIVEDT - 2*365.25 <= TTEDT < ARRIVEDT THEN TTEPREEF = TTEEJECT;
IF ARRIVEDT - 2*365.25 <= COROANGIODT < ARRIVEDT THEN COROANGIOPREEF = COROANGIOEJECT;
IF ARRIVEDT - 2*365.25 <= TEEDT < ARRIVEDT THEN TEEPREEF = TEEEJECT;

IF ARRIVEDT - 2*365.25 <= TTEDT < ARRIVEDT THEN TTEPRELVSYST = TTEIMPLVSYST;
IF ARRIVEDT - 2*365.25 <= TEEDT < ARRIVEDT THEN TEEPRELVSYST = TEEIMPLVSYST;

IF EJECTFRACYR >= YEAR(ARRIVEDT) THEN LOWEF = LOWEJECTFRAC;

IF TTEPREEF ne . THEN LVEF_PRE = TTEPREEF;
  ELSE IF COROANGIOPREEF ne . THEN LVEF_PRE = COROANGIOPREEF;
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  ELSE IF TEEPREEF ne . THEN LVEF_PRE = TEEPREEF;
  ELSE IF LOWEF ne . THEN LVEF_PRE = LOWEF;

IF LVEF_PRE >= 50.0 THEN LVEF_PRE_LOW = 0;
  ELSE IF . < LVEF_PRE < 50.0 THEN LVEF_PRE_LOW = 1;
  ELSE IF TTEPRELVSYST = 4 THEN LVEF_PRE_LOW = 0;
  ELSE IF TTEPRELVSYST IN(1,2,3,5) THEN LVEF_PRE_LOW = 1;
  ELSE IF TEEPRELVSYST = 4 THEN LVEF_PRE_LOW = 0;
  ELSE IF TEEPRELVSYST IN(1,2,3,5) THEN LVEF_PRE_LOW = 1;
  ELSE IF LOWEJECTFRAC >= 50.0 THEN LVEF_PRE_LOW = 0;
  ELSE IF . < LOWEJECTFRAC < 50.0 THEN LVEF_PRE_LOW = 1;


IF HFDIAG IN(1,2) THEN DO;
     IF LVEF_CUR_LOW = . AND LVEF_PRE_LOW = . THEN ADHFTYPE = .;
     IF LVEF_CUR_LOW = . AND LVEF_PRE_LOW = 0 THEN ADHFTYPE = 1; /* preserved EF */
     IF LVEF_CUR_LOW = . AND LVEF_PRE_LOW = 1 THEN ADHFTYPE = 3; /* systolic */
     IF LVEF_CUR_LOW = 0 AND LVEF_PRE_LOW = . THEN ADHFTYPE = 1; /* preserved EF */
     IF LVEF_CUR_LOW = 0 AND LVEF_PRE_LOW = 0 THEN ADHFTYPE = 1; /* preserved EF */
     IF LVEF_CUR_LOW = 0 AND LVEF_PRE_LOW = 1 THEN ADHFTYPE = 2; /* recovered EF */
     IF LVEF_CUR_LOW = 1 AND LVEF_PRE_LOW = . THEN ADHFTYPE = 3; /* systolic */
     IF LVEF_CUR_LOW = 1 AND LVEF_PRE_LOW = 0 THEN ADHFTYPE = 3; /* systolic */
     IF LVEF_CUR_LOW = 1 AND LVEF_PRE_LOW = 1 THEN ADHFTYPE = 3; /* systolic */
END;
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