Data Management System

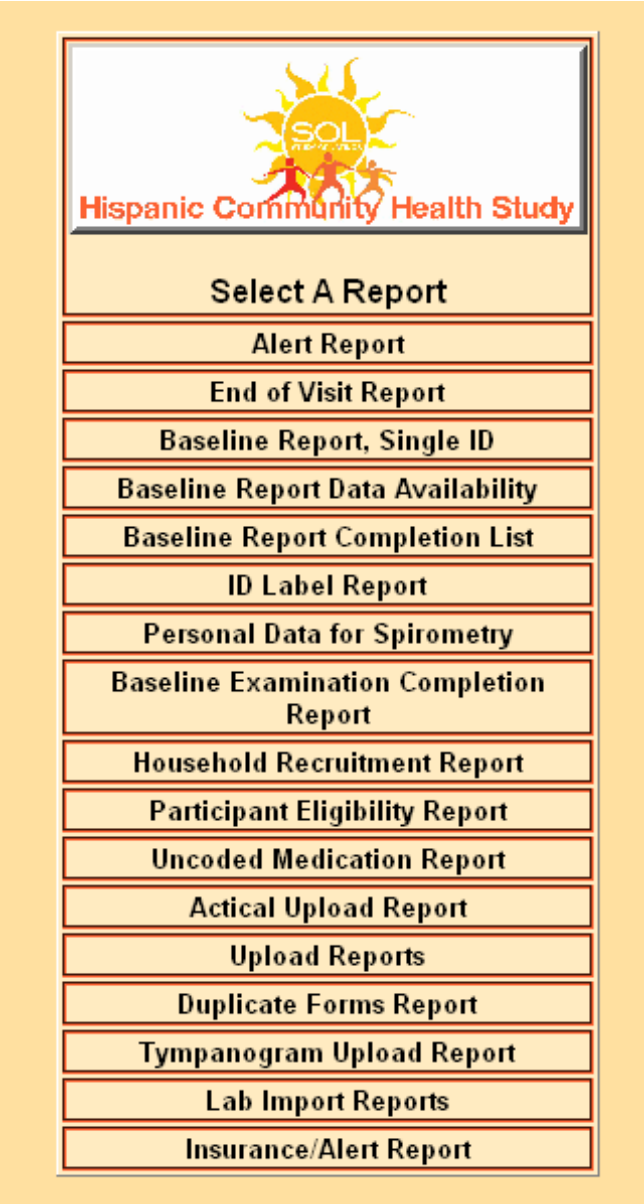
Guide to Reports

Version 1.3
January 7, 2009

Prepared by the
Collaborative Studies Coordinating Center

HCHS Data Management System Reports

The Report Menu displays all reports available in the HCHS Data Management System.



Alert Report

The purpose of the Alert Report is to notify a site when values of concern are reported in the chemistry lab and sleep reading center data.

The Alert Report evaluates the following analytes from the blood lab: triglycerides; glucose; white blood count; hemoglobin; platelets ceatinine; hepatitis B and C. It evaluates the following values from the sleep reading center: AHI > 50; baseline oxygen < 90; oxygen saturation < 90; heart rate > 150; and heart rate < 30.

The Alerts Report displays all IDs with a value in the alert range.

EXPEDITED NOTIFICATIONS 5/23/2008

ID	Source	Value	Alert Type	Date of Alert
C6000161	Triglycerides	1416	Expedited Alert	04/11/2008
C6000161	Glucose Fasting	307	Expedited Alert	04/11/2008
M7000803	Glucose Fasting	244	Expedited Alert	04/22/2008
M7001319	Glucose Fasting	464	Expedited Alert	04/22/2008
M7001343	AHI > 50	62.1	Expedited Alert	04/07/2008
M7001462	AHI > 50	62.4	Expedited Alert	04/07/2008
M7001462	O2 Saturation < 90	< 90%	Expedited Alert	04/07/2008
M7002433	Glucose Fasting	274	Expedited Alert	04/11/2008

For sleep alerts clicking on the ID brings up the Sleep Report:

HCHS/SOL STUDY

SLEEP STUDY QUALITY REPORT

ID NUMBER: X9000000 Date: Data Not Available

SIGNAL QUALITY

	Hours Recording Time	Hours Artifact-Free Recording Time
Nasal Cannula	Data Not Available	Data Not Available
Oxygen Saturation	Data Not Available	Data Not Available

OVERALL STUDY QUALITY: **Data Not Available**

URGENT REFERRALS

Type	0=No; 1=Yes	Comments
AHI > 50	Data Not Available	Data Not Available
Baseline Oxygen Saturation <90%	Data Not Available	Data Not Available
Oxygen Saturation <90% for 10%	Data Not Available	Data Not Available
Heart Rate > 150 bpm > 2 min.	Data Not Available	Data Not Available
Heart Rate < 30 bpm for > 2 min.	Data Not Available	Data Not Available

COMMENTS:

Data Not Available

Done

Alerts are displayed as long as the date on the alert record is earlier than the date on the RET which indicates whether you have notified the participant of the alert value. Thus, to remove an ID and its alert from the report list, you must enter the notification date on the RET form.

Warning: If a lab resends data for the same participant, the dates of the participant's alerts are updated. If this date is later than the date entered on the RET indicating when you notified the participant, the alert will again be displayed. You should check to see if the value changed or not in order to decide whether to notify the participant again. You must update the RET date to turn off the display of the alert.

End of Visit Report

The End of Visit report should be generated at the end of the participant's clinic visit. It contains a summary of information collected during the visit with some recommendations based on data values.

Baseline Reports

The Baseline report summarized information collected at a participant visit and gives recommendations based on that information.

There are three ways to access the Baseline Reports:

- Baseline Report-Single Id – allows user to enter a participant's ID to view the Baseline Report for that participant.
- Baseline Report Data Availability – brings up a list of IDs which have at least one record in the database from a lab or reading center (chemistry lab, sleep reading center, audiometry reading center, ECG reading center or pulmonary reading center.)
- Baseline Report Completion List – displays the list of participants whose Baseline reports have been sent to them, as indicated by the RET form.

The Baseline Report Data Availability is shown below.

LAB INFORMATION AVAILABILITY 9/22/2008

Subject ID	Chemistry Date	Sleep Date	Audio Date	ECG Date	PFT Date	Baseline Report Last Reviewed	Partial Baseline Report Sent
S8000177	06/11/2008	-	06/10/2008	05/08/2008	05/09/2008	-	-
S8000231	07/02/2008	07/08/2008	-	-	07/08/2008	-	-
S8000264	07/02/2008	07/08/2008	-	-	07/08/2008	-	-
S8000270	04/11/2008	05/11/2008	05/05/2008	-	04/09/2008	-	-
S8000329	04/15/2008	05/11/2008	-	05/08/2008	-	-	-
S8001107	06/20/2008	07/08/2008	-	06/24/2008	06/11/2008	-	-

Clicking on the ID brings up the Baseline Report. The next time you review this report the Baseline Report Last Reviewed column will be populated with the date last viewed.

If a date is followed by "**", it means that some of the data needed for the Baseline Report from that center is missing. To see what is missing, review the report.

If a date column is '-', there is no data for the participant from the lab or reading center.

When all columns have dates, a report with complete reading center data can be generated. There might be missing data from forms keyed into the DMS and that will be evident by viewing the report.

The Baseline Completion List Report lists all of the reports that have been completed. This report is sorted by the Participant ID. It looks the same as the Baseline Data Availability Report except that the Baseline Report Sent column shows the date the report was sent out, as recorded in the RETA form.

Use of the RET form

The report tracking form (RET) is designed to track when and how referrals were made for medical care, and to track the final study results being sent to the participants.

For all expedited notifications (alerts), fill in the date the test result was received at the Field Center in column 1, the date the notification was made in column 2, the method used in column 3 and the staff code number who implemented the notification (column 4). Alerts will be displayed on the Alerts Report until the date of notification has been entered into the RET form.

IDs will be displayed in the Baseline Data Availability Report until Question 4 (Date Final Report of Study Results sent) on the RET form is completed. This field is used to record the date by which all results have been received and the final report is mailed. If it is not possible to obtain all results from a lab or reading center by 3 months after the exam visit, an incomplete report is prepared and mailed.

ID Label Report

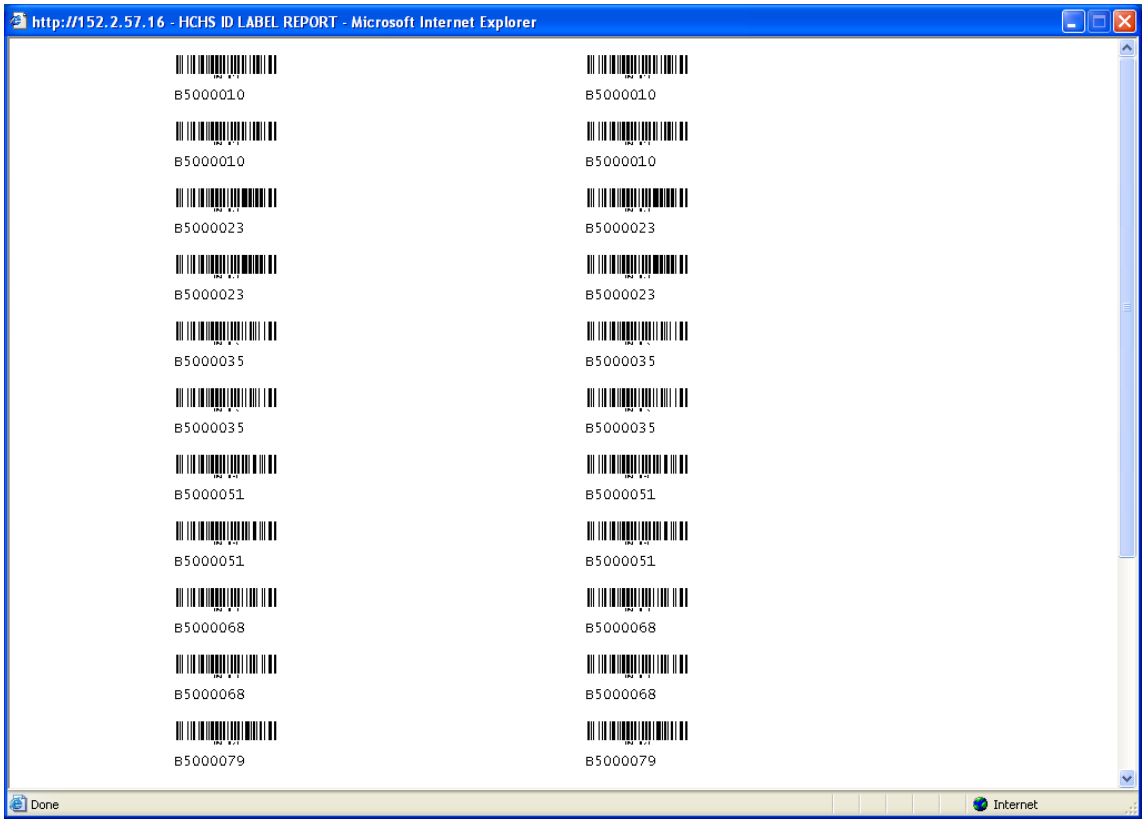
The ID label report is designed to print HCHS ID labels for 8 participants (4 per participant ID) on one 32-label Avery-#6571/6577 sheet. Each label has the ID in barcode format and the ID in regular alphanumeric format below the barcode.

The HCHS/SOL bar code ID report is to be used for the local field center production of ID labels that can be used with scanners for the reliable input of ID fields. The Central Laboratory in particular has requested that all sites use the report to produce labels for the "Participant ID" fields on the bio-specimen collection and processing form (BIOA) so that the lab can scan the IDs in the process of specimen inventory. Use of the bar code

labels with the BIOA will reduce the error rates in the matching of specimen number to participant ID. Centers may also find the use of the labels on the special purpose phantom form, where many participant IDs are paired with one QC phantom ID to create a collection of specimens for a dummy participant.

To run the report, select 'ID Label Report' from the list of Reports in the HCHS DMS. Input 8 Participant Ids and click on 'Submit'. You can see an example of the input screen below:

Below you can see a portion of the ID Label Report. To print the report, right click on the report and answer 'Yes' to the 'Print Report? Yes/No' dialog box that comes up.



Personal Data for Spirometry

The Personal Data for Spirometry Report displays 2 lines. The first line is a list of variables and the second is the list of corresponding values. Use this report to cut and paste values entered in the DMS into the Spirometry software. The report looks like this:

ID,Race,Age,Height,Gender,SBP,DBP,Status
X0000000,5,46,65,F,124,100,OK

STATUS tells whether the patient is taking medications which contra-indicate bronco-dilation. It has 3 possible values:

- OK – indicates that the MUE form has been entered and that the form indicates no medications which contraindicate bronco-dilation.
- NoDATA – indicates that the MUE form is not present or the relevant fields have not been entered.
- RESTRICT – indicates that the participant is taking medications which contra-indicate bronco-dilation.

Baseline Examination Completion Report

The Baseline Examination Completion report gives a list of all forms and a count of how many have been entered for a participant. Some forms are groups, for example the Dental Exam shows as a single row. A portion of the report is shown below:

Baseline Examination Completion Report for HCHS/

ID: X8888886 Visit Date: 04/08/2008

Form/Procedure	Present
A. Administrative:	
Eligibility Checklist (ELE)	0
Informed Consent Checklist (ICT)	0
Participant Safety Screen (PSE/PSS)	0
Clinic Check-off Sheet (CHK)	1
Report Tracking (RET)	0
B. Exam Procedures:	
Anthropometry (ANT)	0
Seated Blood Pressure (SBP)	0
Biospecimen Collection (BIO)	0
Ankle brachial Pressures (ABP)	0
Audiometry (OTO, TYM, AUD)	3
Oral examination battery (INI to END)	11
C. Interviews:	
Alcohol (ALE/ALS)	0

Household Recruitment Report

The Household Recruitment Report displays counts household status, based on the SCT form.

HCHS/SOL Household Recruitment Report by Center

Based on SCT forms entered by 5/28/2008 5:32:04 PM

For Period From 1/1/08 To 5/28/2008

	Miami N=0	
	n	%
1. Address not a household	0	0
2. Unable to contact after repeated attempts	0	0
3. HH refused to be screened	0	0
4. HH screening never completed, eligibility unknown	0	0
5. Screening completed, HH not eligible	0	0
6. HH eligible & not selected	0	0
7. HH eligible and selected, but refused to participate	0	0
8. HH eligible and selected, HH agreed to participate	0	0

Participant Eligibility Report

The Participant Eligibility Report shows, for each center and for a date range entered by the users, the number and percent of participants contacted, screened, ineligible and eligible.

HCHS/SOL Participant Eligibility Report by Center

Based on ELE forms entered by 5/27/2008 4:21:31 PM

For Period From 1/1/08 To 5/27/2008

	Bronx N=1		Chicago N=1		Miami N=0		San Diego N=1		Overall N=3	
	n	%	n	%	n	%	n	%	n	%
1. Unable to Contact	0	0	0	0	0	0	0	0	0	0.0
2. Refused Screen	0	0	1	100.0	0	0	0	0	1	33.3
3. Ineligible	0	0	0	0	0	0	0	0	0	0.0
i. Neither Language Preferred	0	0	0	0	0	0	0	0	0	0.0
ii. Not Hispanic/Latino - Self-Report	0	0	0	0	0	0	0	0	0	0.0
iii. Out of Area - 6 Months	0	0	1	100.0	0	0	1	100.0	2	66.7
iv. Active Military Duty	0	0	1	100.0	0	0	1	100.0	2	66.7
4. Eligible, Refused to Participate	0	0	0	0	0	0	0	0	0	0.0
5. Eligible, Agrees to Participate	1	100.0	0	0	0	0	1	100.0	2	66.7
6. Appointment Scheduled	1	100.0	0	0	0	0	1	100.0	2	66.7

Note: Individuals can have more than one reason for being ineligible. All reasons are counted so percentages of the subgroups will not sum to 100%

Uncoded Medications Report

The Uncoded medications report lists the subject ID and medication name of all medications entered into the MUE/MUS form which were not coded in the DMS. If strength and units have been entered, it is possible that you can still code the medications. Some were probably not found in the dictionary but others might have inadvertently been left uncoded. We would prefer to have most medications coded in the DMS.

Uncoded Medications

Subject ID	Visit	FSeqNo	Staff ID	Form Date	Medication Name	Strength	Units
B0000000	01	01			NUTROCORT		
C0000000	01	01	666	11/07/2007	Ibuprofen Cap 200 MG	200	MG
C0000013	01	01			HYDROCHLOROTHIAZIDE	50	MG
C0000013	01	01			HYDROCHLROTHIAZIDE	50	MG
C6000008	01	01			ASPIRIN	200	MG
C6000008	01	01			IBUPROFEN	200	MG
C6000008	01	01			TYLENOL	200	MG
M0000000	01	01			ASP/TYL		
X8888886	01	01			LISINOPRIL		
X9999994	01	01			IBRUPRO		
X9999994	01	01			Ifarab		
B0000000	01	01			LISINOPRIL		
B0000000	01	01			NUTROCORT		

Actical Upload Report

The Actical Upload report shows all files uploaded for a selected date range and whether the individual files were processed correctly into the study database. The primary problem checked by the processing program is misnamed files Actical files. The data for this report is updated each night. All Actical files uploaded one day will be represented on the report by the following morning.

ACTICAL REPORT

ZIP File Name	Serial Number	ID	StartDate	Process Date	Status
ab060015.zip	B101108	B5000195	3/26/2008	4/3/2008	OK - Data Received
ab060016.zip	B101109	B5000207	3/27/2008	4/11/2008	OK - Data Received
ab060016.zip	B101119	B5000228	3/27/2008	4/11/2008	OK - Data Received
ab060016.zip	B101113	B5000230	3/28/2008	4/11/2008	OK - Data Received
ab060016.zip	B101120	B5000242	3/28/2008	4/11/2008	OK - Data Received
ab060017.zip	B101118	B5000103	4/16/2008	5/2/2008	OK - Data Received
ab060017.zip	B101115	B5000443	4/18/2008	5/2/2008	OK - Data Received
ab060018.zip	B101111	B5000010	4/17/2008	5/10/2008	OK - Data Received
ab060018.zip	B101119	B5000455	4/16/2008	5/10/2008	OK - Data Received
ab060018.zip	B101109	B5000464	4/16/2008	5/10/2008	OK - Data Received

Tympanogram Upload Report

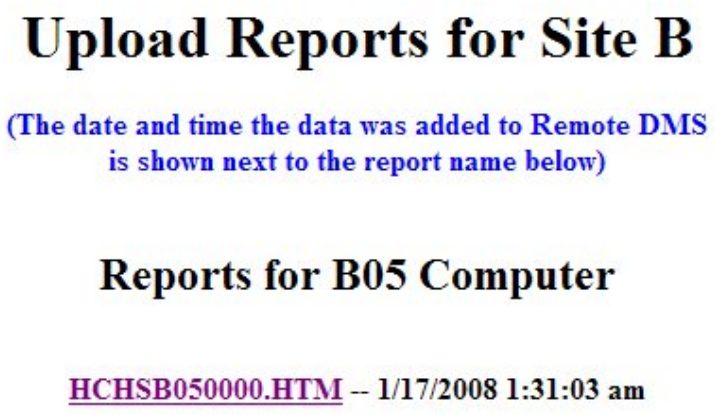
The Typmpanogram Upload report shows all PDF files uploaded for a selected date range and whether the individual files were processed correctly into the study database. The primary problem checked by the processing program is misnamed PDF files. The data for this report is updated each night. All Tympanogram files uploaded one day will be represented on the report by the following morning.

TYMPANOGRAM REPORT

ZIP File Name	ID	Process Date	Status
tb010002.zip	B5000010	9/11/2008	PDF Recieved
tb010002.zip	B5000023	9/11/2008	PDF Recieved
tb010002.zip	B5000051	9/11/2008	PDF Recieved
tb010002.zip	B5000068	9/11/2008	PDF Recieved
tb010002.zip	B5000084	9/11/2008	PDF Recieved
tb010002.zip	B5000103	9/11/2008	PDF Recieved
tb010002.zip	B5000195	9/11/2008	PDF Recieved
tb010002.zip	B5000207	9/11/2008	PDF Recieved
tb010002.zip	B5000228	9/11/2008	PDF Recieved

Upload Report

The Upload report lists all files uploaded from a local DMS system and processed into the study database. The list is categorized by computers within a site.



Click on the link (HCHSB050000.HTM in the example above) to see a summary of data uploaded:

Report For HCHSB050000

Form	Successful	Duplicates to Resolve	Exact Duplicate	Other Errors
COLA	5	0	0	0
COTA	5	0	0	0
COUA	5	0	0	0
DLBA	5	0	0	0
DLLA	5	0	0	0
DUBA	5	0	0	0
DULA	5	0	0	0
ENDA	5	1	0	0
INIA	5	0	0	0
RCAA	5	0	0	0
RESA	5	0	0	0

TSCA	5	0	0	0

					Original		Duplicate	
Subjid	Form	Version	Visit	FSeqNo	UserID	Date Entered	UserID	Date Entered
X0000000	END	A	01/99	00	UCCJAB	1/1/2008	UCCHEB	1/3/2008

Duplicates to resolve have been added to the database with visit=99

Exact Duplicates have been ignored.

CSCC will have information on Other Errors

Resolving Duplicate Records Reported in Upload Reports

Within Remote data entry, it is not possible to create duplicate records. However, when using local mode, it is possible to enter and upload a record with the same key fields as a record already in the remote system.

It is important for each user to check the upload report for any file uploaded, the morning after the upload (or, possibly, later). You may want to print the upload report. It should at least be read to determine the following:

1) Is the report there? If not, you may have merely created the upload file but not uploaded it; in that case, you will need to call the Coordinating Center.

2) Are there Duplicate records to Resolve? In the case of the example above, there is a duplicate ENDA record. UCCJAB entered a record 01/1/2008 (marked "Original"), and UCCHEB entered one on 1/3/2008 (marked "Duplicate"). (In some cases the "Original" may actually have been entered later than the uploaded "Duplicate", if the upload took place a few days after a record was entered in local mode.)

It's good to resolve duplicates as soon as they are reported, so that the Coordinating Center is not potentially using the wrong record. (The Coordinating Center does not use records showing visit 99.) Resolving them right away also keeps you from forgetting about them.

To resolve a duplicate, go into Data Entry and click on the ID of concern. Bring up the regular record, under the contact #01 part of the list in this case, and print it if it looks like a good, full record. Bring up the visit 99 record(s), and print it also if it looks like a good record. (A not so good record is one that is very obviously very

incomplete.) Compare the two to decide which to keep. Delete the unwanted one. If the remaining one has the needed key fields (visit 01 for END), deleting any contact #99 records will resolve the problem. But if the remaining one shows visit 99, you need to do Key Field Change to change the contact 99 to 01 for this case. If the sequence number is something other than 00, you'll need to key field change that to 00 also. **Be sure to keep the good record, if there is one. Don't accidentally delete it!**

When you have finished resolving the duplicate record(s), you should be able to see exactly the appropriate number and kind of records for the ID in the hierarchical ID menu/list.

3) Are there "Other Errors" records? If so, the Coordinating Center for the ID(s) in question. When you get this message, it means you uploaded a different version of a form. You may have to delete the old version and then re-add the newer version.

Insurance/Alert Report

HCHS/SOL Participant Health Insurance Coverage

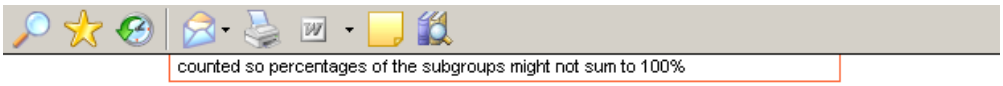
Based on HCE forms entered by 10/24/2008 10:18:19 AM
For Period From 10/01/2008 To 10/21/2008

	n	%
a. Not insured and no current coverage	21	61.8
b. Coverage by employer or union	2	5.9
c. Individual plan coverage	4	11.8
d. Medicaid	4	11.8
e. Medicare	6	17.6
f. Coverage via Military (CHAMPUS, Tri-Care)	4	11.8
g. Indian Health Services coverage	2	5.9
h. Other	3	8.8
i. Refused	1	2.9
j. Don't Know	1	2.9

Note: Individuals can have more than one type of health insurance. All types are counted so percentages of the subgroups might not sum to 100%

After selecting a date range to report on, this report which is actually three reports in one is displayed. The first of the three reports shows the number and percentage of participants that have that type of insurance. Because some participants may have multiple kinds of insurance the sum of the percentages may be larger than 100%.

The second of the three reports:



counted so percentages of the subgroups might not sum to 100%

HCHS/SOL Participant Types of Alerts

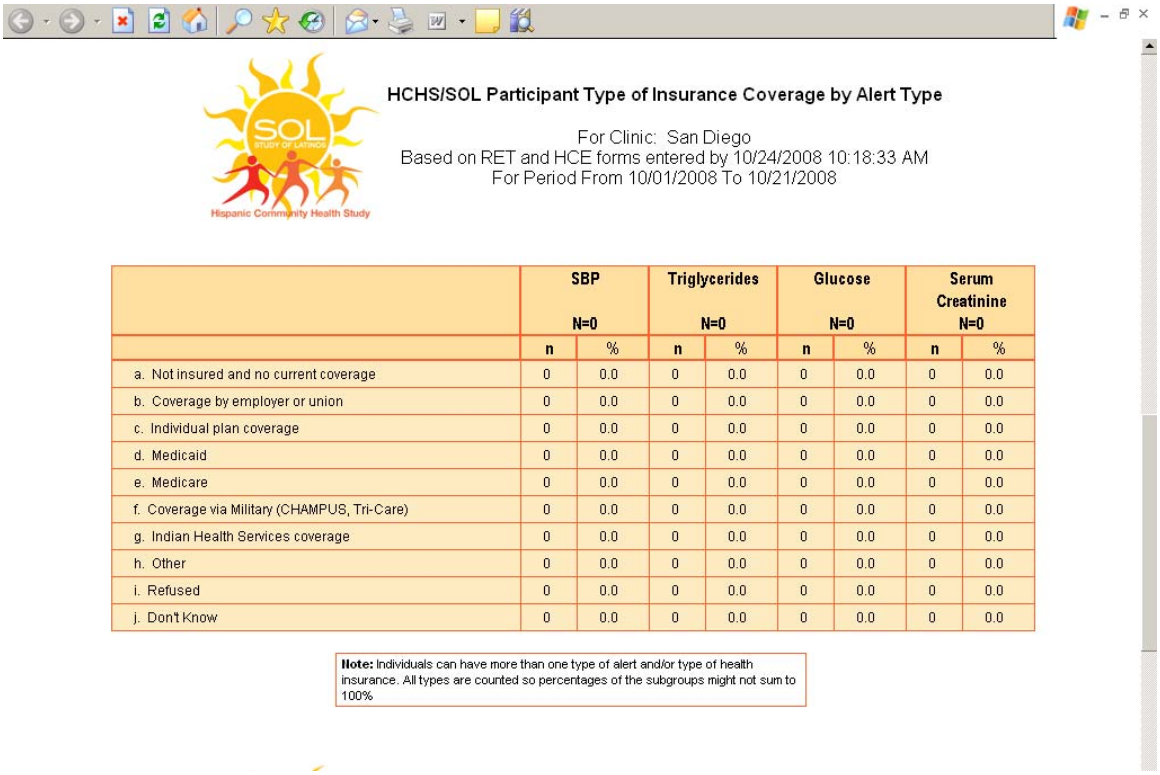
Based on RET forms entered by 10/24/2008 10:18:20 AM
For Period From 10/01/2008 To 10/21/2008

	n	%
a. SBP	0	0.0
b. Triglycerides	0	0.0
c. Blood Glucose	0	0.0
d. Serum Creatinine	0	0.0
e. Hematology	0	0.0
f. ECG	0	0.0
g. Sleep	1	100.0

Note: Individuals can have more than one type of alert. All types are counted so percentages of the subgroups might not sum to 100%

This report shows the number of participants for each alert type and the percentages for that alert of the participants in this date range that had an alert. Again the sum of the percentages will be larger than 100% if one or more participants have multiple alerts.

The third report which shows Insurance coverage by alert type is a two page report:



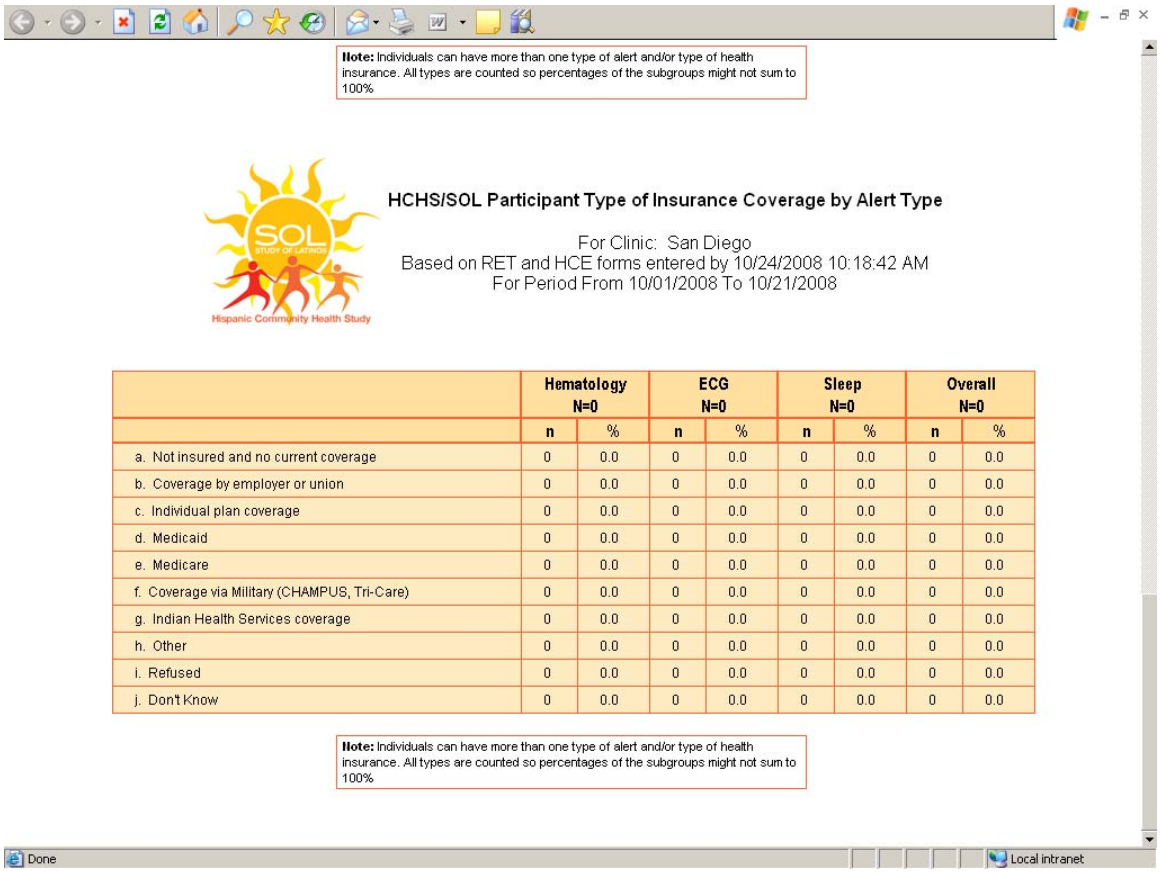
HCHS/SOL Participant Type of Insurance Coverage by Alert Type

For Clinic: San Diego
Based on RET and HCE forms entered by 10/24/2008 10:18:33 AM
For Period From 10/01/2008 To 10/21/2008

	SBP N=0		Triglycerides N=0		Glucose N=0		Serum Creatinine N=0	
	n	%	n	%	n	%	n	%
a. Not insured and no current coverage	0	0.0	0	0.0	0	0.0	0	0.0
b. Coverage by employer or union	0	0.0	0	0.0	0	0.0	0	0.0
c. Individual plan coverage	0	0.0	0	0.0	0	0.0	0	0.0
d. Medicaid	0	0.0	0	0.0	0	0.0	0	0.0
e. Medicare	0	0.0	0	0.0	0	0.0	0	0.0
f. Coverage via Military (CHAMPUS, Tri-Care)	0	0.0	0	0.0	0	0.0	0	0.0
g. Indian Health Services coverage	0	0.0	0	0.0	0	0.0	0	0.0
h. Other	0	0.0	0	0.0	0	0.0	0	0.0
i. Refused	0	0.0	0	0.0	0	0.0	0	0.0
j. Don't Know	0	0.0	0	0.0	0	0.0	0	0.0

Note: Individuals can have more than one type of alert and/or type of health insurance. All types are counted so percentages of the subgroups might not sum to 100%

And



Note: Individuals can have more than one type of alert and/or type of health insurance. All types are counted so percentages of the subgroups might not sum to 100%

HCHS/SOL Participant Type of Insurance Coverage by Alert Type

For Clinic: San Diego
Based on RET and HCE forms entered by 10/24/2008 10:18:42 AM
For Period From 10/01/2008 To 10/21/2008

	Hematology N=0		ECG N=0		Sleep N=0		Overall N=0	
	n	%	n	%	n	%	n	%
a. Not insured and no current coverage	0	0.0	0	0.0	0	0.0	0	0.0
b. Coverage by employer or union	0	0.0	0	0.0	0	0.0	0	0.0
c. Individual plan coverage	0	0.0	0	0.0	0	0.0	0	0.0
d. Medicaid	0	0.0	0	0.0	0	0.0	0	0.0
e. Medicare	0	0.0	0	0.0	0	0.0	0	0.0
f. Coverage via Military (CHAMPUS, Tri-Care)	0	0.0	0	0.0	0	0.0	0	0.0
g. Indian Health Services coverage	0	0.0	0	0.0	0	0.0	0	0.0
h. Other	0	0.0	0	0.0	0	0.0	0	0.0
i. Refused	0	0.0	0	0.0	0	0.0	0	0.0
j. Don't Know	0	0.0	0	0.0	0	0.0	0	0.0

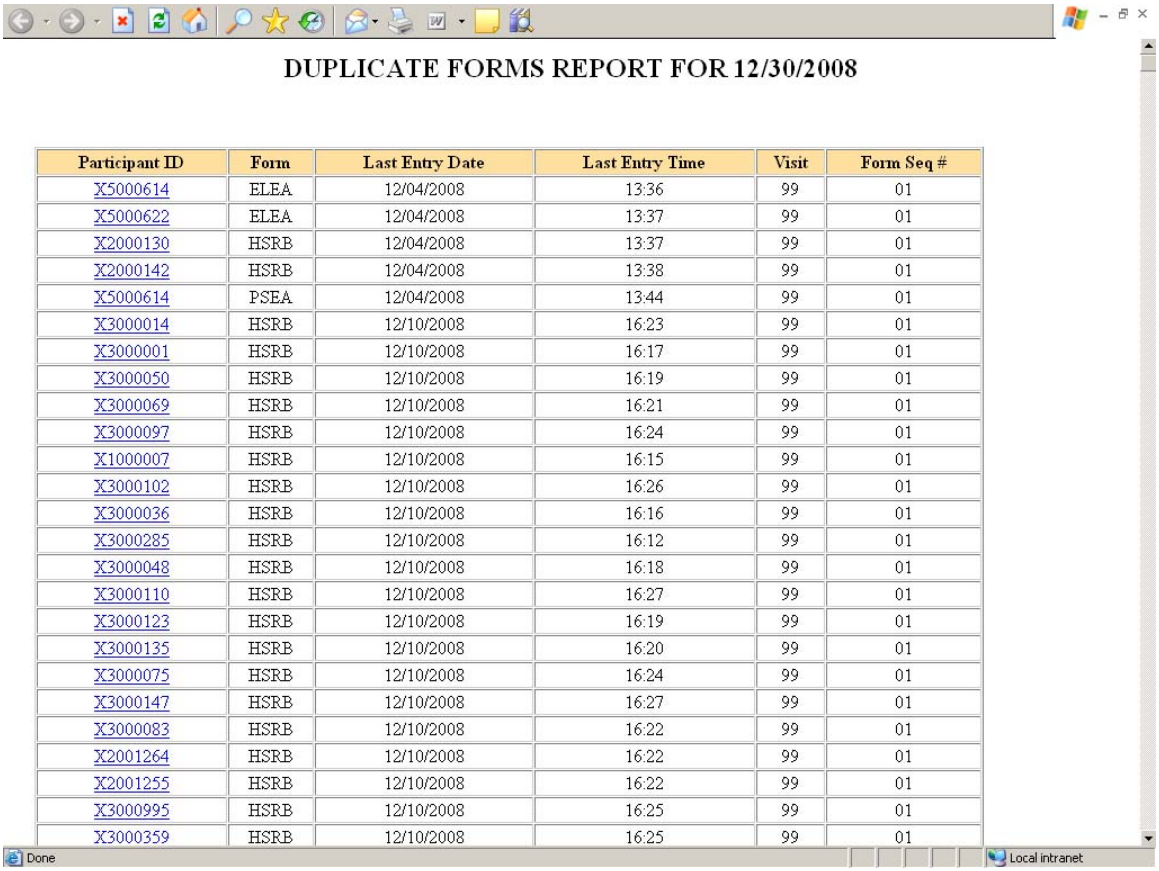
Note: Individuals can have more than one type of alert and/or type of health insurance. All types are counted so percentages of the subgroups might not sum to 100%

Done Local intranet

Percentages are of the number of participants where both the alerts and the insurance type exists.

Duplicate Forms Report

The Duplicate Forms report shows all forms for the users site that are either duplicates visit “99” forms or form sequence “02” Forms. (All forms should be visit “01” and form sequence “01”.)



DUPLICATE FORMS REPORT FOR 12/30/2008

Participant ID	Form	Last Entry Date	Last Entry Time	Visit	Form Seq #
X5000614	ELEA	12/04/2008	13:36	99	01
X5000622	ELEA	12/04/2008	13:37	99	01
X2000130	HSRB	12/04/2008	13:37	99	01
X2000142	HSRB	12/04/2008	13:38	99	01
X5000614	PSEA	12/04/2008	13:44	99	01
X3000014	HSRB	12/10/2008	16:23	99	01
X3000001	HSRB	12/10/2008	16:17	99	01
X3000050	HSRB	12/10/2008	16:19	99	01
X3000069	HSRB	12/10/2008	16:21	99	01
X3000097	HSRB	12/10/2008	16:24	99	01
X1000007	HSRB	12/10/2008	16:15	99	01
X3000102	HSRB	12/10/2008	16:26	99	01
X3000036	HSRB	12/10/2008	16:16	99	01
X3000285	HSRB	12/10/2008	16:12	99	01
X3000048	HSRB	12/10/2008	16:18	99	01
X3000110	HSRB	12/10/2008	16:27	99	01
X3000123	HSRB	12/10/2008	16:19	99	01
X3000135	HSRB	12/10/2008	16:20	99	01
X3000075	HSRB	12/10/2008	16:24	99	01
X3000147	HSRB	12/10/2008	16:27	99	01
X3000083	HSRB	12/10/2008	16:22	99	01
X2001264	HSRB	12/10/2008	16:22	99	01
X2001255	HSRB	12/10/2008	16:22	99	01
X3000995	HSRB	12/10/2008	16:25	99	01
X3000359	HSRB	12/10/2008	16:25	99	01

Done

Local intranet

Clicking on the ID will give the user more information (see next page).

FORM DIFFERENCES
For Participant ID: X5000614 And Form: ELEA

Comparing Visit: 01 and Form Sequence: 01

To Visit 99 and Form Sequence: 01

Field Name	01 Value	99 Value
elea0a	12/05/2008	11/28/2008
elea7a	12/02/2008	12/12/2008
elea7b1	0800	700

This follow-up report shows the user the differences between the two reports.

If there is only one form (form visit “01”, form sequence “01” does not exist) or more than two forms this follow-up report will indicate that information.

This situation can be corrected by deleting unnecessary or incorrect forms and making a keyfield change if necessary to make a form that has a visit other than “01” to be a visit “01” form (original “01” form has to be deleted first).