

# Chart Review Quality Management Protocol

The Chart Review information is a vital component of the Phase II data set. These data will help describe patients' level of engagement and retention in medical care, which is one of our main study outcomes. **It is essential that medical chart data be collected for each client enrolled in the SPNS study, that the collection of these data is as uniform as possible, and that the data be checked for accuracy.**

## I. Process for Obtaining Data/Charts

- Data Abstraction: The information on the chart review form should be transcribed directly from medical records, and should follow this hierarchy of sources:
  - 1) lab reports (connected with a primary care visit, not an ER visit or hospital admission),
  - 2) medical charts with physician notes, and
  - 3) physician reports.
- Chart Retrieval: If data are coming from a hospital system, ensure that the medical records are linked to a primary care visit (see explanation of primary care visit below). Since large hospitals may not have a centralized location for all of a patient's medical information, it is important to chart data from associated clinics as well as the main hospital.
- The efforts to retrieve data should be significant, including:
  - 1) at least two letter requests,
  - 2) at least two telephone follow-ups, and
  - 3) at least one in-person visit.
- If, despite these attempts, the data still are missing, report the situation to CORE.

## II. Data Quality Management

1. Personnel
  - Data collection staff must have sufficient medical knowledge to interpret medical charts.
  - Data collection staff must be trained to extract medical record data and/or have medical experience.
  - Data collection staff must be supervised by a knowledgeable HIV clinician or senior evaluator.
  - Data collection staff should bring any questions of interpretation to the attention of the HIV clinician or senior evaluator.
2. Standards for Quality Management
  - The HIV clinician or senior evaluator should review (at a minimum) the first ten chart abstractions completed by the data collection staff. If errors are found, discuss with data collection staff.

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- The HIV clinician or senior evaluator should conduct a 10% check of all chart abstractions quarterly, or more often if indicated by the results of the previous check.
- A 10% sample of electronic data should be compared to the paper data. The results should be reviewed, and errors should be appropriately revised in the database. If there is a greater than 10% error rate, all data in the database are reviewed against the paper data, and then the quality assurance procedure is repeated.
- The following audit should be conducted on all chart review forms prior to data submission.

### 3. Quality Audit

- Check that forms are complete,
- Check that values are within possible ranges,
- Check that dates are for the right time period, and
- Check that the visit dates correspond to HIV primary care visits.
- Lab dates should also correspond (roughly) with HIV primary care visits, rather than ER visits or inpatient admissions. However, if there are no primary care visits for the baseline period or the last follow up, but CD4 or Viral Load data are available from inpatient or ER visits, these can be recorded in order to obtain baseline or end point values.
- Resolve/clarify issues with CORE if needed.
- Checks for Electronic Data: Quality assurance checks should be conducted monthly by running frequencies for all variables to look for outliers, and to review results in general.
- Standard Check: In preparation for data submission to CORE, all data must be checked by running CORE's multisite SPSS syntax, when available. Errors found are corrected if in error. If the data that are giving the error message are correct, this is noted in submission to CORE. If so, the senior evaluator does not need to conduct the quality audit prior to submission as noted above.
- Discrepancies in Source Documentation: While lab reports should be used when available (following the hierarchy of collection), CORE recommends cross-checking the source documentation when possible to confirm accuracy. If discrepancies exist, this should be brought to the attention of the data manager and reasons investigated.
- Check list: Data quality management efforts should be recorded on the check list cover page to each Chart Review data submission. Essentially, this form summarizes the data quality assurance steps taken and findings.

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**Definition of HIV Primary Care Visit:** HIV primary care refers to care from the provider that most frequently monitors CD4 count and viral load tests, and prescribes HIV medication. Primary care providers may be those specializing in internal medicine, infectious disease, family practice physicians or obstetrics/gynecology. Ophthalmologists, pulmonologists, and other providers that treat conditions secondary to HIV or AIDS are not typically considered primary care providers. If a client reports that a specialist (e.g. oncologist) is their HIV primary care provider, these visits may be recorded as primary care visits, but please document this in a letter accompanying your data submission to CORE.

To determine if the encounter qualifies as a “visit,” an MD, PA, NP or DO must sign the medical charts and physicians’ notes from the HIV primary care visits. Thus, a visit with a nurse to read a PPD does not qualify as a visit unless signed by the MD. Other visits such as nurses’ visits, ER visits, and hospitalizations, for the purposes of this study, are not considered HIV primary care visits. Walk-in visits may be included as primary care visits.