

ARIC Manuscript Proposal # 812S

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SHHS Manuscript/Abstract Proposal Format

1. a. **Full Title:** Polysomnography performed in the unattended home vs attended laboratory setting
- b. **Abbreviated Title:** Home vs laboratory PSG
2. **Lead Author:** Iber, Conrad
3. **Timeline:**

Start date: 6/1/01 Finish Date 8/1/01

4. **Rationale:**

The site where recordings are performed(home vs laboratory)and the degree of supervision of these recordings may affect measurement of physiologic parameters of sleep and disordered breathing.

In the attended setting, technicians are available to monitor signal quality and replace or reposition faulty sensors. If signal quality is poorer in the unattended home recording than in laboratory setting, important diagnostic measurements may be altered or lost. Signal loss and study failures are more common in the unattended setting requiring exclusion of up to 24% of polysomnography recordings performed in the home.

Laboratory studies are performed in a setting unfamiliar to subjects. If sleep duration, sleep stage distribution, or body position are systematically different in the laboratory than in the home, recordings performed at home might better reflect the exposure to the accumulated physiologic stress of disordered breathing than recordings performed in the laboratory.

Published comparisons of home and laboratory monitoring include limited channel recordings and studies with a relatively few subjects selected for suspected sleep-disordered breathing. Lack of standardization of technique and reading has limited the generalizability of findings from these studies. Measurements of sleep staging is lacking in many limited channel recordings. Significant night to night variation in the RDI have been noted in subjects low RDI--this variation may confound the comparison of laboratory vs home polysomnography in a subset of subjects.

The SHHS performed complete polysomnography in population samples from 6 field centers and ensured standardized recording and reading of data. Night to night variation has been studied in the cohort. Analysis of the laboratory vs home data would provide a unique opportunity to determine comparability in non-referred population using more complete and standardized data collection in a non-referred population.

5. **Hypotheses:** Sleep stage distribution and the respiratory disturbance index are similar when derived from home unattended polysomnography and from attended laboratory polysomnography. Variations in these

measurements may be ascribed to normal night to night variation in measurement.

6. **Data:** Existing matched pair data from 64 SHHS subjects randomly assigned to attended laboratory PSG and unattended home PSG using the same sensors, technical application, and recording devices. The variables (listed in the 11. Brief Analysis Plan) are derived from the reading center interpretation of these polysomnograms. Subjects were selected to include both habitual snorers and nonsnorers to provide a range of RDI for analysis.

[information above this line will be used to obtain ARIC approval]

7. **Type of Study:** Secondary Study

8. **Type of Publication:** Journal Article

9. **Analysis Responsibility:** Central Analysis

10. **Introduction:** Polysomnography is a standard research and clinical tool for assessing sleep architecture and the intensity of sleep-disordered breathing. Technological advancement has sufficiently miniaturized data collection to facilitate unattended home monitoring.

11. **Brief Analysis Plan**

a. variables:

home TIMEBEDP, seconds in bed

home SLPPRDP, sleep period in seconds

home SLPEFFP, Sleep Efficiency %

home TMSTG1P, Percentage time stage 1

home TMSTG2P, Percentage time stage 2

home TMSTG34P, Percentage time stages 3&4

home TMREMP, Percent time in REM

home RDI, 3% desat

home RDI, 4% desat

home RDI, No desat or arousal

lab TIMEBEDP, seconds in bed

lab SLPPRDP, sleep period in seconds

lab SLPEFFP, Sleep Efficiency %

lab TMSTG1P, Percentage time stage 1

lab TMSTG2P, Percentage time stage 2

lab TMSTG34P, Percentage time stages 3 & 4

lab TMREMP, Percent time in REM

lab RDI, 3% desat

lab RDI, 4% desat

BMI (visit height)

Age
Sex
Neck circumference
Home Quality rating
Lab Quality rating

b. Statistical Method :

Descriptive statistics of the data set will include range and median age, average and standard deviation for BMI and neck circumference, the number of males and females, the distribution of RDI, sleep efficiency (and sleep staging and fragmentation variables) and technical study quality according to: order, site (home vs lab), age, RDI level. The primary hypothesis will be tested with a paired t-test for each of the summary PSG variables (RDI; arousal index, sleep stage). ANOVA will be used to assess effect of setting (home vs lab), study order, and age. Stratified analyses can explore for differences related to level of obesity (BMI), sex or initial RDI.

Secondary analyses will explore the extent to which the difference between RDIs measured in the two settings is related to study quality of each study. Data obtained will be analyzed with a repeated measures ANCOVA. Order, site, and study quality grade will be considered as covariates and RDI will be considered as the primary dependent variable. Sleep efficiency and age may also be considered as covariates. Similar analyses can be performed for arousal index and sleep stages as dependent variables. Other independent variables that may be considered are: gender and age.

12. Summary Section

The sub study analysis of polysomnography performed in the home vs. the laboratory provides a unique opportunity for SHHS to either verify the concordance of data sets obtained in home and laboratory environments or to determine which factors contribute to systematic differences. Existing analysis of night to night variation and standardization of data collection and polysomnographic reading will make a powerful contribution to this analysis. The generalizability of the data is also enhanced by subject selection—the cohorts are non-referred populations from a multicenter study.

Limitations. The analysis of this sub study data set may not prove concordance in the comparisons. Also, comparison of lab vs home may not necessarily establish that an observed difference confers superiority of one recording site over another if there are competing limitations to both environments. Though direct supervision and laboratory setting is a rationale for superiority of this site for data collection in subjects with sleep-disordered breathing, changing environment also represents a perturbation that may affect measured parameters. Though obesity has been associated with a decreased probability of successful study in SHHS, age, gender, BMI, and RDI were not associated with significant degradation of signal quality. Some potential factors which could contribute to differences between home and laboratory measurements in SHHS include:

- Degradation of sensor signals in the unattended home setting may decrease the detection threshold for respiratory events
- More time supine in the laboratory might result in a higher RDI
- A longer study time in the laboratory may increase duration and therefore desaturation with events
- Increased arousals and decreased efficiency in the laboratory may decrease a)REM or b) slow wave

sleep, altering RDI

13. **References**

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