National Emphysema Treatment Trial (NETT)

Curriculum Vitae

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1. Background and rationale

Origins of trial and NHLBI collaboration with HCFA

After presentation of preliminary results in 1991 and 1994, lung volume reduction surgery (LVRS) began to spread rapidly to medical centers across the country. In response to concerns of the medical community that hundreds of patients were receiving LVRS despite the fact that its effectiveness had never been definitively established, the National Heart, Lung, and Blood Institute (NHLBI) convened a workshop in September, 1995 to elicit the views of experts in pulmonary medicine, thoracic surgery, physiology, outcomes assessment, quality of life evaluation, and statistics on LVRS. The workshop participants concluded (Weinmann and Hyatt, 1996) that although LVRS was a promising procedure, it "must be evaluated in a scientific, coordinated, and cooperative fashion". They recommended that the NHLBI "develop a mechanism for funding data collection and analysis from a multicenter study" and that "a randomized study with a controlled, nonsurgical arm ideally should be undertaken to evaluate the procedure critically".

At the same time, Medicare contractors brought to the attention of the national office the increased number of billings for wedge resections and bullectomies for emphysema patients, referred to as LVRS. The Health Care Financing Administration (HCFA) decided on a nonreimbursement policy in August, 1995 to be implemented in December, 1995 based on the lack of medical evidence and the potential for high morbidity and mortality among Medicare beneficiaries. Because it was apparent that many more patients had received this procedure than appeared in the published literature, HCFA requested a technology assessment of LVRS by the Center for Health Care Technology (CHCT) within the Agency for Health Care Policy and Research (AHCPR) in September, 1995.

Data from the CHCT assessment were compiled in a report (AHCPR Pub. No. 96-0062) that judged "... it cannot reasonably be concluded at this time that the objective data permit a logical and a scientifically defensible conclusion regarding the risks and benefits of LVRS as currently provided". However, the report also concluded that "... an undefinable proportion of patients with COPD may have realized some benefit from this procedure. If the surgery could be accomplished without undue morbidity or mortality, a prospective trial of LVRS under uniform protocol requirements with comprehensive long-term post-operative followup data is both ethically and scientifically essential".

As a result of the CHCT assessment, HCFA approached the NHLBI about collaborating on the evaluation of LVRS. In April, 1996, the NHLBI and HCFA announced their intention to work together to conduct an efficacy trial to establish the risks and benefits of LVRS and to identify patient characteristics that lead to long-term success.

The solicitations requesting proposals to be a clinical center and the coordinating center were released on 3 June 1996. Proposals for the coordinating center were due on 5 August 1996, and proposals for a clinical center were due on 19 August 1996. On the basis of this scientific peer

review, contract awards were made to eighteen clinical centers and one coordinating center on 20 December 1996. Investigators from these centers are charged with the design and conduct of both a randomized clinical trial of medical therapy vs medical therapy plus LVRS for moderate to severe emphysema and an associated registry of patients. This research effort is the National Emphysema Treatment Trial (NETT).

Rationale for the trial

The published reports on LVRS represent relatively small numbers of selected patients without long-term followup or comprehensive assessment of risks, benefits, and costs. There has been considerable variability in baseline assessments, type of surgery performed, procedures for pre-operative, intra-operative, and post-operative care, as well as in the followup evaluations performed. There are also questions about how systematically patients have been followed and whether there are systematic biases in the available data (e.g., sufficient characterization of the patient selection biases and survivor or healthy subject biases in the followup assessments). The historical data reviewed by the NETT investigators highlight the potential problems and biases with such data, leading to a state of equipoise in the group of investigators. Systematic investigations are needed to address important issues of efficacy, safety, and cost for the many patients with advanced emphysematous lung disease who are dyspneic, dysfunctional, disabled, depressed, desperate, and potentially vulnerable and susceptible to any new treatment with the potential of relieving their considerable suffering. The issue of patient selection is also problematic since only a minority of the patients who present for evaluation for LVRS actually have undergone the procedure.

The natural history of patients with advanced emphysema who may be candidates for LVRS is not well defined. It is as important to learn more about the characteristics and natural history of patients not operated upon, as it is to learn more about those who undergo LVRS.

Finally, given the substantial costs and health care resource utilization associated with this new surgical therapy which could be applied to large numbers of patients, there are key questions that need to be answered about whether the benefits of LVRS outweigh the associated risks and costs. To make rational treatment choices, one needs to make value judgements about the mortality, symptoms, and quality of life of such patients with and without surgery, as well as to estimate the value, in both economic and human terms, of the potential benefits of the operation.

2. Design summary

Primary objectives

- The National Emphysema Treatment Trial (NETT) is a randomized clinical trial of medical therapy alone versus medical therapy plus LVRS for emphysema. The trial is designed to determine if the addition of LVRS to medical therapy improves survival and increases exercise capacity (maximum workload).

Secondary objectives

- To determine if the addition of LVRS to medical therapy improves health related quality of life and reduces symptoms.
- To determine if the addition of LVRS to medical therapy improves pulmonary function as measured by ventilatory function (FEV_1), functional capacity (six minute walk distance), gas exchange, and attention and psychomotor functioning (Trail Making Test).

Type of study

- Multicenter, unmasked, randomized, with controlled non-surgical arm

Sample size and recruitment goal*

- Sample size assumptions: The detectable mortality difference over a 4.5 year period of followup, medical therapy vs LVRS, is 16.7% - 12.7% = 4%. This corresponds to a proportionate reduction in cumulative 4-year mortality of 30% in the LVRS groups, factoring in staggered entry, crossover from the medical therapy group to surgery, and the refusal rate. This assumes a two-sided Type I error of 0.01, power of 0.90.
- Recruitment goal: 2,500 patients, 6% minority, 30% female

Randomization

- Medical group: Receives medical therapy
- Surgical group: Receives medical therapy and LVRS
- 1 to 1 allocation ratio, medical to surgical
- Within LVRS group, at clinics doing both types of LVRS, 1 to 1 allocation ratio, MS vs VATS

Stratification

- Clinic

Treatments

- **Medical therapy**
  - Medical management standards
    - Individualized assessment of medical treatment regimen, measures to improve airflow and reduce the work of breathing, evaluation and recommendations for adequate oxygenation, and pulmonary rehabilitation (exercise training, education sessions on emphysema and its management, and psychosocial counseling)

- Management plan for maintaining long-term abstinence from smoking
- Regular inhaled bronchodilator therapy with both ipratropium bromide and a beta-2 agonist
- Oxygen therapy, when necessary, to achieve an arterial oxygen saturation of at least 90%
- Pneumococcal vaccination as needed

- Pulmonary rehabilitation (see Table 3)
  - Pre-randomization phase, lasting 6-10 weeks
  - Begins with initial rehabilitation evaluation and goal setting
  - Moves to core rehabilitation, which includes exercise training, group and/or individual education sessions, and psychosocial evaluation
  - Continued rehabilitation includes education sessions, exercise training sessions, and psychosocial support
  - Rehabilitation re-evaluation assesses whether the rehabilitation goals have been achieved, medical therapy has been optimized, and the patient has adhered to the prescribed treatment plan
  - Post-randomization consolidation phase consists of a 8-9 week program of supervised rehabilitation
  - For patients assigned to medical therapy, these sessions will take place immediately following randomization; for patients assigned to LVRS, the sessions will begin after discharge from hospital when patient is able to return for outpatient therapy
  - Long-term maintenance phase

- **Surgery**
  - LVRS is defined as excision of emphysematous lung parenchyma from both sides performed either via a median sternotomy (MS) or bilateral video-assisted thoracoscopy (VATS).

Masking

- Unmasked

Inclusion criteria

- History and physical exam consistent with emphysema
- CT scan evidence of bilateral emphysema
- Pre rehabilitation post bronchodilator TLC $\geq$ 100% predicted
- Pre rehabilitation post bronchodilator RV $\geq$ 150% predicted
- Pre rehabilitation FEV_1 (maximum of pre and post bronchodilator values) $\leq$ 45% of predicted and, if age $\geq$ 70 years pre rehabilitation, FEV_1 (maximum of pre and post bronchodilator values) $\geq$ 15% of predicted
- Pre rehabilitation room air, resting $PaCO_2 \leq 60$ mmHg ($\leq$ 55 mmHg in Denver)
- Pre rehabilitation room air, resting $PaO_2 \geq 45$ mmHg ($\geq$ 30 mmHg in Denver)
- Pre rehabilitation plasma cotinine $\leq$ 13.7 ng/ml (if not using nicotine products; Jarvis, 1987) or pre rehabilitation arterial carboxyhemoglobin $\leq$ 2.5% (if using nicotine products)
- Body mass index $\leq$ 31.1 kg/m^2 (males) or $\leq$ 32.3 kg/m^2 (females) as of randomization

2. Design summary

- Nonsmoker (tobacco products) for 4 months prior to initial interview and patient remains a nonsmoker throughout screening (by history)
- Approval for surgery by cardiologist if any of the following findings are noted prior to randomization (approval must be obtained prior to randomization):
  - Unstable angina
  - Left ventricular ejection fraction cannot be estimated from the echocardiogram
  - Left ventricular ejection fraction < 45%
  - Dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction
  - > 5 premature ventricular beats/minute (does not apply during exercise testing)
  - Cardiac rhythm other than sinus or premature atrial contractions noted during resting EKG
  - S_3 gallop on physical examination
- Completion of all pre rehabilitation assessments
- Judgment by study physician that patient is likely to be approved for surgery upon completion of the rehabilitation program
- Completion of NETT rehabilitation program
- Completion of all post rehabilitation and all randomization assessments
- Approval for surgery by pulmonary physician and thoracic surgeon in consultation with the anesthesiologist, post rehabilitation and just prior to randomization
- Consent for Screening and Patient Registry signed
- Consent for Pulmonary Rehabilitation signed
- Consent for Randomization to Treatment signed

Exclusion criteria

- s3/rz post bronchodilator $FEV_1 \leq 20\%$ predicted and non heterogenous emphysema on CT scan (as of 17 May 01)
- s3/rz post bronchodilator $FEV_1 \leq 20\%$ predicted and s1/s2 $D_LCO \leq 20\%$ predicted (as of 17 May 01)
- CT scan evidence of diffuse emphysema judged unsuitable for LVRS
- Previous lung volume reduction surgery (laser or excision)
- Pleural or interstitial disease which precludes surgery
- Giant bulla (≥ 1/3 the volume of the lung in which the bulla is located)
- Clinically significant bronchiectasis
- Pulmonary nodule requiring surgery
- Previous sternotomy or lobectomy
- Myocardial infarction within 6 months of interview and ejection fraction < 45%
- Congestive heart failure within 6 months of interview and ejection fraction < 45%
- Uncontrolled hypertension (systolic > 200 mmHg or diastolic > 110 mmHg)
- Pulmonary hypertension: mean P_{PA} on right heart catheterization ≥ 35 mmHg (≥ 38 mmHg in Denver) or peak systolic P_{PA} on right heart catheterization ≥ 45 mmHg (≥ 50 mmHg in Denver); right heart catheterization is required to rule out pulmonary hypertension if peak systolic P_{PA} on echocardiogram ≥ 45 mmHg

- Unplanned weight loss > 10% usual weight in 90 days prior to interview
- History of recurrent infections with daily sputum production judged clinically significant
- Daily use of more than 20 mg prednisone or its equivalent as of randomization
- History of exercise related syncope
- Resting bradycardia (< 50 beats/min), frequent multifocal PVCs, or complex ventricular arrhythmia or sustained SVT
- Other cardiac dysrhythmia which, in the judgment of the supervising physician, might pose a risk to the patient during exercise testing or training
- Oxygen requirement during resting or Part 1 oxygen titration exceeding 6 L/min to keep saturation ≥ 90%
- Evidence of systemic disease or neoplasia that is expected to compromise survival over the duration of the trial
- Any disease or condition which may interfere with completion of tests, therapy, or followup
- Six minute walk distance ≤ 140 meters post rehabilitation six minute walks
- Inability to complete successfully any of the screening or baseline data collection procedures (e.g., hypoxemia to SpO_2 < 80% within 2 minutes of unloaded pedaling despite supplemental oxygen, inability to coordinate a regular cadence of > 40 cpm, inability to complete 3 minutes unloaded pedaling, claudication, lower extremity or back orthopedic problems that prohibit sustained pedaling)

Recruitment

- To sample size goal
- 4.5 years

Duration of followup

- Staggered entry of patients for 4.5 years to a common closing date of December 2002 (average per patient followup = 2.2 years).

Outcomes

- Survival (design variable)
- Maximum exercise capacity
- Quality of life and respiratory symptoms
- Pulmonary function
- Lung mechanics
- Functional capacity
- Radiologic assessments
- Cardiovascular assessments
- Health care utilization, costs, and utility
- Attention and psychomotor functioning

NETT CV

2. Design summary

Data collection schedule

- Baseline: visit 4-6 weeks prior to 6-10 weeks of pulmonary rehabilitation followed by a visit up to 3 weeks prior to randomization
- Follow-up: At 6 month intervals after randomization for two years and annually thereafter. Telephone contacts are scheduled at 1 month, 2 months, 4 months, 8 months, 10 months, 15 months, 18 months, 21 months, 27 months, 30 months, 33 months, 39 months, 42 months, 45 months, 51 months, 54 months, and 57 months after randomization.

Data analysis and monitoring

- Review of data by DSMB at quarterly meetings
- Early termination of the trial or protocol modifications made by the DSMB
- Primary analyses by original treatment assignment
- All events or measurements made after randomization are included in the primary analysis

***** NETT was ended on the planned date despite accrual that was lower than expected (1218 patients instead of 2500). Had the trial been designed with the assumptions of the higher mortality rate and the lower crossover rate than were actually observed (0.11 deaths per person-year and 5.4 % crossover), the recruitment goal would have been 1198 patients.

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3. Summary of pulmonary rehabilitation program

			Rehabilitation Components (supervised)[10]				
PHASE	**LENGTH**	**SITE**	**MEDICAL**	**EXERCISE[1]**	**SKILL/EDUCATION[2]**	**PSYCH-SOCIAL[3]**	**NUTRITION**
PRE-RANDOMIZATION (6-10 wks for Core and Cont Rehab)							
Rehab Evaluation	1 day	CLC[4]	1 rehab or clinic MD visit[5]	1 rehab eval[6]	1 skill/education eval[7]	1 eval[12]	
Core Rehabilitation	5 days	CLC staff at CLC or satellite	1 clinic MD visit[13]	4 individual rehab exer training[8]	3-4 individual/group rehab skill/education	1 individual/group counselling	
Cont Rehabilitation	5-9 weeks	CLC or satellite	1-3 MD(clinic or rehab)/RNP/PA visits if needed	16 group/individual rehab exer train[9]	8-12 group/individual rehab skill/education[11]	4-8 individual/group counselling[11]	1 visit, if needed[11]
Rehab Re-Evaluation	1 day	CLC	1 clinic MD visit	1 rehab eval	1 rehab skill/education eval		
POST-RANDOMIZATION (8-9 wks)							
Medical group (Consolidation)	2 days	CLC or satellite	1 clinic MD visit	2 individual rehab exer train	1 individual rehab skill/education if needed	2 group/individual counselling	
Medical group (Continued Consolidation)	8 weeks	CLC or satellite	1 MD visit if needed	8 group/individual rehab exer train (once weekly)	group/individual rehab skill/education as needed	group/individual counselling as needed	
Surgical group (pre-op)	≤ 2 weeks	Home exer training	Pre-op evals				
Surgical group (Post Discharge Consolidation)	2 days	CLC or satellite	1 clinic MD visit if needed	2 individual rehab exer train	1 individual rehab skill/education	1 group/individual counselling	
Surgical group (Continued Consolidation)	8 weeks	CLC or satellite	1 MD visit if needed	8 group/individual rehab exer train (once weekly)	group/individual rehab kill/education as needed	group/individual counselling as needed	
LONG TERM REHABILITATION	Up to 5 years	CLC and satellite		1 exer train at visits; as needed at other times	1 rehab skill/education at visits; as needed at other times	Individual counselling as needed	Visits as needed

1. Typical rehab exercise training requires 60-90 min, includes stretching, endurance, strength and upper extremity exercises (performed on a single day), and may be performed in 1 or more individual sessions separated by a period of rest.
2. Typical rehabilitation skills/education sessions require 30-60 minutes.
3. Typical psychosocial group/individual sessions require 45-60 minutes.
4. CLC = NETT clinical center
5. Medical evaluation may be completed during NETT diagnostic evaluation.
6. Evaluation requires 60-90 minutes.
7. Usual rehabilitation education evaluation requires 30-45 minutes.
8. Must complete all 4 sessions
9. Must complete at least 12 sessions.
10. It is expected that patients will maintain a daily home exercise and rehabilitation program. Exercise should be performed at least 3-5 times per week. The Table refers only to supervised sessions.
11. Typical rehabilitation session includes exercise training plus one education, psychosocial, or nutrition session; however, exercise and skill/education sessions need not be done on the same day. Total number of education, psychosocial, and nutrition sessions should equal the number of exercise sessions (minimum=12, optimal=16)
12. Includes Self Eval Quest, Trail Making Test, and Beck Depression Inventory and interview with patient
13. Timing is flexible; may occur anytime after screening has started

4. Consent, data collection, and telephone contact schedule through Dec 2002**

Procedure	s1/s2	Core Rehab/ Cont Rehab	s3	Post Cont Rehab/RZ	Months from randomization 6	12	18	24	30	36	42	48	54	60
Consent	C1,C2†			C3†										
Physical/history	X*		X	X△	X	X	.	X	.	X	.	X	.	X
Spiro/lung vol/PI_{max}, PE_{max}	X*		X	X△	X	X	.	X	.	X	.	X	.	X
D_LCO	X		.	.	.	X	.	.	.	.	.	.	.	.
Pulm mech/resp muscle function	S		.	.	S	.	.	.	.	.	.	S	.	.
Partial/max flow-volume	S		.	.	S	.	.	.	.	.	.	S	.	.
Perfusion scan	.		.	X	.	.	.	.	.	.	.	.	.	.
High resolution CT scan	X		.	.	X	.	.	.	.	X	.	.	.	.
Chest x-ray	X		.	.	X	.	.	.	.	X	.	.	.	.
O_2 titration	X*		X	X△	X	X	.	X	.	.	.	.	.	.
6 minute walk	X*		X	X△	X	X	.	X	.	.	.	.	.	.
Blood and urine analysis,A1AT	X		.	.	.	X▽	.	X▽	.	X▽	.	X▽	.	X▽
Plasma cotinine○	X○		X○	.	.	.	.	.	.	.	.	.	.	.
Arterial COHb○	X○		X○	.	X	X	.	X	.	X	.	X	.	X
Resting ABG on room air	X*		X	X△	X	X	.	X	.	X	.	X	.	X
Max exercise: dysp, gas collect, ECG		X*		X	X△	X	X	.	X	.	X	.	X	. X
ABG during exercise (on oxygen)	S*		S	S△	S	S	.	S	.	S	.	S	.	S
Resting ECG	X		.	.	.	.	.	.	.	.	.	.	.	.
Echocardiogram	X		.	.	X	.	.	.	.	.	.	.	.	.
Dobutamine-radionuclide scan	X		.	.	.	.	.	.	.	.	.	.	.	.
Right heart catheterization	X#,S		.	.	S	.	.	.	.	.	.	.	.	.
SF-36, SGRQ, SOBQ, QWB	X*		X	X△	X	X	.	X	.	X	.	X	.	X
Trail making test	X		.	.	.	X	.	X	.	X	.	X	.	X
Psychosoc quest (Beck, Self eval)	X		.	.	.	.	.	.	.	.	.	.	.	.
Telephone contact‡	.		.	.	.	.	X	.	X	.	X	.	X	.

†C1=Consent for screening & registry (obtained after review of data from private MD but before testing at NETT clinic); C2=consent for pulm rehab (obtained after s1/s2 testing & confirmation of eligibility); C3=consent for RZ (obtained after completion of all procedures listed under RZ and confirmation of eligibility)

*=Must have an assessment no more than 42 days prior to enrollment in rehab

△=Can use post-rehab exam values if performed no more than 21 days prior to randomization

▽=Everything but A1AT

○=Before RZ, nonsmoking is checked with plasma cotinine (if not using nicotine) or arterial COHb (if using nicotine); after RZ, all patients have arterial COHb measured at each visit

S=In selected clinics

#=If pulmonary hypertension is suspected; must be done before randomization; all patients in selected clinics (substudy)

‡=Telephone contacts also occur at 1, 2, 4, 8, 10, 15, 18, 21, 27, 33, 39, 45, 51, and 57 months after randomization

** Between 1 Jan 2003 and 31 Dec 2003, follow up contacts were limited to in person visits at 6 mos, 2, 3 and 5 years; 1 and 4 year visits were completed by telephone

5. Substudies

Substudy	Objective	Description
Arterial blood gas analysis during cardiopulmonary exercise	Investigate gas exchange during maximum exercise.	Included 243 patients enrolled at Cedars-Sinai Medical Center, Mayo Clinic Foundation, National Jewish Medical Center, Temple University, and University of Pittsburgh. Assessments pre and post rehabilitation and 6, 12, 24, 36, 48, and 60 months post randomization. Cosponsored by NHLBI and CMS.
Cardiovascular	Investigate effects of LVRS on right heart function and pulmonary hemodynamics. Procedures included right heart catheterization, intrathoracic pressure, multi-gated acquisition scan.	Included 163 patients enrolled at Long Island Jewish Medical Center in consortium with Columbia University, St Louis University, and Temple University. Assessments pre randomization and 6 months post randomization. Cosponsored by NHLBI and CMS.
Cost effectiveness	Evaluate the cost effectiveness of LVRS versus medical	Included all patients with Medicare coverage. Data on prescription medication and patient and family personal costs (time and travel distance) were collected by interview pre and post rehabilitation and periodically throughout follow-up. Survival data obtained from clinics and through matching to the Social Security Death Master File. Medicare claims data provided the health care utilization and cost data. Cosponsored by NHLBI, CMS, and AHRQ.
Pulmonary mechanics	Investigate effects of LVRS on lung elastic recoil pressure, flow-volume relationship, and pulmonary resistance.	Included 263 patients enrolling at Baylor College of Medicine, Brigham and Women's Hospital, Long Island Jewish Medical Center in consortium with Columbia University, National Jewish Medical and Research Center, and Temple University. Assessments pre randomization and 6 and 48 months post randomization. Cosponsored by NHLBI and CMS.

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6. Landmark events

1996	Jun 03	RFP issued
	Dec 20	Funding initiated for clinics and Coordinating Center
1997	Oct 21	First patient screened for NETT
1998	Jan 29	First patient randomized to treatment
1999	Jun 01	Accrual of capitation payments begins
	Sep	Protocol paper published in J Thorac Cardiovasc Surgery
2000	Oct 20	First transmission of NETT CT scans to the Image Analysis Center
2001	May 17	NHLBI accepts recommendation from DSMB to exclude from randomization patients with very low FEV_1 and either very low D_LCO or non heterogeneous emphysema on CT scan
2001	Aug 14	High risk subgroup paper posted on N Engl J Med website
	Oct 11	High risk subgroup paper published in N Engl J Med
2002	Jun 17	Last patient registered
	Jul 31	Last patient randomized
	Dec 31	Last patient visit under original follow up schedule
2003	May 20	Primary outcome paper posted on N Engl J Med website
	May 22	Primary outcome paper published in N Engl J Med
	Aug 20	CMS issues decision memorandum regarding coverage of LVRS for patients meeting certain criteria and at certain facilities
	Oct	CMS issues National Coverage Determination covering LVRS for selected patients
	Dec 31	Completion of patient visits
2004	Jan 01	Effective date for coverage of LVRS by CMS
	Jun 30	Completion of quality of life followup
	Oct 01	Last transmission of NETT data from clinics to CC; clinic closeout begins
	Oct 20	Last DSMB conference call
2006	Jun 28	Deposit of limited access dataset with NHLBI
2008	May 01	NETT issue of the Proceedings of the American Thoracic Society published
2013	Aug 32	End of NETT Coordinating Center funding

7. Participating centers, groups, and committees

Clinical Centers

Baylor College of Medicine (BCM)
Brigham and Women's Hospital (BWH)
Cedars-Sinai Medical Center (CEDR)
Cleveland Clinic Foundation (CLCF)
Columbia University in consortium with Long Island Jewish Medical Center (CU)
Duke University Medical Center (DUKE)
Mayo Foundation (MAYO)
National Jewish Medical and Research Center (NJC)
Ohio State University (OSU)
Saint Louis University (STLU)
Temple University (TU)
University of California, San Diego (UCSD)
University of Maryland in consortium with Johns Hopkins Hospital (UMB)
University of Michigan (UMI)
University of Pennsylvania (UPEN)
University of Pittsburgh (UPIT)
University of Washington (UW)

Resource Centers

Agency for Healthcare Research and Quality (AHRQ): Rockville, MD
Centers for Medicare and Medicaid Services (CMS): Baltimore, MD
Chairman's Office (CO): University of Pennsylvania School of Medicine, Philadelphia, PA
Coordinating Center (CC): The Johns Hopkins University, Department of Epidemiology, Baltimore, MD
Cost Effectiveness Analysis Data Center (CEA): Fred Hutchinson Cancer Research Center, Seattle, WA
CT Scan Image Storage and Analysis Center (IAC): University of Iowa College of Medicine, Iowa City, IA
Marketing Center: Temple University, Philadelphia, PA
Project Office: National, Heart, Lung, and Blood Institute (NHLBI), Bethesda, MD

Major groups and committees

Research Group (RG)
Steering Committee (SC)
Executive Committee (EC)
Data and Safety Monitoring Board (DSMB)

8. Publications

1. **National Emphysema Treatment Trial Research Group**: Rationale and design of the National Emphysema Treatment Trial (NETT): A prospective randomized trial of lung volume reduction surgery. J Thorac Cardiovasc Surg, 118:518-28, **1999**.

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4. **Ramsey S, Sullivan S, Kaplan R, Wood D, Chiang Y, Wagner J, for the NETT Research Group**: Economic analysis of lung volume reduction surgery as part of the National Emphysema Treatment Trial. Ann Thorac Surg; 71: 995-1002, **2001**.

5. **National Emphysema Treatment Trial Research Group**: Patients at high risk of death after lung volume reduction surgery. N Engl J Med; 345:1075-83, **2001**.

6. **Fishman A, Naunheim K, Piantadosi S**: Letter to the Editor, Surgery for Emphysema. N Engl J Med; 346: 861-2, **2002**.

7. **Scharf SM, Iqbal M, Keller C, Criner G, Lee S, Fessler HE:** Hemodynamic characterization of patients with severe emphysema. Am J Respir Crit Med; 166:314-322, **2002**.

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9. **National Emphysema Treatment Trial Research Group**: A randomized trial comparing lung-volume-reduction surgery with medical therapy for severe emphysema. N Engl J Med; 348: 2059-73, **2003**.

10. **National Emphysema Treatment Trial Research Group**: Cost effectiveness of lung-volume-reduction surgery for patients with severe emphysema. N Engl J Med; 348: 2092-2102, **2003**.

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12. **Cohen RI, Marzouk K, Berkoski P, O'Donnell CP, Polotsky VY, Scharf SM:** Body composition and resting energy expenditure in clinically stable, non-weight-losing patients with severe emphysema. Chest; 124: 1365-1372, **2003**.

13. **National Emphysema Treatment Trial Research Group:** Safety and efficacy of median sternotomy versus video-assisted thoracic surgery for lung volume reduction surgery. J Thorac Cardiovasc Surg; 127: 1350-60, **2004**.

14. **Lee SM, Wise R, Sternberg AL, Tonascia J, and Piantadosi S, for the National Emphysema Treatment Trial Research Group:** Methodologic issues in terminating enrollment of a subgroup of patients in a multicenter randomized trial. Clinical Trials; 1: 326-338, **2004**.

15. **Hogg JC, Chu F, Utokaparch S, Woods R, Elliott WM, Buzatu L, Cherniack RM, Rogers RM, Sciurba FC, Coxson HO, Paré PD:** The nature of small-airway obstruction in chronic obstructive pulmonary disease. N Engl J Med; 350: 2645-2653, **2004**.

16. **Kaplan RM, Ries AL, Reilly J, Mohsenifar Z, for the National Emphysema Treatment Trial Research Group:** Measurement of health-related quality of life in the National Emphysema Treatment Trial. Chest; 126: 781-789, **2004**.

17. **Celedón JC, et al:** The transforming growth factor-β1 (TGFB1) gene is associated with chronic obstructive pulmonary disease (COPD). Human Molecular Genetics; 13(15): 1649-1656, **2004**.

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8. Publications

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9. Presentations

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2001

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9. Presentations

2001

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2002

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2003

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2004

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9. Presentations

2004 (cont'd)

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Make, B: Optimization of medical therapy in severe emphysema. American Thoracic Society. San Francisco, CA: 21 May 2007.

Martinez, F: Natural history of severe emphysema. American Thoracic Society. San Francisco, CA: 21 May 2007.

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Sciurba, F: Parameters to evaluate and select appropriate LVRS candidates. American Thoracic Society. San Francisco, CA: 21 May 2007.

Wise, R: Research in emphysema: Role of NETT. American Thoracic Society. San Francisco, CA; 21 May, 2005.

10. Meetings

	Date	Place
Steering Committee		
1997	27 - 28 Jan	Bethesda, MD
	24 - 25 Feb	Bethesda, MD
	24 - 25 Mar	Rockville, MD
	01 May	Washington, DC
	14 Jul	Washington, DC
	12 Nov	Washington, DC
1998	23 Jan	Washington, DC
	12 Jun	Washington, DC
	30 Oct	Washington, DC
1999	5 - 6 Apr	Washington, DC
	08 Jun	Washington, DC
	22 Oct	Washington, DC
2000	28 Jun	Rockville, MD
	17 Nov	Rockville, MD
2001	05 Jun	Washington, DC
	02 Nov	Washington, DC
2002	25 Jun	Washington, DC
2003	10 Jan	Washington, DC
	08 Oct	Baltimore, MD
2004	10 Sep	Rockville, MD
2005	14 Sep	Washington, DC
2006	05 Oct	Washington, DC

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10. Meetings

	Date	Place
Executive Committee		
1997	17 Jan	Conference Call
	28 Jan	Bethesda, MD
	04 Feb	Conference Call
	11 Feb	Conference Call
	24 Feb	Conference Call
	04 Mar	Conference Call
	11 Mar	Conference Call
	24 Mar	Conference Call
	01 Apr	Conference Call
	15 Apr	Conference Call
	18 Apr	Conference Call
	29 Apr	Conference Call
	30 Apr	Washington, DC
	02 May	Washington, DC
	13 May	Conference Call
	27 May	Conference Call
	2 - 3 Jun	Washington, DC
	17 Jun	Conference Call
	24 Jun	Conference Call
	13 Jul	Washington, DC
	15 Jul	Washington, DC
	06 Aug	Conference Call
	19 Aug	Conference Call
	05 Sep	Conference Call
	19 Sep	Conference Call
	30 Sep	Conference Call
	14 Oct	Conference Call
	28 Oct	Conference Call
	11 Nov	Washington, DC
	25 Nov	Conference Call
1998	06 Jan	Conference Call
	20 Jan	Conference Call
	22 Jan	Washington, DC
	03 Feb	Conference Call
	17 Feb	Conference Call

10. Meetings

	Date	Place
Executive Committee (cont'd)		
1998	03 Mar	Conference Call
	17 Mar	Conference Call
	31 Mar	Conference Call
	14 Apr	Conference Call
	30 Apr	Conference Call
	11 May	Conference Call
	26 May	Conference Call
	10 Jun	Washington, DC
	07 Jul	Conference Call
	21 Jul	Conference Call
	15 Sep	Conference Cal
	29 Sep	Conference Call
	13 Oct	Conference Call
	29 Oct	Washington, DC
	06 Nov	Conference Call
	24 Nov	Conference Call
	22 Dec	Conference Call
1999	12 Jan	Conference Call
	02 Feb	Conference Call
	23 Feb	Conference Call
	22 Mar	Conference Call
	04 May	Conference Call
	18 May	Conference Call
	07 Jun	Washington, DC
	21 Jun	Conference Call
	13 Jul	Conference Call
	03 Aug	Conference Call
	02 Sep	Conference Call
	14 Sep	Conference Call
	05 Oct	Conference Call
	21 Oct	Conference Call
	16 Nov	Conference Call
	07 Dec	Conference Call
	21 Dec	Conference Call

10. Meetings

	Date	Place
Executive Committee (cont'd)		
2000	13 Jan	Conference Call
	15 Feb	Conference Call
	14 Mar	Conference Call
	12 Apr	Conference Call
	12 May	Conference Call
	14 Jun	Conference Call
	27 Jun	Rockville, MD
	11 Jul	Conference Call
	08 Aug	Conference Call
	12 Sep	Conference Call
	10 Oct	Conference Call
	14 Nov	Conference Call
	16 Nov	Rockville, MD
	12 Dec	Conference Call
2001	08 Jan	Conference Call
	13 Feb	Conference Call
	13 Mar	Conference Call
	09 Apr	Conference Call
	08 May	Conference Call
	04 Jun	Washington, DC
	13 Jun	Conference Call
	10 Jul	Conference Call
	09 Oct	Conference Call
	01 Nov	Washington, DC
	11 Dec	Conference Call
2002	08 Jan	Conference Call
	12 Feb	Conference Call
	12 Mar	Conference Call
	09 Apr	Conference Call
	07 May	Conference Call
	11 Jun	Conference Call
	25 Jun	Washington, DC

10. Meetings

	Date	Place
Executive Committee (cont'd)		
2002	13 Aug	Conference Call
	09 Sep	Conference Call
	18 Oct	Conference Call
	12 Nov	Conference Call
2003	13 Jan	Conference Call
	11 Feb	Conference Call
	10 Mar	Conference Call
	01 Apr	Conference Call
	13 May	Conference Call
	10 Jun	Conference Call
	21 Jul	Conference Call
	12 Aug	Conference Call
	09 Sep	Conference Call
	07 Oct	Baltimore, MD
	12 Nov	Conference Call
	09 Dec	Conference Call
2004	13 Jan	Conference Call
	02 Mar	Conference Call
	13 Apr	Conference Call
	11 May	Conference Call
	15 Jun	Conference Call
	10 Aug	Conference Call
	14 Sep	Conference Call
	12 Oct	Conference Call
	09 Nov	Conference Call
	08 Dec	Conference Call
2005	07 Feb	Conference Call
	09 Jun	Conference Call
	11 Aug	Conference Call
	03 Oct	Conference Call
2006	12 Apr	Conference Call
	15 Jun	Conference Call
	12 Oct	Conference Call
	06 Dec	Conference Call

NETT CV

10. Meetings

	Date	Place
Research Group		
1998	11 - 12 Jun	Washington, DC
1999	07 Jun	Washington, DC
2000	27 Jun	Rockville, MD
2001	04 Jun	Washington, DC
Training		
1997		
Clinic Coordinators	15 Sep	Baltimore, MD
U-Titer Computer program	16 Sep	Baltimore, MD
Pulmonary Rehab Staff	3-4 Dec	Baltimore, MD
Pulmonary Function and Exercise Testing staff	4-5 Dec	Baltimore, MD
Center Coordinators		
1998	12 Mar	Conference Call
	02 Apr	Conference Call
	07 May	Conference Call
	09 Jul	Conference Call
	03 Sep	Conference Call
	01 Oct	Conference Call
	05 Nov	Conference Call
	03 Dec	Conference Call
1999	07 Jan	Conference Call
	04 Feb	Conference Call
	04 Mar	Conference Call
	01 Jul	Conference Call
	02 Sep	Conference Call
	04 Nov	Conference Call
2000	02 Mar	Conference Call
	04 May	Conference Call
2001	03 May	Conference Call

10. Meetings

	Date	Place
Center Coordinators (cont'd)		
2002	24 Jun	Washington, DC
2003	11 Mar	Chicago, IL
Data and Safety Monitoring Board		
1997	20 Jun	Washington, DC
	01 Aug	Conference Call
	28 Aug	Conference Call
1998	27 Mar	Washington, DC
	09 Sep	Conference Call
	05 Oct	Washington, DC
1999	07 Apr	Washington, DC
	04 Oct	Washington, DC
2000	24 Jan	Conference Call
	14 Feb	Conference Call
	14 Apr	Washington, DC
	19 Jul	Conference Call
	15 Sep	Washington, DC
	17 Oct	Conference Call
	30 Sep	Conference Call
	17 Dec	Conference Call
2001	17 Jan	Conference Call
	23 Jan	Conference Call
	19 Apr	Washington, DC
	16 May	Conference Call
	19 Jul	Conference Call
	14 Sep	Conference Call
2002	25 Jan	Conference Call
	12 Apr	Washington, DC
	11 Jul	Conference Call
	30 Sep	Washington, DC
	17 Dec	Washington, DC
2003	24 Oct	Conference Call
2004	20 Oct	Conference Call

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10. Meetings

	Date	Place
Pulmonary Function Coordinators		
1998	06 Apr	Conference Call
	04 May	Conference Call
	06 Jul	Conference Call
	14 Sep	Conference Call
	05 Oct	Conference Call
	07 Dec	Conference Call
1999	01 Feb	Conference Call
	05 Apr	Conference Call
	14 Jun	Conference Call
	13 Sep	Conference Call
	08 Nov	Conference Call
2000	14 Feb	Conference Call
Rehabilitation Coordinators		
1998	21 Apr	Conference Call
	19 May	Conference Call
	21 Jul	Conference Call
	15 Sep	Conference Call
	18 Oct	Denver, CO
	17 Nov	Conference Call
	15 Dec	Conference Call
1999	19 Jan	Conference Call
	16 Feb	Conference Call
	20 Apr	Conference Call
	15 Jun	Conference Call
	20 Jul	Conference Call
	19 Sep	Phoenix, AZ
	21 Sep	Conference Call
	23 Nov	Conference Call
2000	22 Feb	Conference Call
	24 Sep	Tampa, FL
2002	19 Jul	Conference Call

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10. Meetings

	Date	Place
Cost Effectiveness Subcommittee		
1998	24 Aug	Seattle,WA
1999	24 Aug	Seattle, WA
2000	16 Nov	Rockville, MD
2001	01 Nov	Washington, DC
IAC Advisory Committee		
2000	24 Jul	Iowa City, IA
	17 Nov	Rockville, MD
2001	15 Feb	Conference Call
	05 Jun	Washington, DC
	02 Nov	Washington, DC
2002	25 Jun	Washington, DC
2003	08 Oct	Baltimore, MD
2004	10 Sep	Rockville, MD
Publications and Presentations Committee		
1997	21 Oct	Conference Call
2001	10 Jan	Conference Call
	14 Feb	Conference Call
	30 Mar	Conference Call
	27 Apr	Conference Call
	28 Sep	Conference Call
	23 Oct	Conference Call
	30 Nov	Conference Call
2002	29 Jan	Conference Call
	31 May	Conference Call
	06 Sep	Conference Call
	13 Dec	Conference Call

10. Meetings

	Date	Place
Publications and Presentations Committee (cont'd)		
2003	17 Jun	Conference Call
	04 Aug	Conference Call
	19 Sep	Conference Call
2004	27 Jan	Conference Call
	19 Mar	Conference Call
	01 Jun	Conference Call
	30 Jul	Conference Call
	28 Sep	Conference Call
	19 Nov	Conference Call
2005	14 Jan	Conference Call
	08 Mar	Conference Call
	06 May	Conference Call
	26 Jul	Conference Call
	23 Sep	Conference Call
	04 Nov	Conference Call
2006	17 Jan	Conference Call
	12 May	Conference Call
	11 Jul	Conference Call
	22 Sep	Conference Call
2007	26 Jan	Conference Call
	20 Mar	Conference Call
	08 May	Conference Call
	27 Jul	Conference Call
	25 Sep	Conference Call
	30 Nov	Conference Call
2008	25 Jan	Conference Call
	18 Mar	Conference Call
	30 May	Conference Call
	20 Jun	Conference Call
	08 Jul	Conference Call
	23 Sep	Conference Call
	21 Nov	Conference Call

10. Meetings

	Date	Place
Publications and Presentations Committee (cont'd)		
2009	16 Jan	Conference Call
	18 Mar	Conference Call
	29 May	Conference Call
	24 Jul	Conference Call
	18 Dec	Conference Call
2010	22 Jan	Conference Call
	16 Apr	Conference Call
	16 Jul	Conference Call
	19 Nov	Conference Call
2011	14 Jan	Conference Call
	18 Nov	Conference Call
2012	27 Jan	Conference Call
	27 Apr	Conference Call
	27 Jul	Conference Call
	26 Oct	Conference Call
2013	18 Jan	Conference Call
	12 Apr	Conference Call
	21 Jun	Conference Call
	19 Jul	Conference Call
	30 Aug	Conference Call

11. Site visits

Site	Year	Date	Place
Clinics	**1999**	08 Mar	St. Louis, MO
		30 Mar	Philadelphia, PA (UPEN)
		11 May	Philadelphia, PA (TU)
		24 May	Baltimore, MD
		17 Jun	Boston, MA
		12 Jul	Columbus, OH
		19 Jul	Durham, NC
		27 Sep	Rochester, MN
		01 Oct	San Diego, CA
		07 Oct	Houston, TX
		18 Oct	Baltimore, MD (JHU)
		12 Nov	Ann Arbor, MI
		03 Dec	Pittsburgh, PA
		09 Dec	Denver, CO
	2000	14 Jan	Seattle,WA
		28 Jan	Los Angeles, CA
		7-8 Feb	New York City, NY (CU&LIJ)
		22 Feb	Cleveland, OH
		20 Jun	Durham, NC
	2001	28 Feb	Boston, MA
		01 Mar	Baltimore, MD
		20 Mar	Philadelphia, PA (UPEN)
		10 May	Columbus, OH
		15 Jun	Ann Arbor, MI
CEA Data Center	**2000**	11 Dec	Seattle, WA

12. Meetings/conference calls and site visits by year of study

	Study year																	
Type of meeting	97	98	99	00	01	02	03	04	05	06	07	08	09	10	11	12	13	**Total**
Steering Committee	6	3	3	2	2	1	2	1	1	1	0	0	0	0	0	0	0	**22**
Research Group	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	**4**
Executive Committee	30	22	17	14	11	11	12	10	4	4	0	0	0	0	0	0	0	**135**
Center coordinators	0	8	6	2	1	1	1	0	0	0	0	0	0	0	0	0	0	**19**
Pulm function coords	0	6	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	**12**
Rehab coordinators	0	7	8	2	0	1	0	0	0	0	0	0	0	0	0	0	0	**18**
Cost Effect Subcomm	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	**4**
IAC Advisory Comm	0	0	0	2	3	1	1	1	0	0	0	0	0	0	0	0	0	**8**
P&P Committee*	1	0	0	0	7	4	3	6	6	4	6	7	5	4	2	4	5	**64**
DSMB*	3	3	2	8	6	5	1	1	0	0	0	0	0	0	0	0	0	**29**
Training	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**4**
Site visits																		
Clinics	0	0	14	5	5	0	0	0	0	0	0	0	0	0	0	0	0	**24**
CEA Data Center	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	**1**
Total	**44**	**51**	**57**	**39**	**37**	**24**	**20**	**19**	**11**	**9**	**6**	**7**	**5**	**4**	**2**	**4**	**5**	**344**

* P&P Committee = Publications and Presentations Committee
DSMB = Data and Safety Monitoring Board

13. Support statement

Source of funding

The National Emphysema Treatment Trial (NETT) is supported by the National Heart, Lung, and Blood Institute (NHLBI); Centers for Medicare and Medicaid Services (CMS); and the Agency for Healthcare Research and Quality (AHRQ).

14. Contract numbers, funding period, and ClinicalTrials.gov number

Codes	Center	Contract number	Funding period
BCM	Baylor College of Medicine	N01-HR-76101	17 Dec 96 -31 Dec 05
BWH	Brigham and Women's Hospital	N01-HR-76102	17 Dec 96 -31 Dec 05
CEDR	Cedars-Sinai Medical Center	N01-HR-76104	17 Dec 96 -31 Dec 05
CLCF	Cleveland Clinic Foundation	N01-HR-76105	17 Dec 96 -31 Dec 05
CU	Columbia University	N01-HR-76106	17 Dec 96 -31 Dec 05
DUKE	Duke University Medical Center	N01-HR-76107	17 Dec 96 -31 Dec 05
MAYO	Mayo Foundation	N01-HR-76109	17 Dec 96 -31 Dec 05
NJC	National Jewish Medical and Research Center	N01-HR-76111	17 Dec 96 -31 Dec 05
OSU	Ohio State University	N01-HR-76112	17 Dec 96 -31 Dec 05
STLU	Saint Louis University	N01-HR-76115	17 Dec 96 -31 Dec 05
TU	Temple University	N01-HR-76116	17 Dec 96 -31 Dec 05
UCSD	University of California, San Diego	N01-HR-76103	17 Dec 96 -31 Dec 05
UMB	University of Maryland	N01-HR-76108	17 Dec 96 -31 Dec 05
UMI	University of Michigan	N01-HR-76110	17 Dec 96 -31 Dec 05
UPEN	University of Pennsylvania	N01-HR-76113	17 Dec 96 -31 Dec 05
UPIT	University of Pittsburgh	N01-HR-76114	17 Dec 96 -31 Dec 05
UW	University of Washington	N01-HR-76118	17 Dec 96 -31 Dec 05
CC	Coordinating Center	N01-HR-76119	17 Dec 96 -31 Aug 13

NETT is registered with www.clinicaltrials.gov (NCT00000606)

15. Repositories

Document	Official repository	Other location
Minutes		
EC	CC	Distributed to EC members
SC	CC	Distributed to SC members
DSMB	NHLBI	Distributed to DSMB members
P&P	CC	Distributed to SC members
PPMs	CC	Distributed to clinics and resource centers
Study reports		
Performance monitoring	CC	Distributed to RG members
Treatment monitoring	CC	Distributed to DSMB members
Recruitment	CC	Distributed to RG members
Site visit	CC	Distributed to site visitors and clinic staff
Forms		
Patient visit forms	Clinics	None
Certification materials	CC	Clinics
Consent statements	Clinics	None
Study reference documents		
Protocol	CC	NTIS, distributed to RG members
Forms and charts	CC	NTIS, distributed to RG members
Manual of operations	CC	NTIS, distributed to RG members
Curriculum vitae	CC	Distributed to RG members
Database		
Electronic data form files	Clinics	CC
Analysis programs	CC	None
CT scans	IAC	Clinics

16. Items on file at the National Technical Information Service

Title	Accession No.
National Emphysema Treatment Trial (NETT) Protocol (21 Jun 1999)	PB2001-102646
National Emphysema Treatment Trial (NETT) Manual of Operations, Part 1: Patient Procedures (29 Nov 2000)	PB2001-102647
National Emphysema Treatment Trial (NETT) Forms, Charts, and Flash Cards Book (13 Feb 2001)	PB2001-103545

NTIS Contact Information:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
1-800-553-6847
Fax: (703) 605-6900
http://www.ntis.gov

17. NETT website

The NETT website address is:

https://jhuccs1.us/nett/default.asp

The following information may be accessed through the website. Some information is password protected:

- Center listing
- Rehab satellite directory
- Clinic directory
- PFT and Exercise Testing directory
- Pulmonary Rehab directory
- Recruitment report (final report posted, Apr 03)
- Monthly report (final report posted July 04)
- Consent statements (3)
- Credit roster
- Curriculum Vitae
- PPMs
- ATS and ACCP Presentations (slides available to download)
- Aids for NETT presentations:
  - Slides based on high risk subgroup
  - Methodologic issues in clinical trials
  - DHHS, NIH, NHLBI logos (for downloading)
- Publications (pdf version of most publications available)
- Abstract/Publication proposal (PP) form
- Ancillary study proposal (SP) form
- Submitted Abstract/Publication proposals and approval status
- List of suggested and proposed publications topics

18. Accessing the NETT Limited Access Dataset

NETT has deposited a data set with NHLBI and the data set is available through the NHLBI's Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC). Information about this program can be found on the website at:

https://biolincc.nhlbi.nih.gov.

To request a copy of the NETT data, and for information about the NETT trial and documentation for the data, please visit:

https://biolincc.nhlbi.nih.gov/studies/nett.