Long-term Oxygen Treatment Trial

LOTT

Limited Access Database Documentation

April 2017 Version

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Dataset Specifications

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1. These are the Limited Access Database files for the Long-term Oxygen Treatment Trial (LOTT) as of April 2017.

2. Data files are provided as .sas7bdat files (SAS V9).

3. Data files included are:

ac2.sas7bdat	ie2.sas7bdat	sp4.sas7bdat
ae2.sas7bdat	mm4.sas7bdat	tc1.sas7bdat
ah2.sas7bdat	mo3.sas7bdat	valids.sas7bdat
ap1.sas7bdat	mp2.sas7bdat	xz2.sas7bdat
aq1.sas7bdat	mq1.sas7bdat	
as1.sas7bdat	mv1.sas7bdat	
bc1.sas7bdat	nejmdat.sas7bdat	
bv1.sas7bdat	oe1.sas7bdat	
dc2.sas7bdat	of2.sas7bdat	
dr1.sas7bdat	oxim6mw.sas7bdat	
ep1.sas7bdat	oximrest.sas7bdat	
ex2.sas7bdat	pe1.sas7bdat	
exernadir.sas7bdat	pq1.sas7bdat	
fr1.sas7bdat	qf1.sas7bdat	
ha1.sas7bdat	qg2.sas7bdat	
hb3.sas7bdat	qw2.sas7bdat	
hi2.sas7bdat	rg3.sas7bdat	
ht2.sas7bdat	rr4.sas7bdat	

4. Other items included in the lottlad.pdf:

   LOTT prototype consent statement (13 Mar 2013 version)
   LOTT design tables
   Summary of amendments to LOTT protocol
   List of LOTT publications

   Attachments to the LimAcc-LOTT.pdf
   - LOTT Protocol (uses its own page numbering)
   - LOTT Manual of Operations (uses its own page numbering)

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General Comments on Database

Introduction: This version of the LOTT Limited Access Database is derived from the April 2017 version of the LOTT Master Database. LOTT data were collected from January 2009 through August 2015. LOTT participant enrollment began in January 2009 and ended in August 2014. LOTT participant follow-up ended in August 2015. Vital status was determined as of 31 August 2015.

Files are provided for specific data forms or for types of data. Each file has a SAS Proc Contents listing. In the case of files that correspond to specific forms, early form revisions have been recoded to the last revision of the form; copies of the last revision of a form are included with this documentation.

Forms were constructed with some duplication of information to make completion easier and less error-prone. Some of this redundancy has been eliminated in these data files. The dataset supporting the LOTT primary outcome paper (nejmdat.sas7bdat) includes most data items needed to replicate the analyses included in the paper; there is overlap between that file and other database datasets. Some data items such as clinic identifier and some demographic variables that could be used to break participant confidentiality have been dropped from the nejmdat.sas7bdat dataset.

The HADS, SF-36, St George's Respiratory Questionnaire, Quality of Well-Being Scale, Pittsburgh Sleep Quality Index, Epworth Sleepiness Scale questionnaires are copyrighted and/or were used in LOTT with permission. The copyright ownership information as known in 2009 is included in the instruction box for each questionnaire. If you wish to use these questionnaires for purposes other than LOTT analysis, you must obtain permission from the owners for that new use.

Data collection levels: All LOTT participants completed Core data collection. Sites could choose if they would complete Expanded data collection. Expanded data collection added these elements to LOTT data collection for those sites choosing to participate in Expanded data collection:

- Completion of the SF-36, HADS, and PSQI questionnaires at visits sb, f12, f24, f36, f48, f60, and f72
- Completion of spirometry at visits f12, f24, f36, f48, f60, and f72 (Core data collection included spirometry at visit sb)
- A1AT testing at visit sb
- Collection of serum for banking at visit sb (if the site participated in specimen collection)

Some sites did not participate in specimen banking.

Specimen banking: LOTT collected DNA, plasma and serum from consenting participants at participating sites at baseline. Approximately 50% of the randomized participants provided at least 1 type of specimen. The participant consented to provide each type of specimen separately and could also specify how his/her specimen(s) could be used (COPD research and/or non COPD health research) and by whom (LOTT investigators and/or non LOTT investigators); the permissions are documented in the DC2 dataset. The Channing Division of Network Medicine at Harvard University is the custodian for the LOTT biospecimens; please contact Leanna Farnam (leanna.farnam@channing.harvard.edu) if interested in accessing the biospecimens. Costs of preparation and shipment of specimens will be the responsibility of the requester.

File formats, variable names, and variable formats: All files are SAS V9 .sas7bdat files. Each variable on each file has an associated SAS label. Variables which are in direct correspondence to a form item (and the response categories on the form) are named ffxiii where ffx is the form abbreviation and revision number and iii is the item number. For example, rg341b is item 41b on form RG3. A variable that is in direct correspondence with a form item remains in the format that it

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was keyed, i.e., character data and without a decimal point. These character data may need to be transformed into numeric data: you must divide by 10, 100, or other appropriate denominator depending on the format of the item on the LOTT form. If there is no denominator (i.e., the item was recorded in integer format), then add 0 to the item to transform the data from character to numeric. If the variable name is not in the format ffxiii, then it most likely has already been put into analysis ready format.

Deletions and edits to protect participant confidentiality: The Limited Access Database does not include these items of information, even though they were collected on LOTT forms: social secuirity number, zipcode of residence, Regional Clinical Center (RCC) or satellite identifier, data in response to Other (specify) items, data in response to administrative information sections on forms (e.g., staff identification number (PIN), date and time of next appointment, form review date), and comment fields. All dates have been converted to a number of days before or after randomization (i.e., enrolldt, the date of randomization, is 0 and dates before randomization are negative numbers and dates after randomization are positive numbers). Thus age is available, but the calendar time the participant was that age is masked. Race/ethnicity information is limited to White or Caucasian (yes/no), Black or African American (yes/no), and Minority (yes/no) variables (in the valids and nejmdat datasets) due to the small numbers of Hispanic, American Indian, Asian and other non African American minority participants randomized in LOTT.

Identifiers: Every record includes a recoded ID number for the participant that the record refers to. The variable corresponding to the recoded participant ID number (variable name newlott) is a 5 character numeric text string (eg, 11111). Participant code (which appears on forms) has been deleted from all files.

Visit codes and windows: Each scheduled LOTT visit had an ideal date and a permissible window surrounding that ideal date during which the visit could be completed and the visit data count toward completion of the visit; these dates were constructed using the date of randomization. The procedures for a visit could be split over several days; each procedure had to be completed within the window for the visit. Visit codes and windows are:

Code	Description	Ideal date	Permissible window
sb	screening/baseline visit	NA	sites had 60 days from initiating screening to complete randomization; screening started with completion of the Registration (RG) form
rz	randomization visit (assignment to supplemental oxygen or no supplemental oxygen)	rz date = time 0	NA
rx	Ambulatory dosing visit for participants assigned to supplemental oxygen	rz+1	rz to rz+7
w01	1-week adherence promotion contact	rz+7	rz+1 to rz+10*

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General Comments on Database (cont'd)

Code	Description	Ideal date	Permissible window
w02	2-week adherence promotion contact	rz+14	rz+11 to rz+17
w03	3-week adherence promotion contact	rz+21	rz+18 to rz+24
w04	4-week adherence promotion contact	rz+28	rz+25 to rz+42
a02	2 month adherence promotion contact	rz+61	rz+43 to rz+76
a03	3 month adherence promotion contact	rz+91	rz+77 to rz+106
f04	4 month telephone and mail contact	rz+122	rz+62 to rz+183
a04	4 month adherence promotion contact	rz+	rz+107 to rz+137
a05	5 month adherence promotion contact	rz+	rz+138 to rz+167
a06	6 month adherence promotion contact	rz+	rz+168 to rz+213
f08	8 month telephone contact	rz+244	rz+184 to rz+304
a08	8 month adherence promotion contact	rz+	rz+214 to rz+274
a10	10 month adherence promotion contact	rz+	rz+275 to rz+335
f12	1 year follow-up clinic visit	rz+365	rz+305 to rz+426
f16	16 month telephone and mail contact	rz+487	rz+427 to rz+548
f20	20 month telephone contact	rz+609	rz+549 to rz+670
f24	2 year clinic visit	rz+730	rz+671 to rz+791
f28	28 month telephone contact	rz+852	rz+792 to rz+913
f32	32 month telephone contact	rz+974	rz+914 to rz+1035
f36	3 year clinic visit	rz+1096	rz+1036 to rz+1157
f40	40 month telephone contact	rz+1218	rz+1158 to rz+1278
f44	44 month telephone contact	rz+1339	rz+1279 to rz+1400
f48	4 year clinic visit	rz+1461	rz+1401 to rz+1522
f52	52 month telephone contact	rz+1583	rz+1523 to rz+1644
f56	56 month telephone contact	rz+1705	rz+1645 to rz+1765
f60	5 year clinic visit	rz+1826	rz+1766 to rz+1887
f64	64 month telephone contact	rz+1948	rz+1888 to rz+2009

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General Comments on Database (cont'd)

Code	Description	Ideal date	Permissible window
f68	68 month telephone contact	rz+2070	rz+2010 to rz+2131
f72	6 year clinic visit	rz+2313	rz+2132 to rz+2252
f76	76 month telephone contact	rz+2435	rz+2253 to rz+2374

*Oxygen group participants were allowed to skip visit w01 if visit rx was completed within 4 days of the closing date for visit w01.

Unscheduled contacts used visit code n.

Dates: Dates are recoded to a number of days before or after randomization.

1st and 2nd keyings and subsequent transactions: All data were keyed twice in succession during data entry, and all subsequent transactions (changes and deletes) are present in the Data Coordinating Center's database. Only the final transaction is included in this Database.

Death data: Death information is included in 3 datasets: valids, nejmdat, and dr1. Both the valids and nejmdat files include date of death as a number of days after randomization. The dr1 file includes keyed Death Report (DR) forms; these are forms completed by clinic staff for deaths that they discovered and reported to the DCC. The DCC also matched social security numbers collected at baseline to the SSA Master Death File periodically and resolved discrepancies with clinics. Death information in the valids and nejmdat files is complete; death information in the DR file is incomplete since it is limited to deaths that were identified by clinics while the participant was active in LOTT.

Race/ethnicity data: Race data are included in the valids and nejmdat files and are deleted from the Registration (RG) form file. Because so few Asian, Indian, and Pacific Islander participants enrolled in LOTT, race data are limited to the white, black, and minority variables. Ethnicity is not provided since so few participants were of Hispanic ethnicity.

Oximetry data: Oximetry data are included in 3 files: exernadir, oxim6mw, and oximrest. At each scheduled in person visit (visits sb, f12, f24, f36, f48, f60, f72), each participant underwent a room air 6 minute resting saturation assessment and also had saturation data collected during the room air 6 minute walk. The oximetry system recorded SpO_2 and heart rate. Resting data were obtained every second (360 records per each resting evaluation). Exercise data were obtained every other second (180 records per each complete evaluation). See the LOTT Manual of Operations for more information on the assessments programmed into the oximetry evaluation software. Not every evaluation yielded a recoverable, analyzable dataset. Not every participant completed the 6 minute walk each time it was scheduled. Not every 6 minute walk oximetry dataset included 180 records. Available data have been harvested into the oxim6mw and oximrest files. Each record in each of these files has the participant's ID number, the visit code, the date of the evaluation (as programmed on the oximeter; this should match the form date but may not match in all cases). Time of the reading is also on each record; this is time as known by the oximeter; for various reasons this time may or may not match the time recorded by the technician on the paper form (MM or MO form) corresponding to the test session and oximetry file. Date and time were user specified settings on the oximeter; these oximeters were not synched to a computer network; user error could have set the time

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to midnight instead of 12 noon or 1 am instead of 1 pm etc or not corrected for daylight savings time changes.

The LOTT primary outcome paper included one oximetry metric – 10th lowest nadir SpO_2 during the 6 minute walk. This metric has been determined for each analyzable 6 minute walk oximetry session, and the values are collected in the exernadir file. Please note: since the LOTT primary outcome paper was published, the nadir dataset has been updated. The nejmdat file has been updated accordingly.

Primary outcome paper citation: Long-Term Oxygen Treatment Trial Research Group: A randomized trial of long-term oxygen for COPD with moderate desaturation. New Eng J Med 2016;375:1617-27. The nejmdat dataset includes the data reported in the primary outcome paper, with some edits for confidentiality and some updates made since publication (dates of some COPD exacerbations have been corrected and additional 6 minute walk oximetry data were found, resulting in additional exercise nadir values).

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Specific Comments on Database Files

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ac2.sas7bdat (No oxygen group only): AC forms in AC2 format. This adherence contact form was used with the No oxygen group only and only at visit w01.

ae2.sas7bdat (Oxygen group only): AE forms in AE2 format. This adherence contact form was used with the Oxygen group only at visit rx.

ah2.sas7bdat (Oxygen group only): AH forms in AH2 format. This adherence contact form was used with the Oxygen group only at the adherence contacts starting with w01. Note that w01 could be skipped if visit rx occurred within 4 days of the closing date for w01.

ap1.sas7bdat (Oxygen group only): AP forms in AP1 format. This form was completed by Oxygen group participants who used portable concentrators. Compliance with providing the data on the form was very spotty – most meters were inaccessible, participants changed out concentrators frequently and final reading and date read on the old system might not be obtained and similarly for first reading and date read on the new system, some participants were unable or unwilling to keep records.

aq1.sas7bdat (Oxygen group only): AQ forms in AQ1 format. This form was completed by Oxygen group participants who used liquid oxygen systems. Compliance with providing the data on the form was very spotty and it is not always clear which weight is being provided if a weight was provided (weight of oxygen delivered or weight of container once refilled). Participants used tanks of varying size simultaneously and over time, and it is not clear if tanks were completely emptied or if the count is of tanks partially emptied and then refilled. Some participants were unable or unwilling to keep records.

as1.sas7bdat (Oxygen group only): AS forms in AS1 format. This form was completed by Oxygen group participants who used a stationary concentrator and/or gaseous oxygen tanks. Compliance with providing the data on the form was very spotty. Participants changed out concentrators frequently and final readings and date read on the old system might not be obtained and similarly for first reading and date read on the new system. Participants could use gas tanks of several sizes in a reporting period and different sizes over time. Some participants were unable or unwilling to keep records.

bc1.sas7bdat (all): BC forms in BC1 format. This form was completed for participants who agreed to provide DNA, serum and/or plasma specimens for banking. Serum and plasma specimens were collected for banking at baseline only; DNA was collected at baseline for almost all participants who consented to provide DNA but was collected in follow-up for one participant who changed their mind after baseline. See the General Comments section of this PDF for information about accessing LOTT specimens.

bv1.sas7bdat (all): BV forms in BV1 format. This form was completed for all participants at baseline and at f12. It documents collection of blood and values for hematocrit and hemoglobin at baseline, collection of blood and values for A1AT genotype and phenotype (or reason for not collecting) at baseline (note that A1AT testing was part of Expanded data collection and not included in Core data collection), and collection of blood and values for cotinine measurement at baseline and 1 year (or reason for not collecting).

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dc2.sas7bdat (all): DC forms in DC2 format. This form documents options selected for specimen banking and use of samples. Each site could choose whether it collected any biospecimens for banking, as well as choose whether it was participating in Core or Expanded data collection. Core data collection included collection of blood for DNA and plasma banking. Expanded data collection included collection of blood for serum banking. The DC form was required for randomization; if the participant was at a site that was not participating in biospecimen banking, items 7, 8, and 9 on the form were each completed as No. See the General Comments section of this PDF for information about accessing LOTT specimens.

dr1.sas7bdat (all): DR forms in DR1 format. This form was completed by the clinic staff during the course of follow-up whenever they discovered that a participant had died. Not every death identified by the match to the SSA master death file has a DR form completed. Therefore, this file is not a source of vital status information for all participants.

ep1.sas7bdat (all): EP forms in EP1 format. The Epworth Sleepiness Scale (EP) form was completed at visit sb only and the score had to be 15 or less for the participant to be eligible for LOTT.

ex2.sas7bdat (all): EX forms in EX2 format. An EX form was completed for each COPD exacerbation occurring after randomization. Staff were instructed to consider pneumonia a COPD exacerbation and complete an EX form for each incidence of pneumonia.

exernadir.sas7bdat (all): The nadir value for an exercise oximetry evaluation was defined as the 10^{th} lowest SpO_2 collected during each room air 6 minute walk oximetry session. Quality of the data point was ignored.

fr1.sas7bdat (all): FR forms in FR1 format. This form was used to provide follow-up information on events previously reported on an EX or IE form. It would have been used if additional information became available after the initial report was completed and keyed. It was an optional form. Most information is on the initial report form; the FR form would be used if there was some "significant" time passage in acquiring information or an event had a complicated time course for resolution.

ha1.sas7bdat (Expanded): HA forms in HA1 format. This form was used to record the score and item responses for the Hospital Anxiety and Depression Scale (HADS). The HADS was part of Expanded data collection and was completed at visits sb, f12, f24, f36, f48, f60, and f72. The HADS is a copyrighted questionnaire and was used with permission of the copyright owner. Copyright information is provided on the form.

hb3.sas7bdat (all): HB forms in HB3 format. This form was used to record the participant's medical history at baseline and was completed for all participants.

hi2.sas7bdat (all): HI forms in HI2 format. This form was used at in person visits (f12, f24, f36, f48, f60, and f72) to record the participant's history since the prior telephone and in person interviews. It was completed for all participants.

ht2.sas7bdat (all): HT forms in HT2 format. This form was used at the q4 months telephone visits (f04, f08, f16, f20, f28, f32, f40, f44, f52, f56, f64, f68, f76) to record the participant's history since the most recent telephone or in person interview.

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ie2.sas7bdat (all): IE forms in IE2 format. This form was used as needed to document hospitalizations that were not associated with a COPD exacerbation or unexpected serious adverse event judged related to LOTT participation, or to report an event judged by the clinic to be reportable to LOTT.

mm4.sas7bdat (all): MM forms in MM4 format. This form was used to document completion, events, and results of the room air 6 minute walk. Detection of exercise desaturation in the range for LOTT eligibility is documented on the visit sb MM form. Detection of severe exercise desaturation sufficient to require prescription of home oxygen is documented on the follow-up phase MM forms. Information on the algorithm for determination of eligible exercise desaturation and severe exercise desaturation is included in the Manual of Operations.

mo3.sas7bdat (all): MO forms in MO3 format. This form was used to document completion, events, and results of the room air resting oximetry. The resting saturation evaluation result (single SpO2 value) is documented on the MO form. Information on the algorithm for determination of the resting saturation level is included in the Manual of Operations.

mp2.sas7bdat (all): MP forms in MP2 format. This form was used to document completion and results of determination of the ambulatory oxygen dose for participants randomized to oxygen or control group participants who developed severe resting desaturation or severe exercise desaturation.

mq1.sas7bdat (all): MQ forms in MQ2 format. This form was used to document completion and results of determination of the resting oxygen dose for a participant who developed severe resting desaturation.

mv1.sas7bdat (all): MV forms in MV1 format. This form was used to document completely missed visits or procedures missed for a partially completed visit.

nejmdat.sas7bdat (all): This dataset contains all of the data used in the primary outcome paper (N Eng J Med 2016;375:1617-1627) in analysis format. There is overlap between this dataset and other limited access datasets. As noted in the General Comments sections, some exacerbation dates and some exercise nadir data have been updated since publication.

oe1.sas7bdat (Oxygen group only): OE forms in OE1 format. This form was used to document the oxygen supply company and stationary and portable equipment issued to oxygen group participants. Oxygen supply company name is retained but the representative name and telephone number information have been dropped. Please note that items 8 and 9 on the OE form were problematic and their values should be viewed with skepticism.

of2.sas7bdat (Oxygen group only): OF forms in OF2 format. This "form" was actually a listing generated at the DCC and sent to the site; the idea was to keep track of the equipment in use by each participant. The site would mark changes on the listing as reported by the participant and send the annotated listing to the DCC and an updated listing was returned to the site. In theory, the collected listing records for a participant provide a history of their equipment use in LOTT. The collected records provided here are known to be incomplete.

oxim6mw.sas7bdat (all): Masimo Rad 7 oximetry data from all 6 minute walks for which oximetry data could be harvested; technical issues prevented harvesting of all walk files. The Masimo Rad 7 captured SpO_2 and heart rate every 2 seconds for the 6 minutes of the 6 minute walk; each 6 minute

walk session therefore should have generated 180 lines of data. Non oximetry data from the walk and summary evaluations from the oximetry data are recorded on the MM form.

oximrest.sas7bdat (all): Masimo Rad 7 oximetry data from all resting saturation evaluation sessions for which oximetry data could be harvested; technical issues prevented harvesting of all resting files. The Masimo Rad 7 captured SpO_2 and heart rate every second for the 6 minutes of the resting evaluation; the first minute was ignored and the last 5 minutes were evaluated. Each resting session therefore generated 360 lines of data, 300 of which were evaluated to determine the saturation level for the session. Non oximetry data from the resting evaluation and summary evaluations from the oximetry data are recorded on the MO form.

pe1.sas7bdat (all): PE forms in PE1 format. This form was used to record the findings of the physical examination completed for LOTT. The exam was limited in scope.

pq1.sas7bdat (Expanded): PQ forms in PQ1 format. This form was used to record the item responses for the Pittsburgh Sleep Quality Index (PSQI) questionnaire. The PSQI was part of Expanded data collection and was completed at visits sb, f12, f24, f36, f48, f60, and f72. The total score has been included in the dataset. The PSQI form is a copyrighted form and was used with permission.

qf1.sas7bdat (Expanded): QF forms in QF1 format. This form was used to record the item responses for the SF-36 Health Survey (SF-36). The SF-36 was part of Expanded data collection and was completed at visits sb, f12, f24, f36, f48, f60, and f72. The PCS, MCS, and scale scores have been included in the dataset. The SF-36 Health Survey is a copyrighted form and was used with permission.

qg2.sas7bdat (all): QG forms in QG2 format. This form was used to record the item responses for the St George's Respiratory Questionnaire (SGRQ). The SGRQ was completed at visits sb, f04 (by mail), f12, f16 (by mail), f24, f36, f48, f60, and f72. The total score and activities, impacts and symptoms subscale scores have been included in the dataset. The St George's Respiratory Questionnaire was used with permission of the creator.

qw2.sas7bdat (all): QW forms in QW2 format. This form was used to record the item responses for the Quality of Well-being Scale (QWB). The QWB was completed at visits sb, f04 (by mail), f12, f16 (by mail), f24, f36, f48, f60, and f72. The total score and daily scores have been included in the dataset. The Quality of Well-Being Scale was used with permission of the creator.

rg3.sas7bdat (all): RG and RS forms in RG3 format. Form RS documented rescreening for LOTT. Note that date of birth, race, ethnicity, and gender dropped from the RG file; this demographic information, edited for confidentiality, is included in the valids file. Only the final RG/RS form for an individual person is included. This file includes records for people who screened for LOTT but did not proceed to randomization.

rr4.sas7bdat (all): RR forms in RR4 format. Only the final RR form for an individual person is included. This file includes records for people who screened for LOTT but did not proceed to randomization.

sp4.sas7bdat (all at baseline, Expanded during follow-up): SP forms in SP4 format. This form was used to record the results of pre and post bronchodilator spirometry. Spirometry in follow-up

was an element of Expanded data collection. Percent predicted FEV_1 and FVC using the reference values of Hankinson et al (Am J Resp Crit Care Med 1999;159:179-187) have been included in the dataset.

tc1.sas7bdat (all): TC forms in TC1 format. This form was used to document initial prescription of home oxygen for Control group participants or cancellation of home oxygen for Oxygen group participants post randomization. It documents many, but not all, changes in oxygen treatment during LOTT.

valids.sas7bdat (all): This file includes ID, demographic (edited for confidentiality), randomization date (if randomized), and treatment assignment (if randomized) information. This file also includes vital status (death, 1=dead, blank=alive) and date of death if dead as of 31 August 2015. This file establishes the census for the LOTT study population, both screenees and randomized participants.

xz2.sas7bdat (all): XZ forms in XZ2 format. This form was used to document completion of the randomization visit after the treatment assignment was generated.

Long-term Oxygen Treatment Trial (LOTT)
Consent for Enrollment, Randomization, and Biospecimen Banking
March 2013 Protocol
[Delete biospecimen section if not yet proceeding with biospecimen portion of protocol]

Introduction

We are inviting you to join a research study funded by the National Heart, Lung, and Blood Institute (NHLBI) and the Centers for Medicare and Medicaid Services. The Long-term Oxygen Treatment Trial (LOTT) will take place at 14 regional clinical centers and their associated sites. The LOTT will enroll over 700 people across the United States. This site ____ **[name of site]** ____ is associated with the ____ **[name of RCC]** ____ regional clinical center. We expect __ **[specify number]** __ patients to enroll at this site. The ___ **[name of RCC]** ___ regional clinical center expects to enroll a total of 81 patients across all of their associated sites.

Why is this study being done?

This study is investigating the effects of oxygen therapy in two types of patients with Chronic Obstructive Pulmonary Disease (COPD). We already know that 24-hour oxygen therapy improves and prolongs the lives of people with COPD who have a very low level of oxygen in their blood at rest, but we don't know if oxygen therapy helps two other types of people with COPD:

- COPD patients who have a moderately low level of oxygen in their blood at rest
- COPD patients who have normal blood oxygen level at rest but low or very low blood oxygen during exercise

This study will help us understand if oxygen therapy is helpful for these two types of COPD patients.

What treatment is done in this study?

At the end of the screening process, if you are still eligible and still want to join the study, we will randomly assign you to one of two treatment groups. "Randomly" means by chance, like a coin toss. Neither you nor your doctor may choose your treatment group.

- One group will use oxygen every day and night for the whole study. The oxygen use will be tailored to your needs in one of two ways:
  - If you have moderately low blood oxygen at rest, you will use the oxygen all the time (24-hour oxygen)
  - If you have normal blood oxygen at rest but low or very low blood oxygen during exercise, you will use the oxygen during physical activity and during sleep.
- The other group will not use oxygen.

It is important to remember that neither treatment is known to be better for you than the other. You should be willing to be in either treatment group before you agree to take part in this study.

Which COPD patients qualify to receive oxygen through Medicare under current medical practice?

- If you have very low oxygen at rest, you can get 24-hour oxygen from Medicare now, without enrolling in LOTT.
- If you have very low oxygen during exercise or sleep, you may qualify to receive oxygen from Medicare for use during exercise or sleep. The study doctor can tell you if you qualify. If you are in this category and you are uncomfortable about not receiving oxygen, then you should not enroll in LOTT.

How do we determine if you are eligible for LOTT?

We are inviting you to complete a series of screening tests and questionnaires. The test results and your questionnaire answers will help us decide if you are eligible to join the study. If you want to join the study and sign this consent form, we will start the tests and we will keep your information in a database.

To be eligible for the LOTT study, you must meet certain criteria, including at least the following: you must be at least age 40 years and you must have COPD. You must have a moderately low level of oxygen in your blood at rest or a low or very low level of oxygen in your blood during exercise. You must be in a stable state of health when you complete the screening tests. You must agree to use oxygen as prescribed if you are assigned to oxygen treatment. You must be willing to return for all follow-up visits, participate in follow-up phone calls, keep records of your oxygen use if assigned to oxygen, and complete and return the study questionnaires that will be mailed to you. You must sign a contract agreeing not to smoke while using oxygen.

The screening process may take several days to complete and will take place at **__[specify location(s) where patient will complete LOTT screening; indicate if patient must go to a separate RCC as well as this site to complete screening]__**. To see if you can join the study, we will:

1. Ask you to fill out **some questionnaires** that ask about your health, how you feel, and for information such as your age and race.
2. Give you a **breathing test** in which you blow hard into a machine called a spirometer. You will do this before and after inhaling a medicine called albuterol (a bronchodilator) to open up your airways.
3. Measure your **blood oxygen level while you are resting and breathing room air**. This will be done with a monitor, most likely on your finger. There is no needle stick.
4. Measure your **blood oxygen level while you are walking for 6 minutes and breathing room air.** This will be done with a monitor, most likely on your finger. There is no needle stick. If your resting heart rate or blood pressure is high, the physician must review a resting EKG (electrocardiogram) done in the past 6 months before you may complete the walk test. If you have not had the resting EKG and it is

needed, it will be done before you complete the walk test. The EKG checks for problems with the electrical activity of your heart. During this test, you will lie quietly on a table or bed, and several electrodes (metal discs) will be attached to the skin of your chest, arms, and legs. The electrodes have wires which are attached to a machine that traces your heart's activity on paper.

5. Measure your **height, weight, pulse** and **blood pressure**.
6. Check for **ankle swelling**.
7. **Draw blood** (about 1 tablespoonful) from a vein to measure your hematocrit (the percentage of blood that is taken up by red blood cells) and hemoglobin (a blood protein relating to oxygenation contained in your red blood cells). If you are not smoking or using other products with nicotine, we will also measure the cotinine (an indicator of tobacco smoke exposure) level in your blood. [**Increase amount to 1-2 tablespoonfuls and add A1AT (a protein that is abnormally low in some COPD patients) to the measurement list if doing Expanded Data Collection]**
8. We will collect and analyze your Medicare claims data for the year prior to entering the study to obtain additional data about your medical history.

It will likely take a few days but it may take up to two months to review your information and decide if you are eligible to join the study. If you are not eligible, you cannot continue in the study and we will forward your test results to your doctor with your permission.

What if I am using oxygen now?

If you are using oxygen now, you may still be able to enroll in the LOTT study, depending on your blood oxygen level when you are breathing room air. If you meet the criteria for enrolling in LOTT, then you and your physician must agree that you will stop using home oxygen for at least 4 days. We ask you to do this to make sure that you are comfortable and able to manage your COPD without oxygen. If you do well while not using oxygen for 4 days and if you and your physician agree that you will follow the treatment assigned to you by LOTT, then you may participate in LOTT. Your physician must agree in writing that he/she will cancel your prescription for home oxygen if you are assigned to no oxygen treatment in LOTT. We want to make sure you can manage without oxygen and that your physician will agree to stop your oxygen before you are assigned to a LOTT treatment group.

What happens if I am eligible for the study?

If you are eligible, we will ask you to return for a second visit. This visit will take place at **___ [indicate site] __** and will take about 1 hour. At this visit, we will ask you questions about your health since the last visit and, if you are still eligible and still want to join the study, we will randomly assign you to one of the two treatment groups.

What will happen in the study?

There are two different treatment groups.

<u>If you are in the oxygen treatment group:</u>

1. We will prescribe everyone both a portable oxygen system and a stationary oxygen system. Everyone assigned to oxygen will use the portable system whenever they are physically active. Everyone assigned to oxygen will use the stationary system at night during sleep. If you are prescribed 24-hour oxygen, you will also use the stationary

system during the day at home when you are not physically active. An oxygen supply company will deliver the equipment to your home and will service it regularly (usually monthly). If you already have oxygen equipment at home and are assigned to the oxygen group, then you will restart using your oxygen at the LOTT prescribed dose. We will work with your oxygen company to start billing the oxygen as a LOTT service. This may require that you change your oxygen company, but we will try to make this work with the company of your choice. If you do not have oxygen equipment in the home and are assigned to the oxygen group, we will arrange for delivery of oxygen equipment to your home and teach you how to use it.

2. We will ask you to return to the clinic shortly after you receive your portable oxygen system. This visit will take about 1 hour. During this visit, we will determine how much oxygen you should use when walking and will show you how to use the oxygen equipment. We will also give you a form for you to keep over the next two months. This form asks for information on use of your oxygen equipment, such as meter readings and counts of tanks of oxygen emptied or amount of oxygen delivered to your home. Two months from this visit, and every two months until the end of the study, we will send you three items: a new blank form for you to complete over the next two months, a form on which you may mark any changes to your equipment, and a stamped envelope to use to return the completed forms to the clinic.
3. We will call you weekly for the first month to see how you are doing with the equipment and answer any questions you may have.
4. After the first month, we will call you monthly for five months and then every two months until it is time for your 1 year visit to see how you are doing with the equipment and answer questions.

If you are in the group that does not use oxygen:

1. If you have oxygen equipment in the home and are assigned to the group that does not use oxygen, we will work with you, the physician who prescribed the oxygen, and your oxygen supply company to have the equipment removed from your home.
2. We will call you one week after you are assigned to the group that does not use oxygen to see how you are doing and answer any questions.
3. At any time during the study, if you become severely hypoxemic at rest (have very low blood oxygen at rest), then supplemental oxygen will be prescribed for you.

Both treatment groups will:

1. Return for a clinic visit at__ **[specify site(s)]** __, which will last about 4 hours, each year for up to 7 years. At each of these visits, you will complete some of the same tests and questionnaires that you completed at the start of the study. At the 1 year visit, if you are not using products with nicotine, we will draw about 1 tablespoonful of blood from a vein and measure the cotinine (nicotine) in your blood.
2. Receive two phone calls each year for up to 7 years. You will be asked about your health and use of oxygen since the last call or visit. Each call will take about 5-10 minutes. The first call will occur 4 months after you are assigned to treatment. Thereafter, the calls will occur 4 months before and 4 months after your yearly clinic visit.
3. Complete questionnaires by mail once in the first year and once in the second year. We will mail you two of the questionnaires that you completed during screening 4 months

after you are assigned to a treatment group and again 4 months after your clinic visit at 1 year. Each time, we will provide a stamped addressed envelope for you to return the questionnaires to us.

4. Complete additional visits if needed, to adjust your oxygen treatment (e.g., if you have a COPD exacerbation and need to start or change your oxygen use).
5. Sign a release of medical records form each year.
6. We will collect and analyze your Medicare claims data for the time you are in the study to obtain additional data about your medical history.

How long will I be in the study?

If you are able to take part in this study, your participation will last at least 1 year and up to the projected end of the study in December 2015.

When will I be informed of the results of the study?

The results from this study will not be available until the study is completed. You will be informed about the study results as soon as they are available.

Are there reasons I might leave the study early?

Taking part in this study is up to you. You can decide to stop at any time and do not have to give a reason. If you decide to leave the study, this will not affect your regular medical care or health benefits. You should tell the study doctor if you decide to leave the study. The study doctor will forward your study records to your doctor with your permission.

In addition, we may need to stop you from taking part in this study at any time if we think it would be best for you or if the study is stopped.

You are expected to return for study visits regardless of your treatment. If you are assigned to no oxygen and start oxygen, we still want you to complete visits. Likewise, if you are assigned to oxygen and it has to be stopped for some reason, we still want you to complete visits.

What are the risks of the study?

1. It is possible that the use of oxygen by patients with moderately low levels of oxygen at rest or a normal level at rest but low blood oxygen during exercise could make their lungs worse.
2. Using oxygen can be inconvenient. The tube used for breathing the oxygen could cause you or others to trip.
3. Some people feel self conscious when using oxygen in public. You should think about how you would feel if assigned to oxygen and how you would use it. You should discuss any problems that you foresee with the staff now. If you enroll and are assigned to oxygen, you should always feel free to discuss any problems that you have with using oxygen with the LOTT staff. One of their jobs is to help you use your oxygen treatment.
4. Using oxygen can be drying to your nose, causing an uncomfortable feeling in your nose or causing nosebleed or bloody nasal discharge. Drinking lots of fluids (to keep yourself hydrated) and using a saline spray or gel inside your nostrils can help. If you

use anticoagulant medication (blood thinners such as heparin or warfarin or aspirin), you should seek medical attention if bleeding persists despite compression.

5. People who use oxygen need to be careful around open flames, such as stoves, candles, fireplaces and barbecue grills, because anything that is flammable will burn more easily in an oxygen-rich environment. You must not smoke while using oxygen.
6. People who use liquid oxygen can be burned on the skin from frost buildup on the oxygen equipment. You can choose the type of oxygen system you want to use. The study staff or oxygen company staff will explain the advantages and disadvantages of each type.
7. The bronchodilating medication (albuterol) that you will inhale as part of the breathing test with the spirometer should open up the airways in your lungs. People sometimes have side effects from this medication. These may include throat irritation, palpitations, nervousness, shakiness, stomach upset, headache, dizziness, weakness, sweating, and chest pains. These effects, if they occur, only last a few minutes. Some people become lightheaded from blowing into the spirometer during the breathing test. The staff giving you the breathing test will monitor and treat you if necessary. Also, staff trained in emergency procedures and basic first aid will be available.
8. The six-minute walking test may be tiring. Some people become lightheaded from walking for six minutes. The staff giving you the six minute walk test will monitor and treat you if necessary. Also, staff trained in emergency procedures and basic first aid will be available.
9. A needle will be inserted into your vein to draw blood at screening and at the 1 year visit. The puncture site may become sore or bruised for a while, and some people become faint or dizzy when blood is drawn. It doesn't happen often, but the puncture site can become infected.
10. You may be uncomfortable talking about your symptoms and how they affect your life. You do not have to answer any questions that you don't want to answer.
11. If you are not in the group using oxygen and testing during study visits tells us that you have developed very low blood oxygen levels at rest, we will either refer you to your doctor who can prescribe oxygen treatment or the study doctor will prescribe it for you. While using oxygen, you will continue to return to our clinic for visits to monitor your condition. If your blood oxygen level improves, you can stop using oxygen.
12. There are no known reproductive risks.
13. Taking part in this study might involve risks and side effects we don't currently know about. An outside panel of experts will regularly look at study data to monitor patient safety. You will be told about any information that may affect your decision to stay in the study.
14. There is a small risk of breach of confidentiality. We have procedures in place to protect your information.
15. If you enroll in LOTT and are assigned to the no oxygen group, we ask that you not use oxygen at any time unless you qualify for oxygen at rest under current medical practice (that is, unless you develop severely low blood oxygen at rest). However, if you qualify for oxygen during exercise or sleep after you enroll in LOTT and are uncomfortable about not being prescribed it, we will work with you and your physician to come up with a solution that you are comfortable with. It has not been shown that oxygen during exercise or sleep benefits patients who have normal or moderately low

oxygen level at rest and low or very low oxygen level during exercise or sleep, and it is possible that the oxygen could be harmful. At this point, we do not know if the oxygen is helpful, harmful, or has no effect.

Are there benefits for taking part in this study?

This study wants to find out if oxygen therapy helps people with a moderately low level of oxygen in their blood at rest or a normal oxygen level at rest but a low or very low oxygen level during exercise live longer, feel better, and avoid hospitalization. If the study shows that oxygen helps these people, Medicare and other insurers may agree to pay for oxygen therapy for people like them. If oxygen therapy helps such people, you could perhaps live longer and feel better by using oxygen. But we do not know that it will help such people, so you may get no direct benefit from being in this study.

Will I need to pay for tests and procedures?

If you have Medicare Part A and Part B, or if you are a Medicare Advantage patient (Medicare HMO patient, Medicare PPO patient), you may be enrolled in LOTT and Medicare will pay for the screening tests, follow-up tests, and oxygen therapy prescribed by the study. You will pay any deductible and co-payment amounts that Medicare requires. We estimate that the co-payments for oxygen therapy (stationary and portable system) at about $100 per month in 2013. The yearly deductible for all Part B services is $147 in 2013. You may have other insurance such as Medigap that may help pay for deductible and co-payment amounts. **[Sites that are waiving copays and deductibles and have identified oxygen providers that will waive copays and deductibles should modify these statements to match their plans regarding copays and deductibles, but should mention that the provider will bill the patient's Medigap policy for the amounts if the patient has a Medigap policy]**

If you do not have Medicare Part A and Part B and are not a Medicare Advantage patient (Medicare HMO patient, Medicare PPO patient), you or your insurance company must pay for the screening tests, follow-up tests, and oxygen therapy prescribed by the study in order for you to participate in the LOTT.

Will I receive any money for my participation in LOTT?

If you are assigned to a LOTT treatment group (oxygen or no oxygen), you will receive a $100 payment at or shortly after the visit when you receive your treatment assignment. You will also receive a $100 payment whenever you complete an annual follow-up visit, either at the visit or shortly afterwards. These payments are made to help cover the costs of your participation in this study.

Additionally, if you are assigned to the oxygen treatment group, you will receive $350 each year to help you pay for your increased electricity costs. Using oxygen daily can increase your monthly electric bill, depending on the type of equipment you use and how much you use it. The company supplying your equipment can provide an estimate of the electricity consumption by different equipment choices. Stationary concentrators consume the most electricity. We estimate that use of a stationary concentrator daily could increase your electric bill by about $29 per month or $350 per year. The first payment will be provided

shortly after you get your treatment assignment to oxygen. After that, the payment will be made at or shortly after your annual clinic visit.

If you are found to be ineligible for LOTT after qualifying on the initial interview and starting at least one other screening test, you will receive $50 to help compensate for your time and effort.

Study staff will inform you if the study site reports these payments to the IRS as income payments to you. **[Site should customize this text as needed to inform the patient of the site's policy on reporting payments that the site makes to patients]**

You or your insurance company must pay for medications, including inhalers and other drugs, which you use outside of the study.

What if I am injured because I took part in this study?

If you have side effects from the study treatment, you should report them to the study doctor or nurse at _____ [specify number] _____. If you are injured or disabled because of participation in the LOTT, you can be treated at _____. The costs for this treatment will be covered by _____. However, _____ and the Federal Government do not have any program to compensate you or your family, if you are injured, disabled, or otherwise experience other bad effects which are not the fault of investigators, or die during the study. **[Each site to use their language on treatment for research related injuries]**

Choosing to join or leave the study

Taking part in this study is your choice. You decide whether to join the study. You may leave the study at any time and you do not have to give a reason. Leaving the study will not affect your regular medical care or your medical benefits. If you choose to leave the study, tell your study doctor. He or she will provide your regular doctor with your study records with your permission.

What other choices do I have if I do not want to take part in this research study?

Currently Medicare does not pay for oxygen therapy for people with moderately low levels of oxygen in their blood at rest or low level of blood oxygen during exercise or sleep outside of LOTT. However, people who have a very low blood oxygen level during exercise or sleep may meet Medicare qualifications for oxygen during exercise or sleep. You can still receive inhalers and drug therapy for your medical condition from your regular doctor. You can also choose to have no treatment.

Who can answer my questions?

If you have any questions about the study, you can contact the study investigator, ____, at _____. If you have questions about your rights as a research study participant, you can contact the study investigator at the number just provided or you can contact __ **[IRB office contact person]** ___ at _____.

Confidentiality and your personal health information

Your privacy is very important to us. To protect your confidentiality, we will use a study number and code instead of your name whenever possible to identify your information (e.g., on your tests and questionnaires). Your name, address, and telephone number will be known only to the site where you enroll, the regional clinical center associated with your site **[RCCs edit as appropriate for their plans]**, the company that provides your oxygen equipment (if you are prescribed oxygen), and Medicare. The link between your name and study number and code will be known only at the site where you enroll and at the regional clinical center associated with your site **[RCCs edit as appropriate for their plans]**.

Your test results and questionnaire responses, including your date of birth and zip code of residence, will be recorded on study forms, entered into a study computer file, and sent to the LOTT Data Coordinating Center in Baltimore, Maryland. Your Medicare Health Insurance Claim (HIC) number and social security number will be recorded on a study form, entered into a study computer file, and sent to the LOTT Data Coordinating Center in Baltimore, Maryland, but this computer file will be separate from the computer file with your study questionnaire and test results.

Study computer files will be password-protected. All paper records (such as questionnaires) will be kept in locked cabinets or in locked offices at your LOTT clinic __ **[and the LOTT regional clinical center if applicable]** __.

Your identifying information may be disclosed during a medical records review conducted by authorized personnel. Access to your identifying information will be limited to authorized study staff. You will not be identified in published scientific articles, reports, or presentations.

__ **[This site]** __ is committed to protecting your personal health information. Federal laws also protect your privacy. __ **[This site]** __ has agreements with other organizations to protect the confidentiality of your health information. However, if this information is shared with an organization not covered by these policies and laws, there is a remote chance that it would no longer be confidential.

In order to do this study, researchers will be collecting information about you and your health. This will include your prior health history and medical tests or records from other sites. The researchers will need to share your information in the following ways:

- If you are prescribed oxygen, we will provide your contact information (name, address, etc.) to the company providing your oxygen equipment.
- Your Medicare insurance number will be sent to the LOTT Data Coordinating Center in Baltimore, Maryland so that we may collect your Medicare claims.
- Your social security number will be sent to the LOTT Data Coordinating Center in Baltimore, Maryland so that we may search for you in electronic databases in case we lose track of you. We may search for you in electronic databases after the study visits end.
- The results from your tests and questionnaires will be sent to the LOTT Data Coordinating Center in Baltimore, Maryland and will be shared with other LOTT

researchers during the analysis of study findings. These researchers are located at: Johns Hopkins University Bloomberg School of Public Health, Brigham and Woman's Hospital, Cleveland Clinic Foundation, Denver Health and Hospital Authority, Duke University Medical Center, Kaiser Foundation Hospitals, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Ohio State University, Temple University, University of Alabama at Birmingham, University of Michigan, University of Pittsburgh, University of Utah, University of Washington, Washington University of St. Louis, and their associated LOTT sites.

- The results from your tests and questionnaires may be sent to researchers at other sites who are approved by the LOTT Steering Committee to do other studies which use LOTT data; these researchers will not be given your name, address or telephone number, but may be given your social security number and Medicare number if required for their study.
- The LOTT data and safety monitoring board will review study information for safety purposes.
- At the end of the study, a dataset will be created and provided to the National Institutes of Health (NIH), the sponsor of this study. The NIH will make this dataset available to other researchers. This dataset will include your study data, **but it will not include** your name, address, telephone number, social security number, or Medicare number.

By signing this consent form, you are agreeing that we may use and share your study data as explained above. There is no date when this agreement expires. You do not have to agree to the above uses. However, if you do not, you cannot take part in LOTT. If, in the future, you decide to withdraw this permission after enrolling in LOTT, no new study data will be gathered from you after you withdraw your permission. However, data gathered from you before you withdrew your permission will be used and shared as explained above.

By signing this consent form, you have not given up any legal rights that you otherwise would have as a participant in a research study.

By signing this consent form, you permit release of your medical records including but not limited to progress notes, operative notes, laboratory results, and diagnostic tests, to the LOTT study physician for regulatory and research purposes. These medical records include records for care received outside of LOTT.

If at any time you want to withdraw this consent, you must notify us in writing at: _____ **[specify name and address]** ____.

Consent for Storage and Use of a Collected Blood Sample [delete from here to Consent paragraph just prior to signature section if you have not submitted the protocol including biospecimens or are using a separate consent for biospecimens]

LOTT is collecting extra tubes of blood from participants who agree to donate extra blood samples. A total of about 2 tablespoonfuls of extra blood will be collected. DNA, the chemicals that determine heredity, and plasma **[and serum, if doing Expanded data collection]** will be obtained from the tubes of blood.

While the LOTT study is being done, the DNA and plasma **[and serum, if doing Expanded data collection]** will be stored at the Brigham and Women's Hospital in Boston, Massachusetts. After the LOTT is completed, any remaining DNA and plasma **[and serum, if doing Expanded data collection]** will be sent to the NHLBI. During LOTT and afterwards, these samples may be used for research studies about COPD or other smoking-related illness or about other diseases. Some studies might use your DNA sample to look at your genes and why people develop COPD.

You can agree to provide all, some, or none of these samples. You can also choose how these samples may be used by researchers.

If you agree to provide these samples, study personnel will draw the blood from a vein.

Your samples will be identified by a code (rather than your name) when sent to the Brigham and Women's Hospital.

It is your choice to give any or all or none of these samples. Choosing not to give samples will not affect your participation in the LOTT or your medical benefits or regular medical care. You have the right to withdraw or modify your consent to use your samples at any time. To do this you would need to write to: ___ **[specify name and address]** ____. Any leftover samples would be destroyed.

Your samples will be used for research. You will not be paid for allowing your samples to be used in research. Blood provided by you could be valuable for development of a new product that may be distributed commercially. You are not entitled to any financial compensation should this occur. There is no cost to you or your insurance company for any tests performed on the samples.

You or your doctor will not receive any results from the tests on your blood except in very rare cases where the researchers decide that a specific test result would provide important information about your health. An outside researcher wishing to share such information with you would only be able to contact you through the LOTT study.

BLOOD SAMPLE DONATION
Please read the following statements and mark your choices.

A) I will donate the following blood samples

1. I will donate a blood sample that will be used to obtain DNA.
   ☐ Yes ☐ No Initial here_____ Date_____

2. I will donate a blood sample that will be used to obtain plasma.
   ☐ Yes ☐ No Initial here _____ Date _____

[if doing Expanded data collection, add:
3. I will donate a blood sample that will be used to obtain serum.

☐ **Yes** ☐ **No** **Initial here _____ Date _____]**

If you do not want to donate any blood samples you should have marked the box No in all of the above questions and you should skip sections B and C below.

B) Choice of how samples may be used

1. The blood samples I donate may be used for research on COPD or other smoking-related illness.
   ☐ Yes ☐ No Initial here_____ Date_____

2. The blood samples I donate may be used for research on health problems not related to COPD or other smoking-related illness.
   ☐ Yes ☐ No Initial here_____ Date_____

C) Choice of who may use samples

1. My donated blood samples may be used by LOTT researchers.
   ☐ Yes ☐ No Initial here_____ Date_____

2. My donated blood samples may be used by researchers not participating in the LOTT.
   ☐ Yes ☐ No Initial here_____ Date_____

Consent

My signature indicates that:

- I want to join this research study as described above,
- This consent has been explained to me,
- All of my questions have been answered and if I have more questions, I have been told whom to call, and
- I will receive a copy of this consent form after I sign it.

_____	_____	_____
Print Name	Signature of participant	Date
_____	_____	_____
Print Name	Signature of person obtaining consent	Date
_____	_____	_____
Print Name	Signature of LOTT investigator	Date

<u>10th grade reading level</u>

LOTT Design Tables

1. Design synopsis

Study name (abbreviation)

- Long-term Oxygen Treatment Trial (LOTT)

Treatment groups

- Supplemental oxygen therapy tailored to patient's hypoxemia
  - If patient is moderately hypoxemic at rest, prescription is 2 L/min at rest and during sleep and dose is increased as needed to achieve at least 90% SpO_2 during ambulation
  - If patient is normoxic at rest, but desaturates on exercise, prescription is 2 L/min during sleep and dose is increased as needed to achieve at least 90% SpO_2 during ambulation
- No supplemental oxygen
- 1:1 treatment assignment ratio

Sample size calculation assumptions

- Composite outcome variable: time from randomization to the first occurrence of either hospitalization from any cause or death from any cause
- Minimum clinically significant reduction in the composite event rate (composite of either death or hospitalization) in the supplemental oxygen group vs. the no supplemental oxygen group: 40% (hazard ratio = 0.60)
- 5% Type I error
- 90% power
- The percent of patients in the group assigned to no supplemental oxygen who will crossover to oxygen treatment at some point during the trial is estimated to be 11.7% overall, 13.3% in year 1, 19.6% in year 2, and 25% per year thereafter
- The percent of patients in the group assigned to supplemental oxygen who become crossovers by virtue of nonadherence with the tailored oxygen prescription, defined as not receiving at least 75% of the tailored oxygen prescription during a given year, is estimated to be 3.1% overall, 3.9% in year 1, 8.7% in year 2, and 15% per year thereafter
- Crossovers of either type are assumed to experience the risk for the composite of mortality or hospitalization in the opposite group after crossover.
- Patients who become nonadherent (i.e., crossovers) are assumed to assume the risk in the opposite group as of the time of the crossover
- Target patient mix
  - 25% with moderate resting hypoxemia
  - 75% with normal resting saturation, who desaturate during exercise
  - 50% with hospitalization for COPD within the year prior to screening
- Assumed event rates in the no supplemental oxygen group:
  - 33% hospitalization/yr in those with recent COPD hospitalization
  - 10% hospitalization/yr in those without recent COPD hospitalization
  - 7% mortality/yr in those with recent COPD hospitalization
  - 6% mortality/yr in those without recent COPD hospitalization
- 28% composite event rate/yr in the no supplemental oxygen group
- Time to composite events for patients assigned to the group with no supplemental oxygen is assumed to follow an exponential distribution over the period of followup
- The loss to composite event followup rate is assumed to be only 1%, since both direct mortality and hospitalization ascertainment will be supplemented by searches of the Social Security

Master Death File, the National Death Index, and/or the BIRLS system for mortality and similar systems which record hospitalizations at CMS and the VA
- Logrank test statistic
- Calculated sample size: 737 patients (368 per treatment group)
- Expected composite events: 351 (90 all-cause mortality and 261 all-cause hospitalizations)
- Power (N=737): Composite outcome, 90%; all-cause mortality, 39%; all-cause hospitalization, 82%

Recruitment goals
- 737 patients (53 per RCC)
- 50% female
- 9% minority

Outcome measures
- Core
  - PRIMARY OUTCOME: Time to the composite event, all-cause mortality or all-cause hospitalization
  - Time to all-cause mortality
  - Time to all-cause hospitalization
  - Disease-specific quality of life (change in St. George's Respiratory Questionnaire)
  - Preference-weighted health-related quality of life (Quality of Well-Being Scale)
  - Exacerbation rate
  - Dyspnea (change in MMRC dyspnea score)
  - Nutrition (body mass index)
  - Exercise capacity (six minute walk distance)
  - Health resource utilization
  - Time till onset of severe resting hypoxemia
- Expanded
  - General quality of life (SF-36)
  - Sleep quality (Pittsburgh Sleep Quality Scale)
  - Anxiety and depression (Hospital Anxiety and Depression Scale)
  - Spirometry
- Substudy (to be determined)

11.1. Design synopsis

Data collection schedule

- Eligibility evaluation and baseline data collection visit
- Randomization visit
- Followup: Mix of in person, telephone, and mail contacts
  - Treatment adjustment visit shortly after randomization
    - Clinic visit for ambulatory dosing (oxygen group)
    - Telephone visit (no oxygen group)
  - Yearly in person visits (both groups)
  - Telephone visits at 4-month intervals between in person visits (both groups)
  - Quality of life questionnaires collected by mail at 4 and 16 months (both groups)
  - Adherence promotion contacts: weekly for 1 month, monthly for 5 months, then every 2 months to 12 months, and yearly thereafter at annual visits (oxygen group)
  - Adherence monitoring by mailed diary every 2 months (oxygen group)

Expected duration of recruitment and followup

- Recruitment completed by December 2014
- Followup: at least 1 year on every randomized patient and followup on all randomized patients to a common closeout date (maximum followup of 7 years)

Inclusion criteria (all are required)

- Age at least 40 years
- Dyspnea and lung disease process dominated by COPD in the judgment of the study physician
- One of the following must be true:
  - Post-bronchodilator FEV_1 percent predicted $\leq$ 70%
    or
  - Post-bronchodilator FEV_1 percent predicted > 70% and LOTT Study Physician determines that there is radiologic evidence of emphysema
- Post-bronchodilator $FEV_1/FVC < 0.70$
- Desaturation during rest or exercise per one of the following:
  - Resting oxygen saturation 89-93%
  - Desaturation below 90% for at least 10 seconds during 6 minute walk
- Response of Yes to at least one of the following questions:
  - Are you short of breath when hurrying on the level?
  - Are you short of breath when walking up a slight hill?
- If patient is using oxygen at the start of screening, all of the following must be met:
  - Patient agrees to stop using oxygen if randomized to no oxygen
  - Patient's physician agrees in writing to rescind order for oxygen if patient is randomized to no oxygen
  - Patient must report not using oxygen on the day of randomization and must report not using oxygen for the 4 calendar days prior to randomization (run in period where patient tries living without oxygen)
  - Satisfactory resolution of logistics of continuation with same oxygen company with waiver

of cost sharing obligations or switch to new company that will waive cost sharing obligations if patient is randomized to oxygen
- At least 10 pack-years of tobacco cigarette smoking in past
- Agreement not to smoke while using oxygen
- Medicare Part A and Part B beneficiary or insurance or other resource willing to pay costs of treatment and costs of study procedures and visits
- Approval by study physician for randomization to either treatment group
- Completion of all required pre-randomization assessments within 60 days of initiating eligibility evaluation
- Randomization within 60 days of initiating eligibility evaluation
- Consent

Exclusion criteria (any disqualifies a patient from randomization)
- Less than 30 days post treatment for an acute exacerbation of COPD as of initiating eligibility evaluation (less than 30 days from last dose of antibiotics or since a new or increased dose of systemic corticosteroids was initiated); chronic use of systemic corticosteroids while health is stable is not exclusionary
- COPD exacerbation requiring antibiotics, new or increased dose of systemic corticosteroids, or oxygen treatment after screening starts and prior to randomization (chronic use of corticosteroids while health is stable is not exclusionary)
- Less than 30 days post discharge from an acute care hospital after acute care hospitalization for COPD or other condition, as of initiating eligibility evaluation (patient may be in a rehabilitation hospital at time of screening)
- New prescription of supplemental oxygen after screening starts and before randomization
- Thoracotomy, sternotomy, major cardiopulmonary intervention (lung resection, open heart surgery, etc), or other procedure in the 6 months prior to eligibility evaluation likely to cause instability of pulmonary status
- Non COPD lung disease that affects oxygenation or survival
- Epworth Sleepiness Scale score greater than 15
- Desaturation below 80% for at least 1 minute during the six minute walk
- Disease or condition expected to cause death or inability to perform trial procedures or inability to comply with therapy within 6 months of randomization, as judged by study physician
- Participation in another intervention study

Mode of support
- Contracts from NHLBI
- Reimbursement by CMS for allowable clinical services for its beneficiaries conducted as part of the study protocol

11.1. Design synopsis

Participating centers

- 14 Regional Clinical Centers
  - Major affiliates
  - Satellite sites of varying levels of participation in the trial
- Data Coordinating Center
- Chairman's Office
- NHLBI
- CMS

2. Clinic and telephone visit data collection schedule (not including contacts for adherence promotion or monitoring)

			Followup																							
	BL		Year 1			Year 2			Year 3			Year 4			Year 5			Year 6			Year 7		
Months from RZ	-2	0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68	72	76	80	
[C]linic or [T]elephone visit	C	C	T	T	C	T	T	C	T	T	C	T	T	C	T	T	C	T	T	C	T	T	
Core data (all patients)																							
Consent	X	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
History*	B	S	S	S	L	S	S	L	S	S	L	S	S	L	S	S	L	S	S	L	S	S	
RA resting oximetry	X	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
RA 6MW w/oximetry	X	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
Ambulatory oxygen dose	.	X^R	.	.	X^R	.	.	X^R	.	.	X^R	.	.	X^R	.	.	X^R	.	.	X^R	.	.	
FEV_1, FVC†	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Height, arm span	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Weight, edema	X	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
Hemoglobin, hematocrit	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Cotinine	X	.	.	.	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
DNA and plasma banking	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Epworth Sleepiness	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
MMRC	X	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
SGRQ	X	.	M	.	X	M	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
QWB-SA	X	.	M	.	X	M	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
Expanded data (selected sites)																							
SF-36	X	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
Pitts. Sleep Qual. Index	X	.	.		X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
Hosp. Anx. & Depr. Scale	X	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
FEV_1, FVC†	.	.	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	X	.	.	
A1AT	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Serum banking	X	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Substudy data collection (on an as yet unspecified number of patients)																							
(To be determined)																							

*B = Baseline history, S = short interim history, L = long interim history, M = mailed

†Pre- and post-bronchodilator (medication will not be held prior to pre-bronchodilator spirometry)

[R]Only for patients randomized to supplemental oxygen; exercise assessment while using oxygen to determine/check their exercise oxygen dose (done 1 week after randomization).

3. Whole blood (venous; mL) draw schedule

	Baseline[1]		Followup					
Months from RZ	-2	0	12	24	36	48	60	72
Core								
Hemoglobin, hematocrit[2]	3	.	.	.	.	.	.	.
Cotinine[3]	10	.	10	.	.	.	.	.
DNA and plasma banking[4]	18.5	.	.	.	.	.	.	.
Total for Core	**31.5**	**.**	**10**	**.**	**.**	**.**	**.**	**.**
Expanded								
A1AT[5]	3	.	.	.	.	.	.	.
Serum banking[6]	10	.	.	.	.	.	.	.
Total for Expanded[7]	**44.5**	**.**	**10**	**.**	**.**	**.**	**.**	**.**

[1]Note: Blood is to be drawn before randomization.
[2]Hemoglobin, hematocrit: One 3 mL purple top tube (tests done by local lab).
[3]Cotinine: One 10 mL red top tube (not serum separator). Test is done by local lab.
[4]One 8.5 mL Paxgene tube (primary DNA source) and one 10 mL EDTA tube (backup DNA source and plasma for banking). Tubes are sent to Biosample Repository at the Channing Laboratory.
[5]A1AT concentration and phenotype can be obtained from chart review. If concentration is greater than 100 mg/dL (100 mg%, 1 mg/mL, 19 μM), phenotype is not required. If concentration is not available or if concentration is 100 mg/dL (100 mg%, 1 mg/mL, 19 μM) or less and phenotype is not available, fill one 3 mL red top tube and have tests done by local lab.
[6]Serum banking: One 10 mL red top tube. Serum is sent to Biosample Repository at the Channing Laboratory.
[7]Expanded data collection is additional to Core data collection, so total for Expanded is sum of amounts for tests done for Core data collection and tests done for Expanded data collection.

4. Adherence promotion contact schedule

	Weeks from randomization					Months from randomization												
	0	1	2	3	4	2	3	4	5	6	8	10	12	24	36	48	60	72
Supplemental oxygen	CC	T	T	T	T	T	T	T*	T	T	T*	T	C	C	C	C	C	C
No supplemental oxygen	C	T	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

Notes:
C = clinic visit
T = telephone call visit (coordinator calls participant)
* = combined with data collection telephone visit

For supplemental oxygen group:

In person contact at randomization (0 visit) includes: counseling about any dissatisfaction with treatment assignment, initiation of education about using oxygen, prescription of oxygen equipment and arranging for delivery to participant's home and scheduling in person visit to obtain walking prescription and further educate participant.

In person contacts in 1st week after randomization and at 1, 2, 3, 4, 5, and 6 years include: education about participant's personal home and ambulatory systems; walk on oxygen with oximetry (to determine patient's ambulatory oxygen prescription); and adherence promotion discussions (address barriers to adherence, encourage adherence)

Telephone contacts at 1, 2, 3, and 4 weeks and 2, 3, 4, 5, 6, 8 and 10 months include: adherence promotion discussions (address barriers to adherence, encourage adherence) and trouble shoot any problems with oxygen equipment. Additional telephone contacts may occur in year 2 as needed if the patient seems receptive to encouragement.

For no supplemental oxygen group:

In person contact at randomization (0 visit) includes: counseling about any dissatisfaction with treatment assignment, confirmation that any oxygen equipment in the home has been removed, discussion about the importance of adhering to the no oxygen regimen, but keeping LOTT site informed about any prescription for oxygen and if prescribed oxygen, the patient should use it as prescribed.

Telephone contact includes: adherence promotion discussions (address barriers to adherence, encourage adherence)

5. Post randomization contact schedule (summary)

	R	W	Yr 1: Mos						Yr 2: Mos						Yr 3: Mos						Yr 4: Mos						Yr 5: Mos						Yr 6: Mos						Yr 7: Mos					
	Z	k					1	1	1	1	1	2	2	2	2	2	3	3	3	3	3	4	4	4	4	4	5	5	5	5	5	6	6	6	6	6	7	7	7	7	8	8
	0	1	2	4	6	8	0	2	4	6	8	0	2	4	6	8	0	2	4	6	8	0	2	4	6	8	0	2	4	6	8	0	2	4	6	8	0	2	4	6	8	0	2
All patients																																											
Visit	C	.	.	T	.	T	.	C	.	T	.	T	.	C	.	T	.	T	.	C	.	T	.	T	.	C	.	T	.	T	.	C	.	T	.	T	.	C	.	T	.	T	.
Mail	.	.	.	M	.	.	.	.	.	M	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Additional contacts for oxygen patients																																											
Adh promo[1]	.	C	A	A	A	A	A	A	.	.	.	.	.	A	.	.	.	.	.	A	.	.	.	.	.	A	.	.	.	.	.	.	.	.	.	.	.	A	.	.	.	.	.	.
Diary[2]	.	.	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
Additional contacts for control patients																																											
Visit	.	T	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

T=telephone visit with interview, C=clinic visit, A=adherence promotion contact, D=adherence monitoring diary

[2]Adherence promotion telephone contacts are weekly for 1st month, monthly for 2nd - 6th months, every 2 months for 7th - 12th months, in person at annual visits.

[3]Patients are to complete and return diaries indicating oxygen usage every 2 months through all followup.

Summary of Amendments to LOTT Protocol

June 2008 protocol

This is the Protocol under which LOTT opened recruitment.

September 2009 protocol

Major revisions implemented in this Protocol include the new composite primary outcome, death or hospitalization; change in sample size from 3108 to 1134; and eligibility of patients with exercise desaturation only. Information supplied to IRBs regarding the proposed revisions follows:

"After nearly 8 months of implementation, the LOTT investigators and program officers have come to the difficult conclusion that the LOTT cannot be conducted successfully in the current format and are requesting changes to the protocol. As of 23 September 2009, only 34 participants have been randomized among 22 active sites (Regional Clinical centers and satellites). It is the Steering Committee's consensus that it is prudent to make significant adjustments early in the trial rather than continue with a study design that, however valid, cannot be accomplished.

The following changes to the protocol are proposed, therefore, in order to: 1) expand the potential numbers of candidates for the trial; 2) to reduce the number of candidates necessary for the trial; 3) to extend the scientific value of the trial; and 4) to increase the relevance of the use of supplemental oxygen in COPD patients in the trial to clinical practice.

- Participants who desaturate below 90% during the six minute walk, but have resting oxygen saturation greater than 93% at rest will be eligible. Many of those who desaturate below 89% are prescribed oxygen in routine clinical practice without any evidence-based support of long-term benefits. For these individuals who are randomized to the supplemental oxygen group, the LOTT oxygen prescription will be to use oxygen during activity and sleep. Individuals with an oxygen saturation from 89% through 93% at rest (those currently eligible) who are randomized to the supplemental oxygen group will continue to be prescribed continuous oxygen (i.e., 24-hour oxygen). Thus, the LOTT oxygen prescription will be more personalized for patients, which more closely mirrors routine clinical practice.
- The primary outcome measure will be time from randomization to either all-cause death or all-cause hospitalization, whichever occurs first. The investigators believe that this composite outcome is clinically relevant as well as relevant to CMS policy-making. After careful study, the NHLBI program office has concluded that this outcome is consistent with the contract RFP which was initially thought to be a barrier to including hospitalization in the outcome. The investigators have elected to use all-cause mortality and all-cause hospitalization rather than COPD-related events because all-cause mortality and all-cause hospitalization are globally relevant to health and quality of life, better reflect health-care costs, and include the comorbidities of COPD that are common and may also be beneficially impacted by the use of supplemental oxygen (e.g., cardiac and cerebrovascular diseases). This approach also avoids the difficulties associated with adjudicating which deaths or hospitalizations are COPD-related. With the assumption that half of the patients will have had an exacerbation in the past year, we estimate that the total sample size can be reduced from 3108 to 1134, each with a minimum of 1 year of follow-up and a maximum of 4.5 years.
- Participants who meet the other eligibility criteria for the trial do not have to demonstrate a 30-day period that they can tolerate the absence of oxygen. Because the trial recruitment will target patients who have had an exacerbation recently, the treatment assignment whether to maintain or remove the oxygen will better fit into the normal clinical decision-making process.

The proposed protocol changes allow the patients randomized to date to continue on their present

LOTT oxygen prescription and also permit continued recruitment of the originally targeted patients. The proposed protocol changes add data collection of two quality of life questionnaires by mail but otherwise do not change their follow-up schedule.

During their conference call on 21 September 2009, the LOTT Data and Safety Monitoring Board (DSMB) reviewed the revised protocol and approved the revisions. We are now asking for IRB approval of the revised protocol, consent and data collection forms. We will continue to use the currently IRB-approved HIPAA authorization and contract not to smoke.

We believe that these changes do not increase any risks to the patient, that they permit the currently randomized patients to continue in the trial without material change to their treatment and situation in the trial, and that the changes will provide for a more clinically relevant, as well as clinically feasible, study. We believe that the revised outcome is important to patients as well as clinicians and insurers. We believe the revisions make the trial more appealing both to patients and to clinicians with eligible patients."

June 2010 Protocol

In June 2010, the eligibility criterion related to FEV_1 % predicted was modified. Information provided to IRBs included:

"During their conference call on 4 June 2010, the LOTT Steering Committee approved raising the level of FEV_1 percent predicted eligible for LOTT from 65% to 70%. Patients with FEV_1 percent predicted (per the reference equations of Hankinson et al, 1999) of 70% or less will be eligible for LOTT provided that the patient meets the other LOTT eligibility criteria. The LOTT Steering Committee believes that this level of lung function is consistent with a diagnosis of COPD and that it will expand the population eligible for the trial. The other eligibility criteria remain unchanged. This change in eligibility does not alter the risk/benefit profile for the trial, and it does not require a change to the consent statement for the trial. Patients previously randomized in LOTT continue in the study, with no change to their follow-up or treatment."

December 2010 protocol

In December 2010, the eligibility criterion related to FEV_1 % predicted was further modified. Information provided to IRBs included:

"Current protocol criterion:
Post-bronchodilator FEV_1 percent predicted less than or equal to 70%% (reference equations of Hankinson et al, 1999 will be used)

Proposed revision:
One of the following must be true:

- Post-bronchodilator FEV_1 percent predicted less than or equal to 70%% (reference equations of Hankinson et al, 1999 will be used)

or

- Post-bronchodilator FEV_1 percent predicted greater than 70% (reference equations of Hankinson et al, 1999 will be used) and LOTT Study Physician determines that there is radiologic evidence of emphysema (e.g., by chest CT scan or chest X-ray)

All other eligibility criteria will remain unchanged and all patients will continue to have to meet all of

the other eligibility criteria to be randomized to treatment in LOTT.

The LOTT Steering Committee believes that FEV_1 percent predicted above 70% in the presence of emphysema is consistent with a diagnosis of COPD and that this change will expand the population eligible for the trial. This change in eligibility does not alter the risk/benefit profile for the trial, and it does not require a change to the consent statement for the trial. Patients previously randomized in LOTT continue in the study, with no change to their follow-up or treatment."

March 2013 Protocol

In March 2013, the recruitment and follow-up periods for LOTT were extended and the sample size was reduced per observed crossover rates. Information provided to IRBs included:

"The NHLBI has approved extension of the recruitment period for LOTT to 31 December 2014 and follow-up to 31 December 2015, and we are ready to implement the revised sample size for LOTT approved by the DSMB at their 22 March 2012 meeting. The Protocol has been revised as follows:

- We have extended the follow-up schedule to include telephone visits at 56, 64, 68, 76, and 80 months after randomization up to 31 December 2015 and in person visits at 60 and 72 months after randomization

- We have reduced the sample size to 737 patients. By 2012, it had become evident that the original assumptions about treatment group drop-ins and dropouts were much lower than the observed drop-in and dropout rates; therefore, the required sample size for LOTT was lower than the original target sample size of 1,134. In March 2012, the LOTT DSMB approved a revised sample size calculation of 737 patients based on the observed drop-in and dropout rates.

- We have deleted 24 hour oximetry since we have not been able to implement that portion of the protocol and will not try to implement it for the last 25% of patients

- We have cleaned up various typographical errors

These changes do not alter the risk/benefit profile for the trial.

For early enrollees who consent to extended follow-up, these changes add up to 2 additional annual clinic visits (content of visits will be the same as the annual visits completed in years 1-4) and up to 5 additional telephone visits (1 additional telephone visit in year 4 of follow-up and 2 in each of years 5 and 6; content of these telephone visits will be the same as the telephone visits conducted in years 1-4). Patients will continue on their randomized treatment assignment during this extension of follow-up. The patient stipends ($100 per year to help cover expenses of participation for each patient completing the annual visit in person and $350 per year for those randomized to oxygen (to help cover out of pocket expenses of oxygen treatment) will continue unchanged. Medicare will continue to cover the clinical costs of treatment and the in person visit procedures.

If a randomized patient does not agree to the extension of follow-up, then their participation in LOTT will end. Patients assigned to oxygen will transition to standard care supervised by their primary care physician and will have their LOTT oxygen prescription canceled. Results of study tests will be provided to the patient's primary care provider with the patient's permission."

LOTT
- Home
- Centers
- Organization
- Committees
- Meetings
- Staff
- Documents
- Data System
- Presentations
- Publications
- Substudies
- Links
- Ancillary Studies
- For Oxygen Providers
- For Patients

Long-term Oxygen Treatment Trial

Publications

2016

Long-term Oxygen Treatment Trial Research Group: A randomized trial of long-term oxygen for COPD with moderate desaturation. *New Eng J Med*; 375:1617-1627, **2016**. (full text) (supplementary appendix) (editorial) (protocol materials) (PMC5216457, available 4/27/2017)

2015

Stoller JK, Aboussouan LS, Kanner RE, Wilson LA, Diaz P, Wise R for the LOTT Research Group: Characteristics of alpha-1 antitrypsin-deficient individuals in the Long-term Oxygen Treatment Trial and comparison with other subjects with Chronic Obstructive Pulmonary Disease. *Ann Am Thorac Soc*; 12: 1796-1804, **2015**. (MS# 2013-02) (full text) (PMC4722829)

2014

Narewski ER, Blackford A, Desai P, Lammi MR, Fuhlbrigge A, Soler X, Albert RK, Criner GJ: Clinical differences in COPD patients with mild-moderate hypoxemia at rest +/- exertion vs. those nomoxemic at rest who desaturation only with exertion. *Am J Respir Crit Care Med*; 189: A3053, **2014**. (MS# 2013-01) (abstract)

2010

Stoller JK, Panos RJ, Krachman S, Doherty DE, Make B and the Long-term Oxygen Treatment Trial Research Group: Oxygen therapy for patients with COPD: Current evidence and the Long-Term Oxygen Treatment Trial. *Chest*; 138: 179-187, **2010**. (MS# 2009-01) (full text) (PMC2897694)

Make B, Krachman S, Panos RJ, Doherty DE, Stoller JK: Oxygen therapy in advanced COPD: In whom does it work? *Semin Respir Crit Care Med*; 31: 334-342, **2010**. (MS# 2010-01) (full text)

ac2 - Form AC2 Control Grp Adherence Promotion Cntct - Visit WO1

Date file created: 21 Apr 2017
Observations: 370
Variables: 10

Variable Name	Variable Label	Type	Variable Length
ac208	8 Able to speak with patient	Char	1
ac211	11 Understanding of role in study	Char	2
ac212	12 Understanding of need to report O2 use	Char	2
ac209a	9a O2 equipment in home at randomization	Char	1
ac209b	9b Was O2 prescription cancelled	Char	1
ac209c	9c Was equipment removed from home	Char	1
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

AC - Control Group Adherence Promotion Contact - Visit W01

Purpose: To document the control group patient's adherence promotion contact at visit w01.

Data collection level: All patients (Core) assigned to no supplemental oxygen (control group).

When: Visit w01.

Administered by: Adherence Educator.

Respondent: Patient assigned to no supplemental oxygen (control group).

Instructions: Complete one AC form for visit w01 whether or not you are able to speak with the patient (one AC form per control patient, not one AC form per effort). **If you were able to speak with the patient within the window**: Provide adherence promotion contact; objectives include: (1) Verify oxygen equipment has been removed from the home (if applicable); (2) Establish rapport with the patient by assisting the patient in identifying solutions to barriers to living with COPD without supplemental oxygen; (3) Check the patient's level of understanding of the treatment and study protocol, including the need to report oxygen use and to recognize when oxygen would be appropriate; (4) Remind the patient about the telephone (every 4 months) and in person (annually) visit schedule. **If you were unable to speak with the patient within the window**: Enter any date in the window for visit w01 in item 4 and complete item 8 as ''No'' and explain why you were unable to complete the contact within the window. **Note**: Only items 1-6, 8-9, and 11-17 are keyed.

A. Center, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date of visit:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: w 0 1

6. Form & revision: a c 2

B. Contact attempts

7. Notes about contact attempts *(date, time, outcome; do not key this item):*

_____

_____

_____

_____

_____

_____

_____

_____

8. Were you able to speak with the patient within the window for this contact:

Yes (1)

No *(explain why not and describe efforts to complete the contact)* (2)

13.

_____

_____

_____

C. Removal of equipment

9. Check on removal of oxygen equipment from the home

a. Did the patient have oxygen equipment in the home as of randomization in LOTT:

Yes (1)

No (2)

10.

b. Did the prescribing physician cancel the prescription:

Yes (1)

No *(specify why not)* (2)

10.

_____
specify why not

c. Has the equipment been removed from the patient's home:

Yes (1)

No *(specify why not)* (2)

_____
specify why not

D. Adherence promotion contact

10. Ask the patient how he/she is doing living with COPD without supplemental oxygen:

_____

_____

_____

_____

11. Ask the patient to describe his/her role in the study as a control group patient and rate your assessment of the patient's understanding of his/her role in the study, where 0 denotes Poor understanding and 10 denotes Excellent understanding:

____ ____
00-10

12. Ask the patient to describe what he/she should do if prescribed oxygen by his/her private physician and rate your assessment of the patient's understanding of the need to report the prescription to the LOTT Coordinator, where 0 denotes Poor understanding and 10 denotes Excellent understanding:

____ ____
00-10

Discuss with the patient what he/she sees as barriers and solutions to living with COPD without supplemental oxygen. Ask the patient what problems he/she foresees to living with COPD without supplemental oxygen and list those problems as barriers in Section F below. Ask the patient ''How do you think you will handle [mention one barrier at a time]'' and list solutions in Section F as well.

Record in Section G any notes about today's discussion that will be helpful for your next contact with this patient.

E. Administrative information

13. Adherence Educator PIN:

____ ____ ____ ____

14. Adherence Educator signature:

_____

15. Clinical Coordinator PIN:

____ ____ ____ ____

16. Clinical Coordinator signature:

_____

17. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

F. Barriers and solutions *(these discussions may elicit barriers and provide opportunities to explore solutions to living with COPD without supplemental oxygen; please list below)*

18. Are there any problems you are having that make it hard for you to live with COPD without oxygen?

Barriers	**Solutions**

G. Notes *(record any notes about today's discussion that will be helpful for your next contact with this patient)*

19. Notes:

ae2 - Form AE2 Oxygen Grp Adherence Promotion Cntct - Initial Walking Dose Determination

Date file created: 21 Apr 2017
Observations: 368
Variables: 8

Variable Name	Variable Label	Type	Variable Length
ae208	8 Able to speak with patient	Char	1
ae209	9 How ready to use oxygen all the time	Char	2
ae210	10 How important is use of oxygen	Char	2
ae213	13 Confidence in ability to use oxygen	Char	2
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

AE - Oxygen Group Adherence Promotion Contact - Initial Walking Dose Determination

Purpose: To document the adherence promotion contact when the supplemental oxygen patient receives his/her initial walking dose.
Data collection level: All patients (Core) assigned to supplemental oxygen.
When: Visit rx. As soon as possible after patient has received his/her oxygen equipment.
Administered by: Adherence Educator.
Respondent: Patient assigned to 24-hour supplemental oxygen.
Instructions: Complete this form at the in person adherence promotion contact shortly after randomization when the patient has returned to the clinic with his/her ambulatory equipment for ambulatory dose determination. Dose determination is documented on Form MP. Enter the date of the contact in item 4. Finish completing the Oxygen Equipment (OE) form for the patient. Adherence promotion contact objectives include: (1) Establish rapport with the patient by assisting the patient in identifying their feelings about oxygen use, including ambivalence, expected barriers, and solutions to oxygen use at home and out of the house; (2) Determine the patient's level of readiness to use supplemental oxygen; assess and explore how important the patient believes oxygen use is and how confident the patient feels about using oxygen; (3) Review use of the patient's specific equipment, including safe operation of the equipment; (4) Review the contact schedule including the schedule for completion of oxygen usage logs and the telephone contact schedule; (5) Review how to provide the information needed for the oxygen usage logs (where to find the meter if the patient has a stationary concentrator, what LOTT is looking for on the log, how to use and complete the log; (6) Discuss patient's experience with oxygen to date, and explore motivation with motivational enhancement exercises. **Note**: Only items 1-6, 8-10, 13, and 16-20 are keyed.

A. Clinic, visit, and patient identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date of contact:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: **r x** ____

6. Form & revision: **a e 2**

B. Contact attempts

7. Notes about contact attempts *(date, time, outcome; do not key this item)*:

_____

_____

_____

_____

_____

_____

8. Were you able to speak with the patient within the window for this contact:

Yes (1)
No *(specify why not)* (2)

16. ↵

_____

_____

_____

C. Patient responses

(After talking with the patient about oxygen equipment use and issues, ask the patient questions 9-15. Questions 9-15 may elicit barriers and provide opportunities to explore solutions to using supplemental oxygen or provide an opportunity to reinforce oxygen use. Record any barriers or solutions discussed in Section E below.
For questions 9, 10, and 13, if patient responds with fraction, eg, 6.5, seek a whole number response by asking if more 6 or more 7.)

9. On a scale of 0 to 10 where 0 means Not at all ready and 10 means Very ready, how ready are you today to use oxygen all of the time *(as much as prescribed)*:

_____ _____
00-10

10. On a scale of 0 to 10 where 0 means Not at all important and 10 means Very important, how important is using oxygen to you:

_____ _____
00-10

If item 10 is 5 or greater:

11. Why did you give yourself a ____ *[quote number response to item 10]* instead of a 2 or 3:

_____

_____

_____

If item 10 is 4 or less:

12. What would it take to get you to a 6 or 7 instead of a ____ *[quote number response to item 10]*:

_____

_____

_____

13. On a scale of 0 to 10 where 0 means Not at all confident and 10 means Very confident, how confident are you today that you can use oxygen all the time *(as much as prescribed)*:

_____ _____
00-10

If item 13 is 5 or greater:

14. Why did you give yourself a ____ *[quote number response to item 13]* instead of a 2 or 3:

_____

_____

_____

If item 13 is 4 or less:

15. What would it take to get you to a 6 or 7 instead of a ____ *[quote number response to item 13]*:

_____

_____

_____

Record in Section F any notes about today's discussion that will be helpful for your next contact with this patient.

D. Administrative information

16. Adherence Educator PIN:

_____ _____ _____ _____

17. Adherence Educator signature:

_____

18. Clinical Coordinator PIN:

_____ _____ _____ _____

19. Clinical Coordinator signature:

_____

20. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

E. Barriers and solutions *(these discussions may elicit barriers and provide opportunities to explore solutions to using supplemental oxygen; please list below)*

21. Are there any other problems you are having that make it hard for you to use oxygen? How do you think you might handle [mention one barrier at a time]?

Barriers	**Solutions**

F. Notes *(record any notes about today's discussion that will be helpful for your next contact with this patient)*

22. Notes:

ah2 - Form AH2 Oxygen Grp Adherence Promotion Cntct - Telephone or Annual Visit

Date file created: 21 Apr 2017
Observations: 4938
Variables: 9

Variable Name	Variable Label	Type	Variable Length
ah208	8 Able to speak with patient	Char	1
ah209	9 Hours/day of O2 use in past week	Char	2
ah210	10 Readiness to use O2 as much as prescribed	Char	2
ah211	11 Importance of O2 use	Char	2
ah213	13 Confidence of O2 equipment use as prescribed	Char	2
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

AH - Oxygen Group Adherence Promotion Contact - Telephone or Annual Visit

Purpose: To document a telephone or annual visit adherence promotion contact with a patient assigned to supplemental oxygen. Use Form XZ for the visit rz adherence promotion contact with oxygen or control patients and use Form AE for the visit rx adherence promotion contact when ambulatory dose is determined. Use form AC for the visit w01 adherence promotion contact with control patients.

Data collection level: All patients (Core) assigned to supplemental oxygen.

When: Visits w01, w02, w03, w04, a02, a03, a04, a05, a06, a08, a10, f12, f24, f36, f48, f60, f72. Additional promotion contacts may be completed as needed and as acceptable to the patient (use visit code n).

Administered by: Adherence Educator.

Respondent: Patient assigned to supplemental oxygen.

Instructions: Adherence promotion contacts are done by telephone at visits w01, w02, w03, w04, a02, a03, a04, a05, a06, a08, a10 and are done in person at visits f12, f24, f36, and f48. Adherence promotion contacts should include: review of the patient's oxygen equipment listing (OF printout) for any updates to the patient's equipment; discussions with the patient about adherence to use of their oxygen equipment (motivational enhancement: e.g., identify barriers and brainstorm solutions), review of safe operation of the equipment, review of patient's understanding of what is wanted on the oxygen usage logs, address any issues inhibiting completion of logs (e.g., can't find meter, can't read meter, lost log), and issues the patient has related to delivery and operation of oxygen equipment. **All contacts**: Complete one AH form for each of visits w01, w02, w03, w04, a02, a03, a04, a05, a06, a08, a10 whether or not you are able to speak with the patient (one AH form per patient visit, not one AH form per effort). **Note**: You may skip the w01 adherence promotion contact if visit rx is done 3 or fewer days before the window for visit w01 closes. **If you were able to speak with the patient within the window**: After talking with the patient about using supplemental oxygen, ask the patient the questions in Section C. **If you were unable to speak with the patient within the window**: Enter any date in the window for the contact in item 4 and complete item 8 as ''No'' and explain why you were unable to complete the contact within the window. **Note**: Only items 1-6, 8-11, 13 and 15-19 are keyed.

A. Center, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: a h 2

B. Contact attempts

7. Notes about contact attempts *(date, time, outcome; do not key this item):*

_____

_____

_____

_____

_____

_____

8. Were you able to speak with the patient within the window for this contact:

Yes (1)

No *(explain why not and describe efforts to complete the contact)* (2)

15.

_____

_____

_____

C. Patient responses

(After talking with the patient about oxygen equipment use and issues, ask the patient questions 9-14. Questions 9-14 may elicit barriers and provide opportunities to explore solutions to using supplemental oxygen or provide an opportunity to reinforce oxygen use. Ask the patient ''How do you think you might handle [mention one barrier at a time]?'' Record any barriers or solutions discussed in Section E below.)

9. During the past week, on average, about how many hours per day have you used your oxygen:

____ ____
hours

For questions 10, 11, and 13, if patient responds with fraction, eg, 6.5, seek a whole number response by asking if more 6 or more 7; if patient responds "already doing it", response should be coded as 10.

10. On a scale of 0 to 10 where 0 means Not at all ready and 10 means Very ready, how ready are you today to use oxygen as much as prescribed:

____ ____
00-10

11. On a scale of 0 to 10 where 0 means Not at all important and 10 means Very important, how important is using oxygen to you:

____ ____
00-10

Go to item 13 if item 11 is 9 or 10.

12. What are your reasons for ranking importance of using oxygen as ___ *[quote number response to item 11]*:

_____

_____

_____

13. On a scale of 0 to 10 where 0 means Not at all confident and 10 means Very confident, how confident are you today that you can use oxygen as much as prescribed:

____ ____
00-10

14. What are your reasons for giving yourself a ___ *[quote the number response to item 13]* for your confidence in using oxygen as much as prescribed:

_____

_____

_____

Record in section F any notes about today's discussion that will be helpful for your next contact with this patient.

D. Administrative information

15. Adherence Educator PIN: ____ ____ ____ ____

16. Adherence Educator signature:

_____

17. Clinical Coordinator PIN: ____ ____ ____ ____

18. Clinical Coordinator signature:

_____

19. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

E. Barriers and solutions *(these discussions may elicit barriers and provide opportunities to explore solutions to using supplemental oxygen; please list below)*

20. Are there any other problems you are having that make it hard for you to use oxygen? How do you think you might handle [mention one barrier at a time]?

Barriers	**Solutions**

F. Notes *(record any notes about today's discussion that will be helpful for your next contact with this patient)*

21. Notes:

ap1 - Form AP1 Portable Oxygen Concentrator Usage Log

Date file created: 21 Apr 2017
Observations: 469
Variables: 8

Variable Name	Variable Label	Type	Variable Length
ap110a	Date port conc meter rdg cnvrtd to # days frm RZ	Num	8
ap110b	Part B, Meter reading (xxxxxx.x)	Char	7
ap111a	Part C, Flow setting (xx) for rest and/or sleep	Char	2
ap111b	Part C, Flow setting (xx) for physical activity	Char	2
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	5

Keyed: ( )

LOTT

AP - Portable Oxygen Concentrator Usage Log

A. RCC, patient, and visit identification

1. RCC ID: _____ _____ _____ _____ _____
2. Patient ID: _____ _____ _____ _____ _____
3. Patient code: _____ _____ _____ _____
4. Date *(date sent from clinic)*:

   _____ _____-_____ _____ _____-_____ _____
   day mon year
5. Visit code: **n** _____ _____
6. Form & revision: **a** **p** **1**

D. Administrative information
(Completed by Clinical Coordinator after log is returned)

7. Date received at clinic:

   _____ _____-_____ _____ _____-_____ _____
   day mon year
8. Clinical Coordinator PIN:

   _____ _____ _____ _____
9. Clinical Coordinator signature:

   _____

Instructions to participant:

Part B. LOTT needs a meter reading from your portable concentrator. Just before mailing this form to your LOTT center, please read the meter, and record the reading and the date that the meter was read.

Date read *(mm/dd/yyyy)*	Meter reading
__ __ / __ __ / __ __ __ __	__ __ __ __ __ __ • __

Part C. Please record the flow setting number (flow rate) that you have usually used with your concentrator for the past 2 months

Flow setting number (flow rate) used with your portable concentrator:	
For rest and/or sleep.	__ __
For physical activity.	__ __

If you have any questions, please call your LOTT coordinator. You will get a new form each time we ask you to send in a form (about every 2 months).

Thank you! Please send to your LOTT center when requested.

aq1 - Form AQ1 Liquid Oxygen System Usage Log

Date file created: 21 Apr 2017
Observations: 501
Variables: 28

Variable Name	Variable Label	Type	Variable Length
aq119	Part A, Total pounds of O2 delivered (xxxx)	Char	4
aq120	Date log started cnvrtd to # days frm RZ	Num	8
aq121	Part B, Number of tanks used (xxx)	Char	3
aq122	Date log endedd cnvrtd to # days frm RZ	Num	8
aq123	Part C, Flow setting (xx) for base	Char	2
aq124	Part C, Flow setting (xx) for tanks	Char	2
aq110a	Delivery date 1 cnvrtd to # days frm RZ	Num	8
aq110b	Part A, 10. pounds of O2 delivered (xxx)	Char	3
aq111a	Delivery date 2 cnvrtd to # days frm RZ	Num	8
aq111b	Part A, 11. pounds of O2 delivered (xxx)	Char	3
aq112a	Delivery date 3 cnvrtd to # days frm RZ	Num	8
aq112b	Part A, 12. pounds of O2 delivered (xxx)	Char	3
aq113a	Delivery date 4 cnvrtd to # days frm RZ	Num	8
aq113b	Part A, 13. pounds of O2 delivered (xxx)	Char	3
aq114a	Delivery date 5 cnvrtd to # days frm RZ	Num	8
aq114b	Part A, 14. pounds of O2 delivered (xxx)	Char	3
aq115a	Delivery date 6 cnvrtd to # days frm RZ	Num	8
aq115b	Part A, 15. pounds of O2 delivered (xxx)	Char	3
aq116a	Delivery date 7 cnvrtd to # days frm RZ	Num	8
aq116b	Part A, 16. pounds of O2 delivered (xxx)	Char	3
aq117a	Delivery date 8 cnvrtd to # days frm RZ	Num	8
aq117b	Part A, 17. pounds of O2 delivered (xxx)	Char	3
aq118a	Delivery date 9 cnvrtd to # days frm RZ	Num	8
aq118b	Part A, 18. pounds of O2 delivered (xxx)	Char	3
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	5

LOTT

AQ - Liquid Oxygen System Usage Log

D. RCC, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____
2. Patient ID: ____ ____ ____ ____ ____
3. Patient code: ____ ____ ____ ____
4. Date *(date sent from clinic)*:

   ____ ____-____ ____ ____-____
   day mon year
5. Visit code: **n** ____ ____
6. Form & revision: **a** **q** **1**

E. Administrative information
(Completed by Clinical Coordinator after log is returned)

7. Date received at clinic:

   ____ ____-____ ____ ____-____
   day mon year
8. Clinical Coordinator PIN:

   ____ ____ ____ ____
9. Clinical Coordinator signature:

   _____

Instructions to participant: The opposite side of this form asks some questions about your use of your oxygen equipment.

Part A: LOTT needs to know how many pounds of oxygen have been delivered to you. Your oxygen delivery person should help you record this information each time oxygen is delivered. Just before you mail the form, please add up the total pounds of oxygen delivered to you (or you may leave that for your LOTT coordinator to complete).

Part B: LOTT needs to know how many oxygen tanks you have used. Please enter the date you start recording on this form and then X out a tank each time you fill a liquid tank more than half way. Just before mailing the form to your LOTT center, count up the total number of tanks X'd out (or you may leave that for your LOTT coordinator to complete) and enter the date this log ended.

Part C: Please record the flow setting number (flow rate) that you usually use with your liquid oxygen base unit, and please record the flow setting number (flow rate) that you usually use with your tanks of oxygen.

If you have any questions, please call your LOTT coordinator. You will get a new form each time we ask you to send in a form (about every 2 months). Thank you!

Patient ID: ___ ___ ___ ___ ___

LOTT Oxygen Usage Log

Part A. LOTT needs to know how much oxygen has been delivered to you. Your provider should help you record this information every time there is a delivery.

	Delivery date *(mm/dd/yyyy)*	Pounds of oxygen delivered
10.	__ __ / __ __ / __ __ __ __	__ __ __
11.	__ __ / __ __ / __ __ __ __	__ __ __
12.	__ __ / __ __ / __ __ __ __	__ __ __
13.	__ __ / __ __ / __ __ __ __	__ __ __
14.	__ __ / __ __ / __ __ __ __	__ __ __
15.	__ __ / __ __ / __ __ __ __	__ __ __
16.	__ __ / __ __ / __ __ __ __	__ __ __
17.	__ __ / __ __ / __ __ __ __	__ __ __
18.	__ __ / __ __ / __ __ __ __	__ __ __

Total pounds . . . . __ __ __ __

Part B. LOTT needs to know how many tanks you have used.

Date started log *(mm/dd/yyyy)*: __ __ / __ __ /__ __ __ __

Please X out a tank each time you fill a liquid tank more than half way:

⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑
⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑   ⇑ ⇑ ⇑ ⇑ ⇑

Total number of tanks used: . . . . __ __ __

Date log ended *(mm/dd/yyyy)*: . . . . . . __ __ / __ __ / __ __ __ __

Part C. For the past 2 months, what has been your usual flow setting number (flow rate) with your:

Liquid oxygen base unit (reservoir): . . . . __ __

Tanks: . . . . __ __

Thank you! Please send to your LOTT center when requested.

as1 - Form AS1 Stationary Concentrator and Tank Usage Log

Date file created: 21 Apr 2017
Observations: 3221
Variables: 11

Variable Name	Variable Label	Type	Variable Length
as110	Date log started cnvrtd to # days frm RZ	Num	8
as111	Part A, Total number of tanks used (xxx)	Char	3
as112	Date log endedd cnvrtd to # days frm RZ	Num	8
as114	Part C, Flow setting (xx) for concentrator	Char	2
as115	Part C, Flow setting (xx) for tanks	Char	2
as113a	Date meter read cnvrtd to # days frm RZ	Num	8
as113b	Part B, Meter reading (xxxxxx.x)	Char	7
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	5

LOTT

Keyed: ( )

AS - Stationary Concentrator and Tank Usage Log

D. RCC, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date *(date sent from clinic)*:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: **n** ____ ____

6. Form & revision: **a** **s** **1**

E. Administrative information
(Completed by Clinical Coordinator after log is returned)

7. Date received at clinic:

____ ____-____ ____ ____-____ ____
day mon year

8. Clinical Coordinator PIN:

____ ____ ____ ____

9. Clinical Coordinator signature:

_____

Instructions to participant: The opposite side of this form asks some questions about your use of your oxygen equipment.

Part A: LOTT needs to know how many oxygen tanks you use. Please enter the date you start recording on this form and then X out a tank each time you start a new tank of oxygen. Just before mailing the form to your LOTT center, count up the total number of tanks X'd out (or you may leave that for your LOTT coordinator to complete) and enter the date this log ended.

Part B: LOTT needs a meter reading from your concentrator. Just before mailing this form to your LOTT center, please read the meter, and record the reading and the date the meter was read.

Part C: Please record the flow setting number (flow rate) that you usually use with your concentrator and please record the flow setting number (flow rate) that you usually use with tanks of oxygen.

If you have any questions, please call your LOTT coordinator. You will get a new form each time we ask you to send in a form (about every 2 months). Thank you!

LOTT

Patient ID: ___ ___ ___ ___ ___

LOTT Oxygen Usage Log

Part A. LOTT needs to know how many tanks you have used.

Date started log *(mm/dd/yyyy)*: __ __ / __ __ /__ __ __ __

Please X out a tank for each tank that you use:

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑ ⇑

Total number of tanks used: . . . . __ __ __

Date log ended *(mm/dd/yyyy)*: . . . . . . __ __ / __ __ / __ __ __ __

Part B. LOTT needs the meter reading from your concentrator. Please read the meter just before mailing this form.

Date read *(mm/dd/yyyy)*	Meter reading
__ __/ __ __/ __ __ __ __	__ __ __ __ __ __•__

Part C. For the past 2 months, what has been your usual flow setting number (flow rate) with your:

Concentrator: . . . . __ __

Tanks: . . . . __ __

Thank you! Please send to your LOTT center when requested.

bc1 - Form BC1 Blood Collection for DNA Serum and Plasma Banking

Date file created: 21 Apr 2017
Observations: 472
Variables: 10

Variable Name	Variable Label	Type	Variable Length
bc107	7 Blood collected in PAXgene tube	Char	1
bc111	11 Blood collected in EDTA tube	Char	1
bc115	15 Blood collected for serum banking	Char	1
bc108a	item 8a cnvrtd to #days from RZ	Num	8
bc112a	item 12a cnvrtd to #days from RZ	Num	8
bc116a	item 16a cnvrtd to #days from RZ	Num	8
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

BC - Blood Collection for DNA, Serum, and Plasma Banking

Purpose: Document the collection of whole blood for DNA, serum and plasma banking. Complete this form only if the patient consented to banking of at least one type of sample (DNA, serum, and/or plasma).

Data collection level: Core and/or Expanded, depending on what patient consented to.

When: Visit sb or in followup as needed. This form is used in followup only for DNA banking - e.g, for redraw because the DNA yield on the original sample was inadequate or if a patient who originally refused consent changes his/her mind and now consents to DNA banking. If needed during followup, use visit code n.

Administered by: Clinical Coordinator and laboratory personnel responsible for collection and processing.

Instructions: Use the patient's Consent Documentation for DNA, Serum, and Plasma Banking (DC) form and Flash Card #11, Tubes to fill for DNA, plasma, and/or serum banking, to determine which tubes should be filled for specimen banking. Then follow the applicable instructions regarding tube processing and shipment.

PAXgene tube: Attach tube ID label to the 8.5 mL PAXgene tube and fill with whole blood. Invert tube gently 6 times to mix blood and additives; refrigerate at 4°C until shipment.

EDTA tube: Attach tube ID label to the 10 mL EDTA tube and fill with whole blood. Invert tube gently 6 times to mix blood and additives; refrigerate at 4°C until shipment.

Red top tube and serum shipment tube: Attach ID labels to the 10 mL red top tube and to the serum shipment tube. Fill the red top tube with whole blood. Let blood clot, but process within 2 hours of drawing whole blood. Spin at 2000 rpm for 10 minutes at 4°C using either a swinging bucket centrifuge or a centrifuge with fixed angle rotor heads. Pour off serum into labeled serum shipment tube. Refrigerate at 4°C until shipment. If you have a centrifuge but it is not refrigerated, spin with the unrefrigerated centrifuge.

Shipment of PAXgene, EDTA, and serum shipment tubes: Pack tubes on frozen cold pak in shipper provided by Channing and ship to Channing by next day delivery. If samples are obtained on a Friday, refrigerate all tubes at 4°C until shipment on the next Monday.

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: b c 1

B. Blood for DNA and/or plasma banking

7. Was blood collected in the PAXgene tube:

Yes (* 1)

No, patient does not consent to DNA banking: (2)

11.

No, *(specify reason):* (3)

11.

_____
specify

** You must have consent for DNA banking to fill the PAXgene tube.*

8. PAXgene tube

a. Date of blood draw for PAXgene tube:

____ ____–____ ____ ____–____ ____
day mon year

9. Form copy of PAXgene tube label:

LOTT form BC, PAXgene
Pt: ___ ___ ___ ___ , ___ ___ ___ ___

10. Phlebotomist:

_____
print name

11. Was blood collected in the EDTA tube:

Yes (* 1)

No, patient does not consent to DNA banking and does not consent to plasma banking: (2) **15.**

No, *(specify reason):* (3) **15.**

_____
specify

** You must have consent for at least 1 of DNA banking or plasma banking to fill the EDTA tube.*

12. EDTA tube

a. Date of blood draw for EDTA tube:

____ ____–____ ____ ____–____ ____
day mon year

13. Form copy of EDTA label:

LOTT form BC, EDTA
Pt: ___ ___ ___ ___ , ___ ___ ___ ___

14. Phlebotomist:

_____
print name

C. Blood for serum banking

15. Was blood collected for serum banking:

Yes (* 1)

No, patient did not consent to serum banking or site is doing Core data collection only: (2) **20.**

No, *(specify reason):* (3) **20.**

_____
specify

** You must have consent for serum banking to fill red top tube.*

16. Red top tube

a. Date of blood draw for red top tube:

____ ____–____ ____ ____–____ ____
day mon year

17. Form copy of red top tube label:

LOTT form BC, Red top
Pt: ___ ___ ___ ___ , ___ ___ ___ ___

18. Form copy of serum shipment tube label:

LOTT form BC, Serum Shipment
Pt: ___ ___ ___ ___ , ___ ___ ___ ___

19. Phlebotomist:

_____
print name

D. Administrative information

20. Clinical Coordinator PIN: ____ ____ ____ ____

21. Clinical Coordinator signature:

_____

22. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

bv1 - Form BV1 Blood Values

Date file created: 21 Apr 2017
Observations: 1334
Variables: 26

Variable Name	Variable Label	Type	Variable Length
bv107	7 sb visit	Char	1
bv108	item 8 cnvrtd to #days from RZ	Num	8
bv109	9 Hemoglobin (g/dL)	Char	3
bv110	10 Hematocrit (%)	Char	3
bv111	11 Expanded data collection	Char	1
bv112	12 A1AT results from chart review	Char	1
bv113	13 A1AT >100 mg/dL	Char	1
bv114	14 A1AT phenotype available	Char	1
bv115	item 15 cnvrtd to #days from RZ	Num	8
bv117	17 A1AT Phenotype	Char	1
bv119	item 19 cnvrtd to #days from RZ	Num	8
bv116a	16a A1AT concentration	Char	5
bv116as	16a A1AT level (< or >)	Char	1
bv116b	16b A1AT units	Char	1
bv118a	18a Tobacco smoking	Char	1
bv118b	18b Chewing tobacco	Char	1
bv118c	18c Use nicotine products	Char	1
bv118d	18d None of above	Char	1
bv120a	20a No cotinine level detected	Char	1
bv120b	20b Cotinine level	Char	4
bv120bs	20b Cotinine level (< or >)	Char	1
bv120c	20c Cotinine units	Char	1
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

BV - Blood Values

Purpose: To record results of blood tests.

Data collection level: Core and Expanded depending on blood test.

When: Visit sb and visit f12.

Administered by: Clinical Coordinator.

Instructions: **Visit sb**: Hemoglobin and hematocrit are required for all (Core) patients. Alpha-1 antitrypsin (A1AT) is required for Expanded data collection patients only. A1AT concentration and phenotype may be obtained from chart review. If concentration is greater than 100 mg/dL (100 mg %; 1 mg/mL; 19 μM), phenotype is not required. If concentration is not available or if concentration is 100 mg/dL (100 mg %; 1 mg/mL; 19 μM) or less and phenotype is not available, have test done by the local lab. Cotinine is required for all (Core) patients who do not report tobacco smoking, tobacco chewing or use of nicotine products (gum, lozenge, patch, inhaler, nasal spray, etc). **Visit f12**: Cotinine is required for all (Core) patients who do not report tobacco smoking, tobacco chewing or use of nicotine products (gum, lozenge, patch, inhaler, nasal spray, etc). **All visits**: All relevant lab reports should be marked with the patient's ID and code and stapled to the back of this form and name should be blacked out. If your lab reports values electronically, print a copy of the report, mark it with the patient's ID and code, and staple it to the back of this form.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: b v 1

B. Hemoglobin, hematocrit, and A1AT

7. Is this visit sb:

( ) Yes (1) ( ) No (2)

18.

8. Date of blood collection hemoglobin and hemtocrit *(required for all patients):*

____ ____–____ ____ ____–____ ____
day mon year

9. Hemoglobin: ____ ____ • ____ ____
g/dL

10. Hematocrit: ____ ____ • ____ ____
%

11. Is the patient an Expanded Data Collection patient:

( ) Yes (1) ( ) No (2)

18.

12. Are alpha-1 antitrypsin deficiency testing results available from chart review:

( ) Yes (1) ( ) No (2)

15.

13. Is the alpha-1 antitrypsin deficiency concentration greater than 100 mg/dL (100 mg %; 1 mg/mL, 19 μM):

( ) Yes (1) ( ) No (2)

18.

14. Is the phenotype available:

( ) Yes (1) ( ) No (2)*

17.

**You must draw blood for alpha-1 antitrypsin testing if patient is an Expanded Data Collection patient.*

15. Date of blood collection for alpha-1 antitrypsin testing *(alpha-1 antitrypsin testing is required for Expanded Data Collection patients whose results are not otherwise available):*

____ ____–____ ____ ____–____ ____
day mon year

16. Alpha-1 antitrypsin concentration

a. Level *(specify > or < if applicable):*

____ >/< ____ ____ ____ • ____ ____

b. Units:

mg/dL (1)
mg % (2)
mg/mL (3)
µM (4)

17. Phenotype *(check only one):*

Concentration > 100 mg/dL (100 mg %; 1 mg/mL; 19 µM) (1)
ZZ (2)
MZ (3)
MM (4)
SS (5)
SZ (6)
Null (7)
Other *(specify)* (8)

_____
specify

C. Cotinine

18. Does the patient report any of the following *(check all that apply)*

a. Tobacco smoking: (1) **21.**

b. Chewing tobacco: (1) **21.**

c. Use of nicotine products *(gum, lozenge, patch, inhaler, nasal spray, etc):* (1) **21.**

d. None of the above (1)

19. Date of blood collection for cotinine:

____ ____–____ ____ ____–____
day mon year

20. Cotinine level

a. None detected: (1) **21.**

b. Level *(specify > or < if applicable):*

____ >/< ____ ____ ____ • ____

c. Units:

ng/mL (1)
µg/L (2)

D. Administrative information

21. Clinical Coordinator PIN:

____ ____ ____ ____

22. Clinical Coordinator signature:

_____

23. Date form reviewed:

____ ____–____ ____ ____–____
day mon year

dc2 - Form DC2 Consent Documentation for DNA Serum and Plasma Banking

Date file created: 21 Apr 2017
Observations: 738
Variables: 13

Variable Name	Variable Label	Type	Variable Length
dc207	7 Consent for DNA banking	Char	1
dc208	8 Consent for plasma banking	Char	1
dc209	9 Consent for serum banking	Char	1
dc210	10 No for items 7-9	Char	1
dc211	11 Consent to use for COPD research	Char	1
dc212	12 Consent to use for nonCOPD research	Char	1
dc213	13 Consent to use by LOTT investigators	Char	1
dc214	14 Consent to use by non-LOTT investigators	Char	1
dc215	15 Other info about consents	Char	1
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

DC - Consent Documentation for DNA, Serum, and Plasma Banking

Purpose: To document options selected for specimen banking and use of samples.

Data collection level: Core (DNA and plasma) and/or Expanded (serum). Patient may opt out of specimen banking and still enroll as a Core or Expanded patient.

When: Visit sb or in followup as needed (e.g., if patient who originally refused consent agrees to banking or patient rescinds consent). If needed during followup, use visit code n.

By whom: Clinical Coordinator.

Instructions: Complete this form for all patients. If your site does not have IRB approval for banking, answer No for items 7-9 and Yes for item 10. If the patient changes his/her mind regarding consent for samples after the initial form is completed, complete a new DC form. Three types of samples are banked in LOTT: DNA, serum, and plasma. The patient may consent to use by LOTT investigators and/or by other investigators outside of LOTT. The patient may consent to use of samples for health research related to COPD and smoking-related illness and/or health research unrelated to COPD. Use Flash Card #11, Tubes to fill for DNA, plasma, and serum banking in accordance with patient's consent, to identify which tubes to fill.

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: d c 2

B. Consent for banking and use of samples

7. Did the patient consent to DNA banking:

(Yes 1) (No 2)

8. Did the patient consent to plasma banking:

(Yes 1) (No 2)

9. Did the patient consent to serum banking *(sites doing Core data collection check No)*

(Yes 1) (No 2)

10. Is No checked for each of items 7, 8, and 9:

(Yes 1) (No 2)

17. ____

11. Did the patient consent to use of samples for research on COPD and smoking-related illness:

(Yes 1) (No 2)

12. Did the patient consent to use of samples for research on health problems unrelated to COPD and smoking related illness:

(Yes 1) (No 2)

13. Did the patient consent to use of samples by LOTT investigators:

(Yes 1) (No 2)

14. Did the patient consent to use of samples by investigators not participating in LOTT:

(Yes 1) (No 2)

15. Is there other information related to consent for use of genetic, serum, and/or plasma specimens that clinic staff feel should be keyed to the study database to assure use of samples will conform to patient's consent:

(Yes 1) (No 2)

17. ____

16. Other information:

_____

_____

_____

_____

_____

C. Administrative information

17. Clinical Coordinator PIN: ____ ____ ____ ____

18. Clinical Coordinator signature:

_____

19. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

dr1 - Form DR1 Death Report

Date file created: 21 Apr 2017
Observations: 138
Variables: 11

Variable Name	Variable Label	Type	Variable Length
dr11O	1O Cause of death	Char	1
dr111	11 Death related to COPD	Char	1
dr108a	8a Patient's family	Char	1
dr108b	8b Friend	Char	1
dr108c	8c Health care provider or LOTT staff	Char	1
dr108d	8d Newspaper	Char	1
dr108e	8e Other	Char	1
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

DR - Death Report

Purpose: To record the report of a patient's death.
Data collection level: All patients (Core).
When: As soon as clinic is notified of a patient's death.
Administered by: Study Physician and Clinical Coordinator.
Instructions: Complete this form whenever the clinical center is informed of a patient's death.

A. Center, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date form is initiated:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____

6. Form & revision: d r 1

B. Death information

7. Date of death:

____ ____–____ ____ ____–____ ____
day mon year

8. Source of death report *(check all that apply)*

a. Patient's family: (1)
b. Friend: (1)
c. Health care provider or LOTT staff: (1)
d. Newspaper: (1)
e. Other *(specify):* (1)

_____
other source

9. Place of death:

_____
city/state/country

_____
city/state/country

10. Probable cause of death
(Study Physician: use whatever knowledge you have on hand and your best medical judgment; this is not the adjudicated cause of death; check only one):

COPD (1)
Cardiovascular (2)
Cerebrovascular (3)
Cancer (4)
Other *(specify):* (5)

_____
specify

_____
specify

Cannot say (6)

11. Was death related to COPD
(Study Physician: use whatever information you have on hand and your best medical judgment; check only one):

Yes (1)
No (2)
Possibly (3)
Probably (4)
Cannot say (5)

C. Administrative information

12. Study Physician PIN: ____ ____ ____ ____

13. Study Physician signature:

_____

14. Clinical Coordinator PIN: ____ ____ ____ ____

15. Clinical Coordinator signature:

_____

16. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

ep1 - Form EP1 Epworth Sleepiness Scale

Date file created: 21 Apr 2017
Observations: 738
Variables: 14

Variable Name	Variable Label	Type	Variable Length
ep107	7 Score - Epworth Sleepiness Scale	Char	2
ep108	8 Score is greater than 15	Char	1
ep111	11 Sitting and reading	Char	1
ep112	12 Watching TV	Char	1
ep113	13 Sitting inactive in public place	Char	1
ep114	14 Car passenger for an hour/no break	Char	1
ep115	15 Resting in afternoon when possible	Char	1
ep116	16 Sitting and talking	Char	1
ep117	17 Sitting after lunch w/o alcohol	Char	1
ep118	18 In car stopped in traffic for few minutes	Char	1
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

EP - Epworth Sleepiness Scale

Purpose: To obtain the patient's views on his/her degree of sleepiness.
Data collection level: All patients (Core).
When: Visit sb.
Administered by: Self-administered, but Clinical Coordinator must be available to answer questions and review completed forms.
Respondent: Patient without help from spouse or family.
Instructions: The Clinical Coordinator completes page 1 of this form; the patient completes page 2. A label (with patient ID, patient code and visit code sb) should be affixed to the upper right corner of page 2. The patient should meet with the Clinical Coordinator, be instructed in completion of the form, and then should complete the form. The Clinical Coordinator should review the completed form for missing responses, resolve any problems before the patient leaves the clinic, and determine the score (add the scores for items 11-18; use a calculator). Page 1 should then be completed by the Clinical Coordinator and re-attached to page 2. If an EHg condition is checked, the patient is ineligible for LOTT. Complete the administrative information section and file the form in the file for ineligible patients. Do not key EP forms for ineligible patients.
Reference: Johns MW: A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. *Sleep* 1991;14(6):540-545.

A. Clinic, visit, and patient identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date patient completed the form)*:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: **s b** ____

6. Form & revision: **e p 1**

B. Administrative information

(To be completed by Clinical Coordinator after questionnaire is completed)

7. Score *(sum of scores for items 11-18)*:

____ ____
range 0-24

8. Is the score *(item 7)* greater than 15:

Yes (1) No (2)

→ EHg

9. Clinical Coordinator
a. PIN: ____ ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

LOTT

Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Epworth Sleepiness Scale

(Items 1-10 are reserved for clinic use)

In contrast to just feeling tired, how likely are you to doze off or fall asleep in the following situations? This refers to your usual life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. For each question, please give one answer:

	Circle one			
	Would never doze or fall asleep	**Slight chance of dozing or falling asleep**	**Moderate chance of dozing or falling asleep**	**High chance of dozing or falling asleep**
11. Sitting and reading	0	1	2	3
12. Watching TV	0	1	2	3
13. Sitting inactive in a public space (like a theater or meeting)	0	1	2	3
14. As a passenger in a car for an hour without a break	0	1	2	3
15. Lying down to rest in the afternoon when circumstances permit	0	1	2	3
16. Sitting and talking to someone	0	1	2	3
17. Sitting quietly after lunch without alcohol	0	1	2	3
18. In a car, while stopping for a few minutes in traffic	0	1	2	3

Thank you!

ex2 - Form EX2 COPD Exacerbation

Date file created: 21 Apr 2017
Observations: 1651
Variables: 49

Variable Name	Variable Label	Type	Variable Length
ex207	date of onset cnvrtd to #days from RZ	Num	8
ex211	11 Require visit(s) to physicians office	Char	1
ex212	12 Require visit(s) to urgent care	Char	1
ex213	date urgent care visit cnvrtd to #days from RZ	Num	8
ex214	14 Require overnight hospital admission	Char	1
ex215	date hosp admit cnvrtd to #days from RZ	Num	8
ex216	date hosp dischg cnvrtd to #days from RZ	Num	8
ex219	19 ICU admission while hospitalized	Char	1
ex220	20 Mechanical ventilation while hospitalized	Char	1
ex222	22 New/changed supplemental O2 prescription	Char	1
ex223	23 O2 prescribed during rest	Char	1
ex224	24 O2 prescribed during exercise	Char	1
ex225	25 O2 prescribed during sleep	Char	1
ex226	date o2 script cnvrtd to #days from RZ	Num	8
ex227	27 Current status of exacerbation	Char	1
ex228	date resolved cnvrtd to #days from RZ	Num	8
ex208a	8a Increased shortness of breath	Char	1
ex208b	8b Increased volume of sputum	Char	1
ex208c	8c Increased sputum purulence	Char	1
ex208d	8d Wheezing	Char	1
ex208e	8e Chest tightness	Char	1
ex208f	8f Increased cough	Char	1
ex208g	8g Increased nasal congestion	Char	1
ex208h	8h None of the above	Char	1
ex209a	9a Pneumonia	Char	1
ex209b	9b Congestive heart failure	Char	1
ex209c	9c Acute coronary syndrome	Char	1
ex209d	9d Cerebrovascular accident	Char	1
ex209e	9e Diabetes (type I or II)	Char	1
ex209f	9f Pulmonary embolism	Char	1
ex209g	9g Deep venous thrombosis	Char	1
ex209h	9h Lung cancer	Char	1
ex209i	9i Cancer other than lung	Char	1
ex209j	9j Other respiratory illness	Char	1
ex209k	9k Other non-respiratory illness	Char	1
ex209l	9l None of the above	Char	1
ex210a	10a Antibiotics	Char	1
ex210b	10b Bronchodilators	Char	1
ex210c	10c Systemic corticosteroids	Char	1
ex210d	10d None of the above	Char	1
ex221a	21a Non-invasive positive pressure ventilation	Char	1
ex221b	21b Endotracheal intubation/positive pressure ventilation	Char	1
ex223a	23a Liter/min O2 prescribed during rest	Char	1
ex224a	24a Liter/min O2 prescribed during exercise	Char	1
ex225a	25a Liter/min O2 prescribed during sleep	Char	1
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

EX - COPD Exacerbation

Purpose: To report occurrence of a COPD exacerbation.

Data collection level: All patients (Core).

When: As needed. Use visit code rz, rx, w01, w02, w03, w04, a01, a02, a03, a04, f04, a05, a06, a08, f08, a10, f12, f16, f20, f24, f28, f32, f36, f40, f44, f48, f52, f56, f60, f64, f68, f72, f76, or f80 if reported at the visit; use visit code n otherwise. If more than one EX form needs to be completed for the patient on the same calendar day, use n2 for the 2nd event, n3 for the 3rd event, etc.

Administered by: Clinical Coordinator and Study Physician.

Instructions: The Study Physician and Clinical Coordinator should use their best medical judgment in completing this form, based on patient self-report and whatever medical records are available. If the exacerbation involves an overnight, acute care hospitalization, obtain the discharge summary from the last hospital admission associated with the exacerbation. In general, initiate this form when an exacerbation is first reported. You may delay finishing the form until the exacerbation is stable or resolved. If additional information is received after this form is completed, update this form or complete a Followup Report (FR) form, whichever makes the most sense to you. Be sure to key this form and any changes or updates to it. If the exacerbation has none of the characteristics listed in item 8, the Study Physician should consider whether the event is truly a COPD exacerbation. Medical conditions reported in item 9 should be conditions that may significantly impact the patient's LOTT treatment regimen, morbidity or mortality (e.g., renal or liver disease, hip fracture, GI bleeding, etc).

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date form initiated:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code ____ ____ ____

6. Form & revision: e x 2

B. COPD exacerbation information

7. Date of onset:

____ ____–____ ____ ____–____ ____
day mon year

8. Characteristics of exacerbation
(Coordinator/Study Physician should use best judgment based on patient self-report and medical records available; check all that apply)

a. Increased shortness of breath: (1)
b. Increased volume of sputum: (1)
c. Increased sputum purulence: (1)
d. Wheezing: (1)
e. Chest tightness: (1)
f. Increased cough: (1)
g. Increased nasal congestion: (1)
h. None of the above: (1)

9. Patient's other medical conditions that may significantly impact the patient's LOTT treatment regimen, morbidity or mortality (e.g., renal or liver disease, hip fracture, GI bleeding, etc) *(check all that apply)*

a. Pneumonia: (1)
b. Congestive heart failure: (1)
c. Acute coronary syndrome: (1)
d. Cerebrovascular accident: (1)
e. Diabetes (type I or II): (1)
f. Pulmonary embolism: (1)
g. Deep venous thrombosis: (1)
h. Lung cancer: (1)
i. Cancer other than lung: (1)
j. Other respiratory illness *(specify):* (1)

_____

_____

k. Other non-respiratory illness *(specify):* (1)

_____

_____

l. None of the above: (1)

10. Did the patient receive new prescription(s) or increased dose(s) of any of these medications for this exacerbation *(check all that apply)*

a. Antibiotics: (1)
b. Bronchodilators: (1)
c. Systemic corticosteroids (PO, IM, or IV): (1)
d. None of the above: (1)

11. Did this exacerbation require one or more visits to a physician's office:

Yes (1) No (2)

12. Did this exacerbation require one or more urgent care (emergency department) visits:

Yes (1) No (2)

14.

13. Date of urgent care visit *(date of 1st urgent care visit if more than one was required):*

____ ____–____ ____ ____–____ ____
day mon year

14. Did this exacerbation require one or more overnight hospital admissions:

Yes (1) No (2)

22.

15. Date of hospital admission*(1st admission if more than one):*

____ ____–____ ____ ____–____ ____
day mon year

16. Date of hospital discharge*(last discharge if more than one):*

____ ____–____ ____ ____–____ ____
day mon year

17. Primary discharge diagnosis *(from discharge summary from last hospitalization):*

_____

18. Secondary discharge diagnosis *(from discharge summary from last hospitalization):*

a. 1st

_____

b. 2nd

_____

c. 3rd

_____

d. 4th

_____

e. 5th

_____

f. 6th

_____

g. 7th

_____

h. 8th

_____

i. 9th

_____

j. 10th

_____

19. Was the patient admitted to ICU during any hospitalization associated with this exacerbation:

Yes (1) No (2)

20. Did the patient receive mechanical ventilation during any hospitalization associated with this exacerbation:

Yes (1) No (2)

22.

21. What type of mechanical ventilation did the patient receive *(check all that apply):*

a. Non invasive positive pressure ventilation by face mask (NPPV) (1)

b. Endotracheal intubation and positive pressure ventilation (1)

22. Did this exacerbation result in a new prescription of supplemental oxygen at home or a change in the patient's existing supplemental oxygen prescription at home, either by the LOTT physician or private physician:

Yes (1) No (2)

27.

23. Is the patient now prescribed oxygen for use during rest:

Yes (1) No (2)

24.

a. Setting prescribed for rest: ____ 1-9

24. Is the patient now prescribed oxygen for use during exercise:

Yes (1) No (2)

25.

a. Setting prescribed for exercise: ____ 1-9

25. Is the patient now prescribed oxygen for use during sleep:

Yes (1) No (2)

26.

a. Setting prescribed for sleep: ____ 1-9

26. Date oxygen prescription given to patient:

____ ____–____ ____ ____–____ ____
day mon year

27. Current status of exacerbation:

Resolved (1)

Resolving (2)

29.

Active and unchanged (3)

29.

Worsening (4)

29.

Unknown (5)

29.

28. Date resolved:

____ ____–____ ____ ____–____ ____
day mon year

29. Additional comments on exacerbation:

_____

_____

_____

C. Administrative information

30. Study Physician PIN: ____ ____ ____ ____

31. Study Physician signature:

_____

32. Clinical Coordinator PIN: ____ ____ ____ ____

33. Clinical Coordinator signature:

_____

34. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

exernadir - Nadir SpO2 (10th lowest value) during 6MW

Date file created: 21 Apr 2017
Observations: 2253
Variables: 3

Variable Name	Variable Label	Type	Variable Length
nadir10	10th lowest SpO2 during 6 minute walk	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

fr1 - Form FR1 Followup Report for Event Previously Reported on AN EX or IE Form

Date file created: 21 Apr 2017
Observations: 44
Variables: 9

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
fr107	7 Initial report form	Char	1
fr108	Date of init report cnvrtd to #days from RZ	Num	8
fr109	9 Visit code of initial report	Char	3
fr110	10 Severity changed	Char	1
fr111	11 Current severity	Char	1
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT FR - Followup Report for Event Previously Reported on AN, EX, or IE Form

Purpose: To report additional information about an event that was previously reported on an AN (Unexpected Related Serious Adverse Event or Unanticipated Problem), EX (COPD Exacerbation), or IE (Interim Event) form.
Data collection level: All patients (Core) as needed.
When: As needed. Use visit code n. If more than one FR form needs to be completed on the same calendar day, use visit code n for the 1st FR form completed, n2 for the 2nd FR form, etc.
Administered by: Clinical Coordinator and Study Physician.
Instructions: Complete this form if there is significant new information (use your judgment) about a previously reported event. However, if you believe an event, which previously was not considered an unexpected, related SAE or unanticipated problem (OHRP definition), has become an unexpected, related SAE or unanticipated problem, then complete the AN form now.

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date form initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____

6. Form & revision: f r 1

B. Identification of event form that this report relates to

7. Form on which event was initially reported *(check only one)*:

AN (1)
EX (2)
IE (3)

8. Date in item 4 of the form on which the event was initially reported *(date in item 4 of the form checked in item 7):*

____ ____–____ ____ ____–____ ____
day mon year

9. Visit code in item 5 of the form on which the event was intially reported *(code in item 5 of the form checked in item 7):*

____ ____ ____

C. Additional information for event

10. Has event severity classification changed:

Yes (1)
No (2)
Event originally reported on EX form (3)

12. ____

11. Current severity classification *(check only one)*:

Not an adverse event (0)
Grade 1, mild adverse event, did not require treatment (1)
Grade 2, Moderate adverse event, resolved with treatment (2)
Grade 3, severe adverse event, inability to carry on normal activities; required professional medical attention (3)
Grade 4, life-threatening or permanently disabling adverse event (4)
Grade 5, fatal adverse event (5)

12. New information to report:

_____

_____

_____

_____

_____

_____

C. Administrative information

13. Study Physician PIN: ____ ____ ____ ____

14. Study Physician signature:

_____

15. Clinical Coordinator PIN: ____ ____ ____ ____

16. Clinical Coordinator signature:

_____

17. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

ha1 - Form HA1 Hospital Anxiety and Depression Scale (HADS)

Date file created: 21 Apr 2017
Observations: 2239
Variables: 21

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
ha108	8 Depression score 11 or greater	Char	1
ha111	11 Feel tense or wound up	Char	1
ha112	12 Still enjoy things I used to enjoy	Char	1
ha113	13 Get a frightened feeling	Char	1
ha114	14 Can laugh and see funny side of things	Char	1
ha115	15 Worrying thoughts go through mind	Char	1
ha116	16 Feel cheerful	Char	1
ha117	17 Can sit at ease and feel relaxed	Char	1
ha118	18 Feel as if slowed down	Char	1
ha119	19 Get frightened feeling like butterflies	Char	1
ha120	20 Lost interest in appearance	Char	1
ha121	21 Feel restless	Char	1
ha122	22 Look forward with enjoyment to things	Char	1
ha123	23 Get sudden feelings of panic	Char	1
ha124	24 Enjoy a good book or radio or TV	Char	1
ha107a	7a Anxiety score	Char	2
ha107b	7b Depression score	Char	2
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

HA - Hospital Anxiety and Depression Scale (HADS)©

Purpose: To assess anxiety and depression.
Data collection level: Expanded.
When: Visits sb, f12, f24, f36, f48, f60, f72.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and review the completed form.
Respondent: Patient, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A below and attach a label to each of pages 2-5. The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-4. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Anxiety and depression domain scores should be calculated using the scoring key on page 5. The Clinical Coordinator should then reattach pages 1 and 5 to pages 2-4 and complete section B below. **Red flag**: A total depression domain score of 11 or greater is suggestive of clinical depression. If a patient has a depression domain score of 11 or greater, inform the LOTT Study Physician of this result. With permission from the patient with a total depression domain score of 11 or greater, the LOTT staff will: (1) inform the patient's healthcare provider that the questionnaire is suggestive of the presence of clinical depression and (2) suggest that the patient undergo timely evaluation and appropriate treatment.

A. Clinic, visit, and patient identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date patient completed the form)*:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **h a 1**

B. Administrative information

(To be completed by Clinical Coordinator after questionnaire is completed)

7. Domain scores

a. Anxiety: ____ ____
00-21

b. Depression: ____ ____
00-21

8. Is the depression domain score *(item 7b)* 11 or greater:

Yes (* 1) No (2)

**Inform the LOTT Study Physician that the questionnaire is suggestive of the presence of clinical depression. With the patient's permission, also inform the patient's healthcare provider and suggest that the patient undergo timely evaluation and appropriate treatment.*

9. Clinical Coordinator
a. PIN: ____ ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

Hospital Anxiety and Depression Scale (HADS)©

(Items 1-10 are reserved for clinic use)

Instructions: Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings, he or she will be able to help you more.

This questionnaire is designed to help your clinician know how you feel. Read each item below and circle the one reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

11. I feel tense or "wound up": **Circle One**

Most of the time 1
A lot of the time 2
From time to time, occasionally 3
Not at all 4

12. I still enjoy the things I used to enjoy:

Definitely as much 1
Not quite so much 2
Only a little 3
Hardly at all 4

13. I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly 1
Yes, but not too badly 2
A little, but it doesn't worry me 3
Not at all 4

14. I can laugh and see the funny side of things:

As much as I always could 1
Not quite so much now 2
Definitely not so much now 3
Not at all 4

15. Worrying thoughts go through my mind: **Circle one**

A great deal of the time 1
A lot of the time 2
Not too often 3
Very little 4

16. I feel cheerful:

Never 1
Not often 2
Sometimes 3
Most of the time 4

17. I can sit at ease and feel relaxed:

Definitely 1
Usually 2
Not often 3
Not at all 4

18. I feel as if I am slowed down:

Nearly all the time 1
Very often 2
Sometimes 3
Not at all 4

19. I get a sort of frightened feeling like “butterflies” in the stomach:

Not at all 1
Occasionally 2
Quite often 3
Very often 4

20. I have lost interest in my appearance: **Circle one**

Definitely 1
I don't take as much care as I should 2
I may not take quite as much care 3
I take just as much care as ever 4

21. I feel restless as if I have to be on the move:

Very much indeed 1
Quite a lot 2
Not very much 3
Not at all 4

22. I look forward with enjoyment to things:

As much as I ever did 1
Rather less than I used to 2
Definitely less than I used to 3
Hardly at all 4

23. I get sudden feelings of panic:

Very often indeed 1
Quite often 2
Not very often 3
Not at all 4

24. I can enjoy a good book or radio or television programme:

Often 1
Sometimes 2
Not often 3
Very seldom 4

Now check that you have answered all the questions.

Thank you!

This edition first published in 1994 by Nelson Publishing Company Ltd, 414 Chiswick High Road, London W4 5TF
GL Assessment is part of the Granada Group.

LOTT

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Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Scoring sheet directions: Circle the scoring weight for the patient's response to each item and then sum the weighted scores. For example, for question #11, if the respondent marked 1, then the weight would be 3.

	Anxiety domain questionnaire response					**Depression domain questionnaire response**			
	1	**2**	**3**	**4**		**1**	**2**	**3**	**4**
11.	3	2	1	0	**12.**	0	1	2	3
13.	3	2	1	0	**14.**	0	1	2	3
15.	3	2	1	0	**16.**	3	2	1	0
17.	0	1	2	3	**18.**	3	2	1	0
19.	0	1	2	3	**20.**	3	2	1	0
21.	3	2	1	0	**22.**	0	1	2	3
23.	3	2	1	0	**24.**	0	1	2	3

Anxiety sum
(record in item 7a):

____ ____

Depression sum
(record in item 7b):

____ ____

Red flag: A total depression domain score of 11 or greater is suggestive of clinical depression. With permission from the patient with a total depression domain score of 11 or greater, the LOTT staff will: (1) inform the patient's healthcare provider that the questionnaire is suggestive of the presence of clinical depression and (2) suggest that the patient undergo timely evaluation and appropriate treatment.

hb3 - Form HB3 Baseline History

Date file created: 21 Apr 2017
Observations: 738
Variables: 172

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
hb307	7 First degree relatives have COPD	Char	1
hb308	8 First degree relatives have emphysema	Char	1
hb309	9 First degree relatives have chronic bronchitis	Char	1
hb310	10 First degree relatives have asthma	Char	1
hb311	11 First degree relatives have other lung disease	Char	1
hb312	12 Usually have a cough	Char	1
hb313	13 Usually bring up phlegm	Char	1
hb314	14 Bring up phlegm most days for 3 months	Char	1
hb315	15 Bring up 2 tablespoons of phlegm most days	Char	1
hb316	16 Years with cough or phlegm	Char	1
hb317	17 Awakened from sleep by shortness of breath	Char	1
hb318	18 Often wheeze or have whistling in chest	Char	1
hb319	19 Days of work missed due to respiratory illness	Char	1
hb320	20 Frequency of nosebleeds or bloody nasal discharge	Char	1
hb321	21 Frequency of very dry nose	Char	1
hb322	22 Frequency of runny nose	Char	1
hb323	23 Usual weight in past few years (lb)	Char	3
hb324	24 How has weight changed over past year	Char	1
hb325	25 Amount of weight lost in past year (lb)	Char	3
hb326	26 Cigarette smoking	Char	1
hb327	27 Number of cigarettes smoked per day	Char	3
hb328	28 Ever smoked 100 cigars or pipes	Char	1
hb329	29 Currently smoke cigars or pipes	Char	1
hb330	30 Age stopped smoking cigars or pipes	Char	2
hb331	31 Average number cigars or pipes smoked per day	Char	1
hb332	32 Number of years smoked cigars or pipes	Char	2
hb333	33 Anyone else in household smoke	Char	1
hb334	34 Hours per day home with smoker	Char	2
hb335	35 Hours per week outside home with smoker	Char	3
hb336	36 Drinking frequency in past year	Char	1
hb337	37 Number of drinks on a typical day	Char	1
hb339	39 Physician said you have diabetes	Char	1
hb341	41 Physician said you have cancer	Char	1
hb344	44 Physician said you have sleep apnea	Char	1
hb345	45 Received nasal surgery for sleep apnea	Char	1
hb347	47 Frequency of positive pressure device use	Char	1
hb348	48 Hours per night use positive pressure device	Char	1
hb349	49 Received other treatment for sleep apnea	Char	1
hb350	50 Ever had any chest operation	Char	1
hb351	51 Ever had lung volume reduction surgery	Char	1
hb353	53 Ever had surgery for lung cancer	Char	1
hb355	55 Ever had coronary artery bypass surgery	Char	1
hb357	57 Ever had other chest surgery	Char	1
hb359	59 Ever attended pulmonary rehab program	Char	1
hb361	61 Current meds for respiratory illness	Char	1
hb366	66 Daily oral or intramuscular corticosteroid	Char	1
hb367	67 COPD exacerbations in past 3 mos	Char	1

hb3 - Form HB3 Baseline History

Date file created: 21 Apr 2017
Observations: 738
Variables: 172

Variable Name	Variable Label	Type	Variable Length
hb368	68 Number of COPD exacerbations in past 3 mos	Char	2
hb369	Date most recent exac cnvrtd to #days from RZ	Num	8
hb371	71 Ever prescribed home supplemental O2	Char	1
hb372	72 Months of home supplemental O2	Char	3
hb376	76 Nights in rehab hospital in past 3 months	Char	3
hb377	77 Visits to emergency room in past 3 months	Char	2
hb378	78 Visits to doctor's office in past 3 months	Char	2
hb379	79 Hours of care in past week	Char	3
hb380	80 Overnight hospitalization in past 30 days	Char	1
hb381	81 Less than 30 days since antibiotics for COPD exacerbation	Char	1
hb382	82 Systemic corticosteroids for COPD	Char	1
hb383	83 At least 30days since systemic corticosteroids prescribed	Char	1
hb384	84 Prescribed supplemental O2	Char	1
hb385	85 Pulmonary instability due to procedure in past 6mos	Char	1
hb338a	38a Anemia	Char	1
hb338b	38b Angina	Char	1
hb338c	38c Chronic allergies	Char	1
hb338d	38d Connective tissue disease	Char	1
hb338e	38e Coronary artery disease	Char	1
hb338f	38f Coronary artery revascularization	Char	1
hb338g	38g Dementia	Char	1
hb338h	38h Depression	Char	1
hb338i	38i Epilepsy or other seizure disorder	Char	1
hb338j	38j GERD	Char	1
hb338k	38k Heart failure or congestive heart failure	Char	1
hb338l	38l HIV or AIDS	Char	1
hb338m	38m Hypercholesteremia	Char	1
hb338n	38n Hypertension	Char	1
hb338o	38o Kidney disease	Char	1
hb338p	38p Limitation in the use of an arm or leg	Char	1
hb338q	38q Liver trouble	Char	1
hb338r	38r Myocardial infarction	Char	1
hb338s	38s Nasal polyps	Char	1
hb338t	38t Osteoarthritis	Char	1
hb338u	38u Peripheral vascular disease	Char	1
hb338v	38v Sciatica or chronic back problems	Char	1
hb338w	38w Seasonal allergies	Char	1
hb338x	38x Stomach ulcers or peptic ulcer disease	Char	1
hb338y	38y Stroke or cerebrovascular disease	Char	1
hb338z	38z None of the above	Char	1
hb340a	40a Diabetes caused problems with kidneys	Char	1
hb340b	40b Diabetes caused problems with eyes	Char	1
hb340c	40c None of the above	Char	1
hb342a	42a Lung cancer	Char	1
hb342b	42b Leukemia or polycythemia vera	Char	1
hb342c	42c Lymphoma	Char	1
hb342d	42d Metastasized cancer	Char	1
hb342e	42e Other cancer	Char	1
hb343a	43a Alpha-1 antitrypsin deficiency	Char	1

hb3 - Form HB3 Baseline History

Date file created: 21 Apr 2017
Observations: 738
Variables: 172

Variable Name	Variable Label	Type	Variable Length
hb343b	43b Asbestos pleural plaques	Char	1
hb343c	43c Asbestosis	Char	1
hb343d	43d Asthma	Char	1
hb343e	43e Bronchiectasis	Char	1
hb343f	43f Chronic bronchitis	Char	1
hb343g	43g COPD	Char	1
hb343h	43h Diaphragmatic weakness	Char	1
hb343i	43i Emphysema	Char	1
hb343j	43j Neuromuscular weakness	Char	1
hb343k	43k Pneumonia	Char	1
hb343l	43l Pneumothorax	Char	1
hb343m	43m Pulmonary fibrosis	Char	1
hb343n	43n Pulmonary nodules	Char	1
hb343o	43o Tuberculosis	Char	1
hb343p	43p Other lung disease	Char	1
hb343q	43q None of the above	Char	1
hb346a	46a Currently prescribed positive pressure device	Char	1
hb346b	46b Use supplemental O2 with CPAP	Char	1
hb362a	62a Comb long-act bronchodilator/corticosteroid	Char	1
hb362b	62b Long-acting sympathomimetics	Char	1
hb362c	62c Inhaled corticosteroid	Char	1
hb362d	62d Short-acting sympathomimetics	Char	1
hb362e	62e Short-acting anticholinergics	Char	1
hb362f	62f Short-acting combo sympathomimetric/anticholinergic	Char	1
hb362g	62g Long-acting anticholinergics	Char	1
hb362h	62h Theophylline	Char	1
hb362i	62i Leukotriene modifiers	Char	1
hb362j	62j Oral or intramuscular corticosteroid	Char	1
hb362k	62k A1AT replacement	Char	1
hb362l	62l Other medication	Char	1
hb363a	63a ACE-1	Char	1
hb363b	63b Anti-platelet, not ASA	Char	1
hb363c	63c ARA/AII-antagonist	Char	1
hb363d	63d Aspirin	Char	1
hb363e	63e Beta-blocker	Char	1
hb363f	63f Calcium channel blocker	Char	1
hb363g	63g Digitalis preparation	Char	1
hb363h	63h Diuretic or combined	Char	1
hb363i	63i Statin	Char	1
hb363j	63j Vasodilator	Char	1
hb363k	63k Other cardiovascular medication	Char	1
hb363l	63l No cardiovascular medication	Char	1
hb364a	64a Aspirin	Char	1
hb364b	64b Clopidigel	Char	1
hb364c	64c Dipyridamole	Char	1
hb364d	64d Enoxaparin	Char	1
hb364e	64e Heparin	Char	1
hb364f	64f Lovenox	Char	1
hb364g	64g Ticlodipine	Char	1

hb3 - Form HB3 Baseline History

Date file created: 21 Apr 2017
Observations: 738
Variables: 172

Variable Name	Variable Label	Type	Variable Length
hb364h	64h Warfarin	Char	1
hb364i	64i Other anticoagulants	Char	1
hb364j	64j No anticoagulants	Char	1
hb365a	65a Insulin	Char	1
hb365b	65b Oral medications	Char	1
hb365c	65c Other diabetes medication	Char	1
hb365d	65d No diabetes medication	Char	1
hb370a	70a Antibiotics	Char	1
hb370b	70b Systemic corticosteroid - pill or shot	Char	1
hb370c	70c ER visit w/o hospitalization	Char	1
hb370d	70d Acute care hospitalization overnight	Char	1
hb370e	70e ICU stay	Char	1
hb370f	70f Invasive mechanical ventilation	Char	1
hb370g	70g Other treatment for COPD	Char	1
hb370h	70h None	Char	1
hb374a	74a O2 used on exertion	Char	1
hb374b	74b O2 used at rest	Char	1
hb374c	74c O2 used during sleep	Char	1
hb375a	75a Spent night in acute care hospital in past year	Char	1
hb375b	75b Hospitalized for COPD in past year	Char	1
hb375c	75c Times in acute care hospital in past year	Char	2
hb375d	75d Nights in acute care hospital in past 3mos	Char	2
hb375e	Date most recent hosp disch cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

HB - Baseline History

Purpose: To collect baseline history information from the patient.

Data collection level: All patients (Core).

When: Visit sb.

Administered by: Clinical Coordinator (reviewed by Study Physician).

Instructions: : Clinical Coordinator should interview the patient. The detailed history elicited in this form may result in determining that the patient meets one of these exclusion criteria:

- Less than 30 days post treatment for an acute exacerbation of COPD (fewer than 30 days since last dose of antibiotics or since a new or increased dose of systemic corticosteroids was initiated)
- Less that 30 days post discharge from an acute care hospital after acute care hospitalization for any condition
- Thoracotomy, sternotomy, major cardiopulmonary intervention (lung resection, open heart surgery, etc) or other procedure in the past 6 months

If an C condition is checked, review the patient's information with the Study Physician to make sure any ineligibility is resolved prior to randomization.

If an Elig condition is checked, the patient is ineligible for LOTT. If the patient is ineligible, complete the administrative information (section M) and file the partially completed form in the file for ineligible patients. Do not key forms for ineligible patients.

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date patient completed the form):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code s b ____

6. Form & revision: h b 3

B. Family history

7. Do any of your first degree relatives (parent, brother, sister, child) have COPD *(check only one):*

Yes (1)
No (2)
Don't know (3)

8. Do any of your first degree relatives (parent, brother, sister, child) have emphysema *(check only one):*

Yes (1)
No (2)
Don't know (3)

9. Do any of your first degree relatives (parent, brother, sister, child) have chronic bronchitis *(check only one):*

Yes (1)
No (2)
Don't know (3)

10. Do any of your first degree relatives (parent, brother, sister, child) have asthma *(check only one):*

Yes (1)
No (2)
Don't know (3)

11. Do any of your first degree relatives (parent, brother, sister, child) have a lung disease other than COPD, emphysema, chronic bronchitis, or asthma *(check only one):*

Yes *(specify):* (1)

_____
specify lung disease

No (2)
Don't know (3)

C. Symptoms

12. Do you usually have a cough *(exclude clearing of throat):*

(Yes 1) (No 2)

→ **17.**

13. Do you usually bring up phlegm (also known as sputum or mucus) from your chest:

(Yes 1) (No 2)

→ **16.**

14. Do you bring up phlegm like this on most days, for 3 or more months in a row during the year:

(Yes 1) (No 2)

15. Do you bring up at least two tablespoonfuls of phlegm on most days:

(Yes 1) (No 2)

16. For how many years have you had trouble with cough or phlegm *(check only one):*

- Less than 2 years (1)
- 2 or more years (2)

17. Are you ever awakened from sleep by shortness of breath or a feeling of tightness in your chest:

(Yes 1) (No 2)

18. Do you often wheeze or have whistling in the chest:

(Yes 1) (No 2)

19. In the past 3 months, about how many days of work or school did you miss because of respiratory illnesses or symptoms *(check only one)*:

- Not applicable *(do not work or go to school)* (0)
- None (1)
- 1-5 days (2)
- 6-15 days (3)
- 16 or more days (4)

20. On average in the past 3 months, how often have you had a nosebleed or bloody nasal discharge *(check only one):*

- Never or rarely (1)
- About once a month (2)
- About once a week (3)
- Most days (4)

21. On average in the past 3 months, how often have you had a feeling of a very dry nose *(check only one):*

- Never or rarely (1)
- About once a month (2)
- About once a week (3)
- Most days (4)

22. On average in the past 3 months, how often have you had a runny nose *(check only one):*

- Never or rarely (1)
- About once a month (2)
- About once a week (3)
- Most days (4)

D. Weight loss

23. What has your usual weight been in the past few years:

___ ___ ___ pounds

24. Overall, how has your weight changed over the past year *(check only one):*

- Increased (1) → **26.**
- Stayed about the same (2) → **26.**
- Decreased (3)

25. How much weight have you lost in the past year:

___ ___ ___ pounds

E. Smoking and alcohol use

26. How many tobacco cigarettes do you currently smoke per day *(check only one):*

- Not currently smoking (0) → **28.**
- Less than 1 a day (1) → **28.**
- 1 or more a day (2)

27. Specify number of cigarettes that you currently smoke per day *(there are 20 cigarettes in a standard U.S. pack of cigarettes):*

___ ___ ___

28. Have you smoked at least 100 tobacco cigars, cigarillos or pipes in your lifetime?

Yes (1) No (2)

33.

29. Do you now smoke cigars, cigarillos or pipes:

Yes (1) No (2)

31.

30. How old were you when you completely stopped smoking cigars, cigarillos, or pipes:

___ ___
years old

31. When smoking, what is the average number of cigars, cigarillos, or pipe bowls you smoke in a day *(answer for when you smoked if you don't smoke now and answer for current smoking if you currently smoke) (check only one):*

Less than 1 daily	(1)
1-2 daily	(2)
3-4 daily	(3)
5-7 daily	(4)
8 or more daily	(5)

32. How many years total have you smoked cigars, cigarillos, or pipes *(add up all the years that you smoked cigars, cigarillos, or pipes):*

___ ___
years

33. Not including yourself, does anyone smoke tobacco cigarettes, cigars, cigarillos, or pipes in your home regularly while you are there *(e.g., someone else living there or someone who visits regularly):*

Yes (1) No (2)

35.

34. On average, about how many hours per day are you at home while someone other than yourself is smoking *(enter 00 if no one smokes while your are home; enter 01 if someone smokes 1 or less than 1 hour per day):*

___ ___
hours/day

35. On average, about how many hours per week do you spend in a place outside of your home where people are smoking *(don't count your own smoking or smoking in your home; enter 000 if none; enter 001 if 1 or less than 1 hour):*

___ ___ ___
hours/week

36. How often did you have a drink containing alcohol in the past year *(consider a drink to be a can or bottle of beer, a glass of wine, a wine cooler, or one cocktail or a shot of hard liquor [e.g., scotch, gin, or vodka]) (check only one):*

Never	(0)
	38.
Monthly or less	(1)
2 to 4 times a month	(2)
2 to 3 times a week	(3)
4 to 5 times a week	(4)
6 or more times a week	(5)

37. How many drinks did you have on a typical day when you were drinking in the past year *(check only one):*

1 to 2 drinks	(1)
3 to 4 drinks	(2)
5 to 6 drinks	(3)
7 to 9 drinks	(4)
10 or more drinks	(5)

F. Medical conditions

38. Has a physician ever said you have or had *(check all that apply)*

- **a.** Anemia: (1)
- **b.** Angina: (1)
- **c.** Chronic allergies or sinus trouble: (1)
- **d.** Connective tissue disease (e.g., rheumatoid arthritis, lupus, or polymalgia rheumatica): (1)
- **e.** Coronary artery disease: (1)
- **f.** Coronary artery revascularization (coronary angioplasty, coronary stent): (1)
- **g.** Dementia (Alzheimer's disease or other type): (1)
- **h.** Depression: (1)
- **i.** Epilepsy or other seizure disorder: (1)
- **j.** GERD (gastroesophageal reflux; persistent heartburn): (1)
- **k.** Heart failure or congestive heart failure (fluid in lungs and heart doesn't pump well): (1)
- **l.** HIV or AIDS: (1)
- **m.** Hypercholesteremia (high blood cholesterol): (1)
- **n.** Hypertension (high blood pressure): (1)
- **o.** Kidney disease (including kidney stones or infections): (1)
- **p.** Limitation in the use of an arm or leg (missing, paralyzed, weakness): (1)
- **q.** Liver trouble (gallstones, cirrhosis, yellow jaundice or hepatitis): (1)
- **r.** Myocardial infarction (heart attack): (1)
- **s.** Nasal polyps (polyps in the nose): (1)
- **t.** Osteoarthritis: (1)
- **u.** Peripheral vascular disease: (1)
- **v.** Sciatica or chronic back problems: (1)
- **w.** Seasonal allergies (such as hayfever): (1)
- **x.** Stomach ulcers or peptic ulcer disease: (1)
- **y.** Stroke or cerebrovascular disease (blood clot or bleeding in the brain, transient ischemic attack [TIA]): (1)
- **z.** None of the above: (1)

39. Has a physician ever said you have or had diabetes:

Yes (1) No (2)

41.

40. Did the diabetes cause *(check all that apply)*

- **a.** Problems with your kidneys: (1)
- **b.** Problems with your eyes that were treated by an ophthalmologist: (1)
- **c.** None of the above: (1)

41. Has a physician ever said you have or had cancer *(other than basal or squamous cell skin cancer):*

Yes (1) No (2)

43.

42. What type of cancer did a physician say you have or had *(check all that apply)*

- **a.** Lung cancer: (1)
- **b.** Leukemia or polycythemia vera: (1)
- **c.** Lymphoma: (1)
- **d.** Metastasized cancer (cancer that has spread to other parts of your body): (1)
- **e.** Other *(specify):* (1)

_____
specify

43. Has a physician ever said you have or had *(check all that apply)*

a. Alpha-1 antitrypsin deficiency: (1)
b. Asbestos pleural plaques: (1)
c. Asbestosis: (1)
d. Asthma: (1)
e. Bronchiectasis: (1)
f. Chronic bronchitis: (1)
g. Chronic obstructive pulmonary disease (COPD): (1)
h. Diaphragmatic weakness: (1)
i. Emphysema: (1)
j. Neuromuscular weakness: (1)
k. Pneumonia: (1)
l. Pneumothorax (collapsed lung): (1)
m. Pulmonary fibrosis: (1)
n. Pulmonary nodules: (1)
o. Tuberculosis: (1)
p. Other lung disease *(specify):* (1)

_____
specify

q. None of the above: (1)

44. Has a physician ever said you have sleep apnea:

Yes (1) No (2)
50.

45. Have you received nasal surgery for sleep apnea:

Yes (1) No (2)

46. Use of positive pressure devices

a. Are you currently prescribed a positive pressure device for use during sleep (e.g., CPAP):

Yes (1) No (2)
49.

b. Do you use supplemental oxygen with your positive pressure device:

Yes (* 1)
C

** Patient and physician must agree to stop the oxygen if the patient is randomized to no oxygen group.*

No (2)

47. How frequently do you use your positive pressure device *(check only one):*

Don't use it (1)
49.
1-4 nights per week (2)
5-7 nights per week (3)

48. When you use your device, about how many hours per night do you use it *(check only one):*

1-4 hours per night (1)
5 or more hours per night (2)

49. Have you received other treatment for sleep apnea:

Yes *(specify):* (1)

_____
specify

No (2)

G. Thoracic surgery and pulmonary rehabilitation history

50. Have you ever had any operations on your chest *(chest surgery; a doctor made an incision into your chest):*

Yes (1) No (2)
59.

51. Have you ever had lung volume reduction surgery (LVRS) or bullectomy:

Yes (1) No (2)
53.

52. In what year did you have the LVRS or bullectomy *(most recent surgery if more than one):*

____ ____ ____ ____
year

53. Have you ever had chest surgery for lung cancer or suspected cancer/nodule:

Yes (1) No (2)
55.

54. In what year did you have the chest surgery for lung cancer or suspected cancer/nodule *(most recent surgery if more than one):*

____ ____ ____ ____
year

55. Have you ever had coronary artery bypass surgery:

Yes (1) No (2)

57.

56. In what year did you have the coronary artery bypass surgery *(most recent surgery if more than one):*

____ ____ ____ ____
year

57. Have you ever had any chest surgery not already mentioned *(eg, median sternotomy, thoracotomy, VATS, endobronchial valve, etc):*

Yes *(specify):* (1)

_____
specify

No (2)

59.

58. In what year did you have this chest surgery *(most recent surgery if more than one):*

____ ____ ____ ____
year

59. Have you ever attended a pulmonary rehabilitation program supervised by a healthcare provider *(not a health club program or a home program):*

Yes (1) No (2)

61.

60. Month and year most recent pulmonary rehabilitation program began *(alpha month and 4 digit year):*

____ ____ ____ - ____ ____ ____ ____
month year

H. Current medications

61. Are you currently prescribed any medications for your respiratory illness:

Yes (1) No (2)

63.

62. What types of medications are you currently prescribed for your respiratory illness *(check all that apply)*

a. Combination long-acting bronchodilator and inhaled corticosteroid in one inhaler (eg, Advair, Symbicort): (1)

b. Long-acting sympathomimetics not combined with another medication (eg, Serevent, Foradil): (1)

c. Inhaled corticosteroid not combined with another medication (eg, Flovent, Vanceril, Asthmacort, Aerobid, Asthmanex, Pulmicort): (1)

d. Short-acting sympathomimetics (beta-agonists such as Ventolin, Proventil, albuterol): (1)

e. Short-acting anticholinergics (such as Atrovent, ipratropium bromide): (1)

f. Short-acting sympathomimetic and short-acting anticholinergic in one inhaler (e.g., Combivent): (1)

g. Long-acting anticholinergics (such as tiotropium; Spiriva): (1)

h. Theophylline: (1)

i. Leukotriene modifiers (such as Singulair, Accolade, Zyflo): (1)

j. Oral or intramuscular corticosteroid: (1)

k. Alpha-1 antitrypsin replacement: (1)

l. Other *(specify):* (1)

_____
specify

63. Are you currently prescribed any cardiovascular medications *(check all that apply)*

a. ACE-I: (1)
b. Anti-platelet (other than ASA): (1)
c. ARA/AII-antagonist: (1)
d. Aspirin: (1)
e. Beta-blocker: (1)
f. Calcium channel blocker (CCB): (1)
g. Digitalis preparation: (1)
h. Diuretic or combined (Maxzide): (1)
i. Statin: (1)
j. Vasodilator: (1)
k. Other *(specify):* (1)

_____
specify

l. None: (1)

64. Are you currently prescribed any anticoagulant or antiplatelet medications *(check all that apply)*

a. Aspirin: (1)
b. Clopidigel (Plavix): (1)
c. Dipyridamole (Persantive): (1)
d. Enoxaparin: (1)
e. Heparin: (1)
f. Lovenox: (1)
g. Ticlodipine (Ticlid): (1)
h. Warfarin (Coumadin): (1)
i. Other *(specify):* (1)

_____
specify

j. None: (1)

65. Are you currently prescribed any diabetes medications *(check all that apply)*

a. Insulin: (1)
b. Oral medications (e.g., metformin, pioglitazone): (1)
c. Other type *(specify)*: (1)

_____
specify

d. None: (1)

66. For most of the past 3 months have you used oral (by mouth) or intravenous or intramuscular corticosteroid medication (such as prednisone) daily or every other day:

Yes (1) No (2)

I. COPD exacerbation history

67. In the past 3 months, have you had any COPD exacerbations *(flare, attack of your breathing problems; if patient is uncertain or unclear, use any records available):*

Yes (1) No (2)

71. ⌊

68. In the past 3 months, how many COPD exacerbations have you had:

____ ____
# of exacerbations

69. Date most recent COPD exacerbation ended:

____ ____ – ____ ____ ____ – ____ ____
day mon year

70. In the past 3 months, what kind of treatment did you receive for the COPD exacerbation(s) *(check all that apply)*

a. Antibiotics: (1)
b. Systemic corticosteroid (as a pill or shot): (1)
c. Emergency/urgent care visit without hospitalization: (1)
d. Acute care hospitalization overnight: (1)
e. Intensive Care Unit (ICU) stay: (1)
f. Invasive mechanical ventilation (breathing tube in your throat or windpipe): (1)
g. Other *(specify):* (1)

_____
specify

h. None: (1)

J. Supplemental oxygen history

71. Have you ever been prescribed supplemental oxygen at your residence:

Yes (1) No (2)

75. ⌊

72. What was the longest period of time that you were prescribed oxygen at your residence:

___ ___ ___
months

73. Month and year when you were last prescribed oxygen at your residence *(alpha month and 4 digit year):*

___ ___ ___ - ___ ___ ___ ___
month year

74. For the most recent time you were prescribed oxygen, were you prescribed oxygen for use

	Yes	No
a. On exertion:	(1)	(2)
b. At rest:	(1)	(2)
c. During sleep:	(1)	(2)

K. General health care utilization

75. Acute care hospitalization

a. In the past year, have you stayed overnight in an acute care hospital or other acute care facility for any reason:

Yes (1) No (2)
76.

b. In the past year, were you hospitalized over night because of your COPD:

Yes (1) No (2)

c. In the past year, how many times were you hospitalized overnight in an acute care hospital or other acute care facility for any reason:
(enter 00 if none):

___ ___
# of times

d. In the past 3 months, how many nights have you stayed overnight in an acute care hospital or other acute care facility for any reason
(enter 00 if none):

___ ___
# of nights

e. Date of most recent acute care hospital discharge:

___ ___–___ ___ ___–___ ___
day mon year

f. Reason for most recent acute care hospitalization:

_____

_____

_____

76. In the past 3 months, how many nights have you stayed overnight in a rehabilitation hospital or nursing home for any reason
(enter 000 if none):

___ ___ ___
# of nights

77. In the past 3 months, how many times have you visited an emergency, triage, or urgent care departement for any reason
(enter 00 if none):

___ ___
# of times

78. In the past 3 months, how many times have you visited a physician, physician's assistant or nurse in their office or have you visited an outpatient clinic for any reason *(exclude hospital stays, visits to acute care facilities, emergency triage or urgent care department visits; enter 00 if none)*:

___ ___
# of times

79. About how many hours in the past week have family members or friends spent in helping you with your care *(enter 000 if none):*

___ ___ ___
hours

L. Review for eligibility

80. Was the patient hospitalized overnight in a acute care hospital for any reason in the past 30 days:

Yes (1) No (2)
Elig

81. Have less than 30 days elapsed since the patient last took antibiotics for a COPD exacerbation:

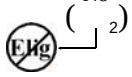
Yes (1) No (2)
Elig

82. Does the patient take systemic corticosteroids for COPD:

Yes (1) No (2)
84.

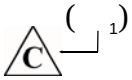
83. Have at least 30 days elasped since the patient's prescription for systemic corticosteroids was initiated or last increased:

( ) Yes ( ) No



84. Is the patient prescribed supplemental (home) oxygen currently (stationary system and/or portable system) for any reason:

Yes ( ) 1

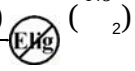


** Caution (patient and prescribing physician must agree to stop the oxygen if the patient is assigned to no oxygen and patient must not use the oxygen for at least the 4 days preceding randomization.*

No ( ) 2

85. Does the patient report having any procedure in the past 6 months that is likely to cause instability of pulmonary status *(eg, thoracotomy, sternotomy, major cardio-pulmonary intervention such as lung resection, open heart surgery, etc):*

( ) Yes ( ) No



M. Administrative information

86. Study Physician PIN: ____ ____ ____ ____

87. Study Physician signature:

_____

88. Clinical Coordinator PIN: ____ ____ ____ ____

89. Clinical Coordinator signature:

_____

90. Date form reviewed:

____ ____–____ ____ ____–____ ____

day mon year

hi2 - Form HI2 Interim History at Annual Visit

Date file created: 21 Apr 2017
Observations: 1971
Variables: 139

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
hi207	7 Describe current residence	Char	1
hi208	8 Describe current living arrangement	Char	1
hi210	10 Describe degree of breathlessness	Char	1
hi211	11 Usually had a cough in past 3 months	Char	1
hi212	12 Usually bring up phlegm in past 3 months	Char	1
hi213	13 Awakened from sleep by shortness of breath	Char	1
hi214	14 Wheezing or whistling in the chest	Char	1
hi215	15 Days of work missed due to respiratory illness	Char	1
hi216	16 Frequency of nosebleed/bloody nasal discharge	Char	1
hi217	17 Frequency of very dry nose	Char	1
hi218	18 Frequency of runny nose	Char	1
hi219	19 Currently smoke cigarettes	Char	1
hi220	20 Number of cigarettes smoke per day	Char	2
hi221	21 Tried to quit smoking cigarettes	Char	1
hi222	22 Currently smoke cigars or pipes	Char	1
hi223	23 Tried to quit smoking cigars or pipes	Char	1
hi224	24 Anyone in household smoke	Char	1
hi225	25 Hours per day home with smoker	Char	2
hi226	26 Hours per week outside home with smoker	Char	3
hi227	27 Drinking frequency in past year	Char	1
hi228	28 Number of drinks on a typical day	Char	1
hi229	Date last HI cmpltd cnvrtd to #days from RZ	Num	8
hi232	32 Received LVRS since last HI form	Char	1
hi234	34 Attended pulmonary rehab program	Char	1
hi235	35 Number of days attended pulmonary rehab	Char	3
hi236	36 Still attending program	Char	1
hi237	37 Currently prescribed positive pressure device	Char	1
hi238	38 Use of positive pressure device	Char	1
hi239	39 Hours per night use device	Char	1
hi240	40 Prescribed medications for respiratory illness	Char	1
hi245	45 Daily oral or intramuscular corticosteroids	Char	1
hi246	Date last HI/HT cmpltd cnvrtd to #days from RZ	Num	8
hi247	47 Had a COPD exacerbation	Char	1
hi248	48 Number of COPD exacerbations	Char	1
hi249	49 Randomized to no supplemental oxygen	Char	1
hi250	50 Used supplemental oxygen	Char	1
hi251	Date strtd O2 cnvrtd to #days from RZ	Num	8
hi252	Date last used O2 cnvrtd to #days from RZ	Num	8
hi253	53 Used oxygen during rest	Char	1
hi254	54 Used oxygen during exercise	Char	1
hi255	55 Used oxygen during sleep	Char	1
hi256	56 Hours per day oxygen used	Char	1
hi257	57 Randomized to supplemental oxygen	Char	1
hi258	58 Outside physician prescribed oxygen	Char	1
hi259	59 Hours per day stationary system used	Char	1
hi260	60 Hours per day ambulatory system used	Char	1
hi261	61 Received new oxygen equipment	Char	1

hi2 - Form HI2 Interim History at Annual Visit

Date file created: 21 Apr 2017
Observations: 1971
Variables: 139

Variable Name	Variable Label	Type	Variable Length
hi262	62 Any fires related to oxygen use	Char	1
hi263	Date of fire cnvrtd to #days from RZ	Num	8
hi266	66 Burns from frost on liquid oxygen system	Char	1
hi267	Date of burn cnvrtd to #days from RZ	Num	8
hi270	70 Injured from tripping on oxygen equipment	Char	1
hi271	Date of injury cnvrtd to #days from RZ	Num	8
hi274	74 Any serious health problem	Char	1
hi275	75 Hospitalized overnight for any reason	Char	1
hi276	76 Times hospitalized overnight for any reason	Char	1
hi278	78 Number of nights in hospital in past 3mos	Char	3
hi279	79 Number of emergency room visits in past 3mos	Char	2
hi280	80 Number of doctor visits in past 3mos	Char	2
hi281	81 Number of hours helped by family/friends	Char	3
hi282	82 Next annual visit scheduled	Char	1
hi230a	30a Anemia	Char	1
hi230b	30b Cancer	Char	1
hi230c	30c Coronary artery disease	Char	1
hi230d	30d Heart failure or congestive heart failure	Char	1
hi230e	30e Hypertension	Char	1
hi230f	30f Lung disease	Char	1
hi230g	30g Myocarial infarction	Char	1
hi230h	30h Stroke or cerebrovasular disease	Char	1
hi230i	30i None of the above	Char	1
hi231a	31a Asthma	Char	1
hi231b	31b Diaphragmatic weakness	Char	1
hi231c	31c Lung cancer	Char	1
hi231d	31d Neuromuscular weakness	Char	1
hi231e	31e Pneumonia	Char	1
hi231f	31f Pulmonary fibrosis	Char	1
hi231g	31g Pulmonary hypertension	Char	1
hi231h	31h Pulmonary nodules	Char	1
hi231i	31i Sleep apnea	Char	1
hi231j	31j Tuberculosis	Char	1
hi231k	31k Other lung disease	Char	1
hi231l	31l None of the above	Char	1
hi241a	41a Long-acting bronchodilator and corticosteroid	Char	1
hi241b	41b Long-acting sympathomimetic	Char	1
hi241c	41c Inhaled corticosteroid not combined	Char	1
hi241d	41d Short-acting sympathomimetic	Char	1
hi241e	41e Short-acting anticholinergic	Char	1
hi241f	41f Short-acting sympathomimetic/anticholinergic	Char	1
hi241g	41g Long-acting anticholinergic	Char	1
hi241h	41h Theophylline	Char	1
hi241i	41i Leukotriene modifier	Char	1
hi241j	41j Oral or intramuscular corticosteroid	Char	1
hi241k	41k Alpha-1 antitrypsin replacement	Char	1
hi241l	41l Other	Char	1
hi242a	42a ACE-I	Char	1
hi242b	42b Anti-platelet	Char	1

hi2 - Form HI2 Interim History at Annual Visit

Date file created: 21 Apr 2017
Observations: 1971
Variables: 139

Variable Name	Variable Label	Type	Variable Length
hi242c	42c ARA/AII-antagonist	Char	1
hi242d	42d Aspirin	Char	1
hi242e	42e Beta-blocker	Char	1
hi242f	42f Calcium channel blocker	Char	1
hi242g	42g Digitalis preparation	Char	1
hi242h	42h Diuretic alone or combined	Char	1
hi242i	42i Statin	Char	1
hi242j	42j Vasodilator	Char	1
hi242k	42k Other	Char	1
hi242l	42l None of the above	Char	1
hi243a	43a Aspirin	Char	1
hi243b	43b Clopidigel	Char	1
hi243c	43c Dipyridamole	Char	1
hi243d	43d Enoxaparin	Char	1
hi243e	43e Heparin	Char	1
hi243f	43f Lovenox	Char	1
hi243g	43g Ticlodipine	Char	1
hi243h	43h Warfarin	Char	1
hi243i	43i Other	Char	1
hi243j	43j None	Char	1
hi244a	44a Insulin	Char	1
hi244b	44b Oral medications	Char	1
hi244c	44c Other	Char	1
hi244d	44d None of the above	Char	1
hi264a	64a Patient had minor injuries	Char	1
hi264b	64b Family member had minor injuries	Char	1
hi264c	64c Patient had major injuries	Char	1
hi264d	64d Family member had major injuries	Char	1
hi264e	64e Property damage	Char	1
hi264f	64f None of these	Char	1
hi268a	68a Patient burned	Char	1
hi268b	68b Family member burned	Char	1
hi268c	68c Other person burned	Char	1
hi272a	72a Patient injured	Char	1
hi272b	72b Family member injured	Char	1
hi272c	72c Other person injured	Char	1
hi277a	Date 1st admit cnvrtd to #days from RZ	Num	8
hi277b	Date 2nd admit cnvrtd to #days from RZ	Num	8
hi277c	Date 3rd admit cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

HI - Interim History at Annual Visit

Purpose: To collect interim history information from the patient at annual followup visits.
Data collection level: Core.
When: Visit f12, f24, f36, f48, f60, and f72.
Administered by: Clinical Coordinator.
Respondent: Patient, with help from spouse or family.
Instructions: This form uses Flash Card #8. Coordinator should complete item 29, date of most recently completed Interim History at Annual Visit (HI) form, and item 46, date of most recently completed Interim History at 4-Month Telephone Visit (HT) or Interim History at Annual Visit (HI) form before interviewing patient. **Patients randomized to supplemental oxygen:** you should have the patient's equipment listing (OF form printout) available for the patient to review and mark with updates to equipment and key any updates after the visit. **All patients:** Be sure that every newly reported overnight acute care hospitalization is documented on an AN, EX or IE form, which ever is appropriate for the event which promped the hospitalization. Complete an EX form for each new report of a COPD exacerbation not previously documented on an EX form. If the patient reports prescription of oxygen by a physician outside of LOTT, and the oxygen use is ongoing, the Study Physician should be informed and the Study Physician should discuss with the patient and his/her private physician whether LOTT treatment (supplemental oxygen or control) may be resumed:

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date patient completed the form):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code f ____ ____

6. Form & revision: h i 2

B. Current residence

7. What best describes your current residence *(check only one)*:

Private home, apartment, condominium, mobile home (1)
Retirement home (2) **9.**
Assisted living facility (3) **9.**
Nursing home (4) **9.**
Rehabilitation facility (5) **9.**
Other *(specify):* (6) **9.**

_____
specify

8. What best describes your current living arrangement *(check only one)*:

Live alone (1)
Live with at least one other person (2)

9. Zip code of current residence:

____ ____ ____ ____ ____

C. MMRC dyspnea score

10. Which category best describes your degree of breathlessness *(show the patient LOTT Flash Card #8 and ask the patient which rating best describes his/her breathlessness; check only one):*

- Not troubled by breathlessness except during strenuous exercise (0)
- Troubled by shortness of breath when hurrying on the level or when walking up a slight hill (1)
- Walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level (2)
- Stops for breath after walking about 100 yards or after a few minutes of walking on the level (3)
- Too breathless to leave house or breathless when dressing or undressing (4)

D. Symptoms

11. In the last 3 months, have you usually had a cough *(exclude clearing of throat):*

(1) Yes (2) No

12. In the last 3 months, did you usually bring up phlegm (also known as sputum or mucus) from your chest:

(1) Yes (2) No

13. In the last 3 months, have you been awakened from sleep by shortness of breath or a feeling of tightness in your chest:

(1) Yes (2) No

14. In the last 3 months, have you often had wheezing or whistling in the chest:

(1) Yes (2) No

15. In the past 3 months, about how many days of work or school did you miss because of respiratory illnesses or symptoms *(check only one)*:

- Not applicable *(do not work or go to school)* (0)
- None (1)
- 1-5 days (2)
- 6-15 days (3)
- 16 or more days (4)

16. On average in the past 3 months, how often have you had a nosebleed or bloody nasal discharge *(check only one):*

- Never or rarely (1)
- About once a month (2)
- About once a week (3)
- Most days (4)

17. On average in the past 3 months, how often have you had a feeling of a very dry nose *(check only one):*

- Never or rarely (1)
- About once a month (2)
- About once a week (3)
- Most days (4)

18. On average in the past 3 months, how often have you had a runny nose *(check only one):*

- Never or rarely (1)
- About once a month (2)
- About once a week (3)
- Most days (4)

E. Smoking and alcohol use

19. Do you currently smoke tobacco cigarettes:

(* 1) Yes (2) No

22. ___

** Remind patient not to smoke while using oxygen.*

20. How many cigarettes do you currently smoke per day *(enter 01 if 1 or less than 1 per day; there are 20 cigarettes in a standard U.S. pack of cigarettes):*

___ ___ cigarettes/day

21. Have you tried quitting smoking tobacco cigarettes since we last spoke with you:

(Yes 1) (No 2)

22. Do you currently smoke cigars, cigarillos or pipes:

(Yes * 1) (No 2)

→ **24.**

** Remind patient not to smoke while using oxygen.*

23. Have you tried quitting smoking cigars, cigarillos, or pipes since we last spoke with you:

(Yes 1) (No 2)

24. Not including yourself, does anyone smoke tobacco cigarettes, cigars, cigarillos, or pipes in your home regularly while you are there *(e.g., someone else living there or someone who visits regularly):*

(Yes * 1) (No 2)

→ **26.**

** Remind patient not to permit smoking around him/her while using oxygen.*

25. On average, about how many hours per day are you at home while someone other than yourself is smoking there *(enter 01 if someone smokes 1 or less than 1 hour per day):*

____ ____
hours/day

26. On average, about how many hours per week do you spend in a place outside of your home where people are smoking *(don't count your own smoking or smoking in your home; enter 000 if none; enter 001 if 1 or less than 1 hour):*

____ ____ ____
hours/week

27. How often did you have a drink containing alcohol in the past year *(consider a drink to be a can or bottle of beer, a glass of wine, a wine cooler, or one cocktail or a shot of hard liquor [e.g., scotch, gin, or vodka]) (check only one):*

Never	(0)
	→ **29.**
Monthly or less	(1)
2 to 4 times a month	(2)
2 to 3 times a week	(3)
4 to 5 times a week	(4)
6 or more times a week	(5)

28. How many drinks did you have on a typical day when you were drinking in the past year *(check only one):*

1 to 2 drinks	(1)
3 to 4 drinks	(2)
5 to 6 drinks	(3)
7 to 9 drinks	(4)
10 or more drinks	(5)

F. Medical conditions

29. Date of last HI form completed *(date of HB form if this is the first HI completed since randomization):*

____ ____–____ ____ ____–____ ____
day mon year

30. Since the date in item 29, has a physician **newly** diagnosed you with *(check all that apply)*

a. Anemia:	(1)
b. Cancer (other than basal or squamous cell skin cancer, lung cancer, leukemia, or lymphoma):	(1)
c. Coronary artery disease/bypass (coronary angioplasty, coronary stent):	(1)
d. Heart failure or congestive heart failure (fluid in lungs and heart doesn't pump well):	(1)
e. Hypertension (high blood pressure):	(1)
f. Lung disease:	(1)
g. Myocardial infarction (heart attack):	(1)
h. Stroke or cerebrovascular disease (blood clot or bleeding in the brain, transient ischemic attack [TIA]):	(1)
i. None of the above:	(1)

31. Since the date in item 29, has a physician **newly** diagnosed you with any of the following lung diseases *(check all that apply)*

a. Asthma: (1)
b. Diaphragmatic weakness: (1)
c. Lung cancer: (1)
d. Neuromuscular weakness: (1)
e. Pneumonia: (1)
f. Pulmonary fibrosis: (1)
g. Pulmonary hypertension (right heart failure): (1)
h. Pulmonary nodules: (1)
i. Sleep apnea: (1)
j. Tuberculosis: (1)
k. Other lung disease *(specify):* (1)

_____
specify

l. None of the above: (1)

32. Since the date in item 29, have you received lung volume reduction surgery (LVRS):

Yes (1) No (2)
34.

33. Month and year of LVRS *(alpha month and 4 digit year):*

____ ____ ____ - ____ ____ ____ ____
month year

34. Since the date in item 29, have you attended a pulmonary rehabilitation program supervised by a health care provider *(not a health club program or home program):*

Yes (1) No (2)
37.

35. Since the date in item 29, how many days did you attend a pulmonary rehabilitation program:

____ ____ ____
# of days

36. Are you still attending the program:

Yes (1) No (2)

37. Are you currently prescribed a positive pressure device for use during sleep *(e.g., CPAP):*

Yes (1) No (2)
40.

38. How frequently do you use your positive pressure device *(check only one):*

Don't use it (1)
40.
1-4 nights per week (2)
5-7 nights per week (3)

39. When you use your device, about how many hours per night do you use it *(check only one):*

1-4 hours (1)
5 or more hours (2)

G. Current medications

40. Are you currently prescribed any medications for your respiratory illness:

Yes (1) No (2)
42.

41. What types of medications are you currently prescribed for your respiratory illness *(check all that apply)*

a. Long-acting bronchodilator and inhaled corticosteroid combined in one inhaler (eg, Advair, Symbicort): (1)

b. Long-acting sympathomimetic not combined with another medication (eg, Serevent, Foradil): (1)

c. Inhaled corticosteroid not combined with another medication (eg, Flovent, Vanceril, Asthmacort, Aerobid, Asthmanex, Pulmicort): (1)

d. Short-acting sympathomimetic (beta-agonists such as Ventolin, Proventil, albuterol): (1)

e. Short-acting antichovlinergic (such as Atrovent; ipratropium bromide): (1)

f. Short-acting sympathomimetic and short-acting anticholinergic in one inhaler (e.g., Combivent): (1)

g. Long-acting anticholinergic (such as tiotropium; Spiriva): (1)

h. Theophylline: (1)

i. Leukotriene modifier (such as Singulair, Accolade, Zyflo): (1)

j. Oral or intramuscular corticosteroid: (1)

k. Alpha-1 antitrypsin replacement: (1)

l. Other *(specify):* (1)

_____
specify

42. Are you currently prescribed any cardiovascular medications *(check all that apply)*

a. ACE-I: (1)

b. Anti-platelet (other than ASA): (1)

c. ARA/AII-antagonist: (1)

d. Aspirin: (1)

e. Beta-blocker: (1)

f. Calcium channel blocker (CCB): (1)

g. Digitalis preparation: (1)

h. Diuretic alone or combined with another medication (e.g., Maxzide): (1)

i. Statin: (1)

j. Vasodilator: (1)

k. Other *(specify):* (1)

_____
specify

l. None of the above: (1)

43. Are you currently prescribed any anticoagulant or antiplatelet medications *(check all that apply)*

a. Aspirin: (1)

b. Clopidigel (Plavix): (1)

c. Dipyridamole (Persantive): (1)

d. Enoxaparin: (1)

e. Heparin: (1)

f. Lovenox: (1)

g. Ticlodipine (Ticlid): (1)

h. Warfarin (Coumadin): (1)

i. Other *(specify):* (1)

_____
specify

j. None: (1)

44. Are you currently prescribed any diabetes medications *(check all that apply)*

a. Insulin: (1)

b. Oral medications (metformin, pioglitazone): (1)

c. Other *(specify):* (1)

_____

d. None of the above: (1)

45. For most of the past 3 months have you used oral (by mouth) or intravenous or intramuscular corticosteroid medication (such as prednisone) daily or every other day:

Yes (1) No (2)

H. Interval since previous interim history (this establishes the recall interval for the questions that follow)

46. Date of most recent HT or HI form completed *(date of HB form if no HI or HT has been completed since randomization):*

____ ____–____ ____ ____–____ ____
day mon year

I. COPD exacerbations and interim use of oxygen

47. Since the date in item 46, have you had a COPD exacerbation *(flare, attack of your breathing problems; if patient is uncertain or unclear, use any records available):*

Yes (*1) No (2)

49.

** Coordinator should be sure an EX form is completed for each exacerbation.*

48. Since the date in item 46, how many COPD exacerbations have you had: ____
# of exacerbations

49. Was the patient randomized to no supplemental oxygen (control):

Yes (1) No (2)

57.

50. Since the date in item 46, have you used supplemental oxygen at home:

Yes (1) No (2)

74.

51. Date started using home oxygen *(date may precede date in item 46 if this is not a new prescription since the date in item 46):*

____ ____–____ ____ ____–____ ____
day mon year

52. Date last used home oxygen *(enter today's date if use is continuing):*

____ ____–____ ____ ____–____ ____
day mon year

If the patient continues to use oxygen, the Study Physician should discuss with the patient and the patient's private physician whether the oxygen may be stopped.

53. Did (do) you use the oxygen during rest :

Yes *(specify dose):* (1)

_____
specify dose

No (2)

54. Did (do) you use the oxygen during exercise:

Yes *(specify dose):* (1)

_____
specify dose

No (2)

55. Did (do) you use the oxygen during sleep:

Yes *(specify dose):* (1)

_____
specify dose

No (2)

56. While using supplemental oxygen, about how many hours per day did (do) you use it *(include all use -- during the day, while walking, and during sleep) (check only one):*

17-24 hours per day (1)
9-16 hours per day (2)
5-8 hours per day (3)
4 or fewer hours per day (4)

57. Was the patient randomized to supplemental oxygen:

Yes (1) No (2)

62.

58. Has a physician outside of LOTT prescribed oxygen for the patient or changed the patient's LOTT prescription:

Yes (*1) No (2)

** The LOTT Study Physician should review with the patient and the patient's private physician whether the patient may resume his/her LOTT prescription.*

59. In the past 7 days, about how many hours per day have you used your stationary oxygen system *(check only one):*

17-24 hours per day	(1)
9-16 hours per day	(2)
5-8 hours per day	(3)
4 or fewer hours per day	(4)
Stationary system no longer in the home	(5)

60. In the past 7 days, about how many hours per day have you used your ambulatory (portable) oxygen system *(check only one):*

17-24 hours per day	(1)
9-16 hours per day	(2)
5-8 hours per day	(3)
4 or fewer hours per day	(4)
Ambulatory system no longer in the home	(5)

61. Since the date in item 46, have you received any new oxygen equipment:

Yes (* 1) No (2)

** Review OF form printout with patient and mark with corrections; complete OE form if a new type of equipment has been issued to the patient.*

J. Adverse events related to oxygen equipment

62. Since the date in item 46, have you experienced any fires related to oxygen use:

Yes (1) No (2)

66.

63. Date of fire:

____ ____–____ ____ ____–____ ____
day mon year

64. What happened *(check all that apply)*

a. Patient was injured - minor injuries:	(1)
b. Family member(s) was injured - minor injuries:	(1)
c. Patient was injured - major injuries:	(1)
d. Family member(s) was injured - major injuries:	(1)
e. Property damage:	(1)
f. None of these:	(1)

65. Other information on incident:

_____

_____

_____

_____

_____

66. Since the date in item 46, have you or a family member or other person been burned by frost buildup on a liquid oxygen system:

Yes (1) No (2)

70.

67. Date of burn:

____ ____–____ ____ ____–____ ____
day mon year

68. Who was burned *(check all that apply):*

a. Patient	(1)
b. Family member	(1)
c. Other person	(1)

69. Describe burn/incident:

_____

_____

_____

_____

_____

70. Since the date in item 46, have you or a family member or other person been injured by tripping over oxygen equipment:

Yes (1) No (2)

74.

71. Date of injury:

____ ____–____ ____ ____–____ ____
day mon year

72. Who was injured *(check all that apply)*

a. Patient:	(1)
b. Family member:	(1)
c. Other person:	(1)

73. Describe injury/incident:

_____

_____

_____

_____

_____

K. Hospitalization and general health care utilization

74. Since the date in item 46, have you had any serious health problem that we have not talked about *(check only one):*

Yes *(specify)* (1)

_____

_____

No (2)

75. Since the date in item 46, have you been hospitalized overnight in an acute care hospital for any reason:

Yes (* 1)

**Coordinator should be sure that an IE, AN, or EX form (whichever is appropriate) has been completed to document each overnight acute care hospitalization. The nature of the event that prompted the hospitalization will dictate which form to report it on (AN - related, unexpected, severe adverse event or unanticipated problem; EX - COPD exacerbation; IE - all other events)*

No (2)

78.

76. Since the date in item 46, how many times have you been hospitalized overnight in an acute care hospital for any reason (i.e., number of acute care hospital admissions):

____
# of times

77. Dates of acute care hospital admissions since date in item 46 *(record admission date for the first 3 admissions since the date in item 46):*

a. Date of 1st admission

____ ____–____ ____ ____–____ ____
day mon year

b. Date of 2nd admission

____ ____–____ ____ ____–____ ____
day mon year

c. Date of 3rd admission

____ ____–____ ____ ____–____ ____
day mon year

78. In the past 3 months, how many nights have you stayed overnight in a rehabitilitation hospital or nursing home for any reason *(enter 000 if none):*

____ ____ ____
# of nights

79. In the past 3 months, how many times have you visited an emergency, triage, or urgent care department for any reason *(enter 00 if none):*

____ ____
# of times

80. In the past 3 months, how many times have you visited a physician, physician's assistant, or nurse in their office or have you visited an outpatient clinic for any reason *(exclude hospital stays, visits to acute care facilities, and emergency, triage, or urgent care department visits; enter 00 if none):*

____ ____
# of times

81. About how many hours in the past week have family members or friends spent helping with your care *(enter 000 if none):*

____ ____ ____
# of hours

L. Annual followup visit

82. Was the next annual visit scheduled:

Yes (1) No (2)

84.

83. Date and time scheduled for next annual visit:

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Time:

____ ____:____ ____ (1) (2)
hour minute am pm

M. Administrative information

84. Clinical Coordinator PIN: ____ ____ ____ ____

85. Clinical Coordinator signature:

_____

86. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

ht2 - Form HT2 Interim History at 4-Month Telephone Visit

Date file created: 21 Apr 2017
Observations: 4585
Variables: 50

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
ht207	7 Frequency of nosebleeds or bloody nasal discharge	Char	1
ht208	8 Frequency of very dry nose	Char	1
ht209	9 Frequency of runny nose	Char	1
ht210	10 Currently smoke cigarettes	Char	1
ht211	11 Tried to quit smoking cigarettes	Char	1
ht212	12 Anyone in household smoke	Char	1
ht213	Date last HI/HT cmpltd cnvrtd to #days from RZ	Num	8
ht214	14 Had a COPD exacerbation	Char	1
ht215	15 Number of COPD exacerbations	Char	1
ht216	16 Randomized to no supplemental oxygen	Char	1
ht217	17 Used supplemental oxygen	Char	1
ht218	Date strtd O2 cnvrtd to #days from RZ	Num	8
ht219	Date last used O2 cnvrtd to #days from RZ	Num	8
ht220	20 Used oxygen during rest	Char	1
ht221	21 Used oxygen during exercise	Char	1
ht222	22 Used oxygen during sleep	Char	1
ht223	23 Hours per day oxygen used	Char	1
ht224	24 Randomized to supplemental oxygen	Char	1
ht225	25 Outside physician prescribed oxygen	Char	1
ht226	26 Hours per day stationary system used	Char	1
ht227	27 Hours per day ambulatory system used	Char	1
ht228	28 Received new oxygen equipment	Char	1
ht229	29 Any fires related to oxygen use	Char	1
ht230	Date of fire cnvrtd to #days from RZ	Num	8
ht233	33 Burns from frost on liquid oxygen system	Char	1
ht234	Date of burn cnvrtd to #days from RZ	Num	8
ht237	37 Injured from tripping on oxygen equipment	Char	1
ht238	Date of injury cnvrtd to #days from RZ	Num	8
ht241	41 Any serious health problem	Char	1
ht242	42 Hospitalized overnight since date in 13	Char	1
ht243	43 Number of overnight hospitalizations	Char	1
ht231a	31a Patient had minor injuries	Char	1
ht231b	31b Family member had minor injuries	Char	1
ht231c	31c Patient had major injuries	Char	1
ht231d	31d Family member had major injuries	Char	1
ht231e	31e Property damage	Char	1
ht231f	31f None of these	Char	1
ht235a	35a Patient burned	Char	1
ht235b	35b Family member burned	Char	1
ht235c	35c Other person burned	Char	1
ht239a	39a Patient injured	Char	1
ht239b	39b Family member injured	Char	1
ht239c	39c Other person injured	Char	1
ht244a	Date 1st admit cnvrtd to #days from RZ	Num	8
ht244b	Date 2nd admit cnvrtd to #days from RZ	Num	8
ht244c	Date 3rd admit cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5

ht2 - Form HT2 Interim History at 4-Month Telephone Visit

Date file created: 21 Apr 2017
Observations: 4585
Variables: 50

Variable Name	Variable Label	Type	Variable Length
visit	Visit code	Char	3

LOTT

HT - Interim History at 4-Month Telephone Visit

Purpose: To collect interim history information from the patient at 4-month telephone visits.

Data collection level: Core.

When: Visits f04, f08, f16, f20, f28, f32, f40, f44, f52, f56, f64, f68, f76, and f80.

Administered by: Clinical Coordinator.

Instructions: Complete item 13, date of most recently completed Interim History at 4-month Telephone Visit (HT) or Interim History at Annual Visit (HI) form before interviewing the patient. **Patients randomized to supplemental oxygen:** You should have the patient's equipment listing (OF form printout) available in case the patient reports a change in his/her oxygen equipment and key any updates after the visit. **All patients:** If the patient is at the clinic for a visit related or unrelated to LOTT and a telephone visit window is open, it is acceptable to do the interview in person. Tell the patient that you will be asking questions similar to those asked previously, so that we can update their health history. The questions relate to nasal symptoms, smoking, COPD exacerbations and use of oxygen equipment. Be sure that every newly reported overnight acute care hospitalization is documented on an AN, IE, or EX form, which ever is appropriate for the event that prompted the hospitalization. Complete an EX form for each new report of a COPD exacerbation not previously documented on an EX form. If the patient reports prescription of oxygen by a physician outside of LOTT, and the oxygen use is ongoing, the Study Physician should be informed and the Study Physician should discuss with the patient and his/her private physician whether LOTT treatment (supplemental oxygen or control) may be resumed.

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date of report:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: f ____ ____

6. Form & revision: h t 2

B. Nasal symptoms

7. On average, in the past 3 months, how often have you had a nosebleed or bloody nasal discharge *(check only one):*

Never or rarely	(1)
About once a month	(2)
About once a week	(3)
Most days	(4)

8. On average, in the past 3 months, how often have you had a feeling of a very dry nose *(check only one):*

Never or rarely	(1)
About once a month	(2)
About once a week	(3)
Most days	(4)

9. On average, in the past 3 months, how often have you had a runny nose *(check only one):*

Never or rarely	(1)
About once a month	(2)
About once a week	(3)
Most days	(4)

C. Smoking

10. Do you currently smoke tobacco cigarettes, cigars, cigarillos, or pipes:

Yes (* 1) No (2)

12. ┘

** Remind the patient not to smoke while using oxygen.*

11. Have you tried to quit smoking since we last spoke to you:

Yes (1) No (2)

12. Not including yourself, does anyone smoke tobacco cigarettes, cigars, cigarillos, or pipes in your home regularly while you are there *(e.g., someone else living there or someone who visits regularly):*

(* 1) Yes (2) No

** Remind patient not to permit smoking around him/her while using oxygen.*

D. Interval since previous interim history *(this establishes the recall interval for questions that follow)*

13. Date of most recently completed HT or HI form *(date of HB form if no HT or HI form has been completed since randomization)*:

____ ____–____ ____ ____–____ ____
day mon year

E. COPD exacerbations and interim use of oxygen

14. Since the date in item 13, have you had a COPD exacerbation: *(flare, attack of your breathing problems; if patient is uncertain or unclear, use any records available):*

(* 1) Yes (2) No → **16.**

** Coordinator should be sure an EX form is completed for each exacerbation*

15. Since the date in item 13, how many COPD exacerbations have you had: ____ # of exacerbations

16. Was the patient randomized to no supplemental oxygen (control):

(1) Yes (2) No → **24.**

17. Since the date in item 13, have you used supplemental oxygen at home:

(1) Yes (2) No → **41.**

18. Date started using home oxygen *(date may precede date in item 13 if this is not a new prescription since the date in item 13):*

____ ____–____ ____ ____–____ ____
day mon year

19. Date last used home oxygen *(enter today's date if use is continuing):*

____ ____–____ ____ ____–____ ____
day mon year

If the patient continues to use oxygen, the Study Physician should discuss with the patient and the patient's private physician whether the oxygen may be stopped.

20. Did (do) you use the oxygen during rest :

Yes *(specify dose):* (1)

_____
specify dose

No (2)

21. Did (do) you use the oxygen during exercise:

Yes *(specify dose):* (1)

_____
specify dose

No (2)

22. Did (do) you use the oxygen during sleep:

Yes *(specify dose):* (1)

_____
specify dose

No (2)

23. While using supplemental oxygen, about how many hours per day did (do) you use it *(include all use -- during the day, while walking, and during sleep) (check only one):*

17-24 hours per day (1)
9-16 hours per day (2)
5-8 hours per day (3)
4 or fewer hours per day (4)

24. Was the patient randomized to supplemental oxygen:

(1) Yes (2) No → **29.**

25. Has a physician outside of LOTT prescribed oxygen for you or changed your LOTT prescription:

(* 1) Yes (2) No

** The LOTT Study Physician should review with the patient and the patient's private physician whether the patient may resume his/her LOTT prescription.*

26. In the past 7 days, about how many hours per day have you used your stationary oxygen system *(check only one):*

- 17-24 hours per day (1)
- 9-16 hours per day (2)
- 5-8 hours per day (3)
- 4 or fewer hours per day (4)
- Stationary system no longer in the home (5)

27. In the past 7 days, about how many hours per day have you used your ambulatory (portable) oxygen system *(check only one):*

- 17-24 hours per day (1)
- 9-16 hours per day (2)
- 5-8 hours per day (3)
- 4 or fewer hours per day (4)
- Ambulatory system no longer in the home (5)

28. Since the date item 13, have you received any new oxygen equipment:

Yes (* 1) No (2)

** Review OF form printout with patient and mark with corrections; complete OE form if new type of equipment has been issued to the patient.*

F. Adverse events related to oxygen equipment

29. Since the date in item 13, have you experienced any fires related to oxygen use:

Yes (1) No (2)

33.

30. Date of fire:

____ ____–____ ____ ____–____ ____
day mon year

31. What happened *(check all that apply)*

- **a.** Patient was injured - minor injuries: (1)
- **b.** Family member(s) was injured - minor injuries: (1)
- **c.** Patient was injured - major injuries: (1)
- **d.** Family member(s) was injured - major injuries: (1)
- **e.** Property damage: (1)
- **f.** None of these: (1)

32. Other information on incident:

_____

_____

_____

_____

_____

33. Since the date in item 13, have you or a family member or other person been burned by frost buildup on a liquid oxygen system:

Yes (1) No (2)

37.

34. Date of burn:

____ ____–____ ____ ____–____ ____
day mon year

35. Who was burned *(check all that apply)*

- **a.** Patient: (1)
- **b.** Family member: (1)
- **c.** Other person: (1)

36. Describe burn/incident:

_____

_____

_____

_____

_____

37. Since the date in item 13, have you or a family member or other person been injured by tripping over oxygen equipment:

Yes (1) No (2)

41.

38. Date of injury:

____ ____–____ ____ ____–____ ____
day mon year

39. Who was injured *(check all that apply):*

- **a.** Patient (1)
- **b.** Family member (1)
- **c.** Other person (1)

40. Describe injury/incident:

_____

_____

_____

_____

_____

G. Other health problem

41. Since the date in item 13, have you had a serious health problem that we have not talked about *(check only one):*

Yes *(specify):* (1)

_____
specify

No (2)

H. Acute care hospitalization

42. Since the date in item 13, have you been hospitalized overnight in an acute care hospital for any reason:

Yes (1)

**Coordinator should be sure that an IE, AN, or EX form (whichever is appropriate) has been completed to document each overnight acute care hospitalization. The nature of the event that prompted the hospitalization will dictate which form to report it on (AN - related, unexpected, severe adverse event or unanticipated problem; EX - COPD exacerbation; IE - all other events)*

No (2)

45.

43. Since the date in item 13, how many times have you been hospitalized overnight in an acute care hospital for any reason (i.e., number of acute care hospital admissions):

____
# of times

44. Dates of acute care hospital admissions since date in item 13 *(record admission date for the first 3 admissions since the date in item 13):*

a. Date of 1st admission

____ ____–____ ____ ____–____ ____
day mon year

b. Date of 2nd admission

____ ____–____ ____ ____–____ ____
day mon year

c. Date of 3rd admission

____ ____–____ ____ ____–____ ____
day mon year

I. Administrative information

45. Clinical Coordinator PIN: ____ ____ ____ ____

46. Clinical Coordinator signature:

_____

47. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

ie2 - Form IE2 Interim Event Report

Date file created: 21 Apr 2017
Observations: 972
Variables: 28

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
ie208	8 Severity of event	Char	1
ie209	9 Related to LOTT participation	Char	1
ie210	10 Expected in LOTT context	Char	1
ie212	Date rzd in LOTT cnvrtd to #days from RZ	Num	8
ie213	13 Gender	Char	1
ie214	14 Age at time of event	Char	2
ie215	15 Prescribed supp O2 at time of event	Char	1
ie217	Date of event onset cnvrtd to #days from RZ	Num	8
ie218	Date event rptd to site cnvrtd to #days from RZ	Num	8
ie220	20 Overnight admission to acute care hospital	Char	1
ie221	Date of hosp admit cnvrtd to #days from RZ	Num	8
ie222	Date of hosp dischg cnvrtd to #days from RZ	Num	8
ie225	25 Hospitalization related to COPD	Char	1
ie226	26 Current status of event	Char	1
ie227	Date resolved cnvrtd to #days from RZ	Num	8
ie207a	7a Burn from smoking near oxygen	Char	1
ie207b	7b Burn from using O2 near open flame	Char	1
ie207c	7c Burn from liquid oxygen frost	Char	1
ie207d	7d Nosebleed	Char	1
ie207e	7e Injury from tripping over O2 equipment	Char	1
ie207f	7f Worsening of co-morbid illness	Char	1
ie207g	7g Other event	Char	1
ie211a	11a LOTT treatment assignment	Char	1
ie211b	11b Oxygen prescription	Char	1
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

IE - Interim Event Report

Purpose: To document a hospitalization not reported on an AN or EX form, to document another adverse event not reported on an AN, EX, HI, or HT form, or to document any other event that the clinic feels should be reported to LOTT. Use the AN form if the event is an unexpected, serious adverse event thought possibly, probably, or definitely related to LOTT participation. Use the AN form if the event is an unanticipated problem (OHRP criteria). Use the EX form if the event is a COPD exacerbation. Use the HI or HT form if the event is reported during an HI or HT interview; if the clinic judges that the event reported on the HI or HT form needs immediate attention, or if the event involves a hospitalization, also complete the IE form for the event. Use the IE form if the event is reported between HI or HT interviews. If the clinic judges that the report needs immediate attention, fax the IE form to the DCC (as well as key the IE form to the LOTT Database). If additional information is received after this form is completed, complete a new IE form or a Followup Report (FR) form, whichever makes the most sense to you.

Data collection level: All patients (Core).

When: As needed. Use visit code n. If more than one event is reported on the same calendar day (i.e., same date in item 4 for all events), use visit code n for the 1st event, n2 for the 2nd event, etc.

Administered by: Clinical Coordinator and Study Physician.

Instructions: If the event involves an overnight, acute care hospitalization, obtain the discharge summary from the last hospitalization admission associated with the event. Complete and key this form for any event meeting the criteria above. Fax the DCC (attention Alice Sternberg) a copy of this form if the clinic judges that the report needs immediate attention.

LOTT Data Coordinating Center telephone number: (410) 955-8175.

LOTT Data Coordinating Center fax number: (410) 955-0932.

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code n ____ ____

6. Form & revision: i e 2

B. Event classification

7. Nature of event *(check all that apply)*

a. Burn from smoking around oxygen: (1)

b. Burn from using oxygen around open flame or equipment that smokes: (1)

c. Burn from liquid oxygen frost: (1)

d. Nosebleed: (1)

e. Musculoskeletal injury from tripping over oxygen equipment: (1)

f. Worsening of a co-morbid illness: (1)

g. Other *(specify):* (1)

_____

_____

8. Severity of event *(check only one):*

Not an adverse event	(0)
Grade 1, mild adverse event, did not require treatment	(1)
Grade 2, moderate adverse event, resolved with treatment	(2)
Grade 3, severe adverse event, inability to carry on normal activities; required professional medical attention	(3)
Grade 4, life-threatening or permanently disabling adverse event	(4)
Grade 5, fatal adverse event	(5)

9. Relatedness to LOTT participation or treatment *(Study Physician uses best medical judgment; check only one):*

Unrelated	(1)
Unlikely	(2)
Possibly	(3)
Probably	(4)
Definitely	(5)

10. Expectedness in context of LOTT *(check only one):*

Expected	(1)
Unexpected	(2)

NOTE: If item 8 = 3, 4, or 5 and item 9 = possibly, probably or definitely, and item 10 = unexpected, STOP -- this event should be reported on the AN form.

C. Patient information

11. LOTT treatment assignment

a. Treatment group:

Supplemental oxygen	(1)
No supplemental oxygen	(2)
	12. ___
Not randomized	(3)
	13. ___

b. Oxygen prescription:

24-hour oxygen	(1)
Oxygen during physical activity and sleep	(2)

12. Date randomized in LOTT:

____ ____–____ ____ ____–____ ____
day mon year

13. Gender

Male	(1)
Female	(2)

14. Age at time of event:

____ ____
years

15. Was the patient prescribed supplemental oxygen at the time of the event *(by LOTT Study Physician or private physician)*

Yes (1) No (2)

16. Summarize the patient's history of treatment with oxygen during LOTT *(eg, have there been any treatment interruptions; if assigned to control, has the patient been prescribed oxygen; if assigned to supplemental oxygen, has the LOTT dose been altered).*

_____

_____

_____

_____

_____

D. Event information

17. Date of event onset:

____ ____–____ ____ ____–____ ____
day mon year

18. Date event was reported to site:

____ ____–____ ____ ____–____ ____
day mon year

19. Describe the event and action taken:

_____

_____

_____

_____

_____

_____

20. Did the event require admission overnight to an acute care hospital:

Yes (1) No (2)

26. ___

21. Date of hospital admission*(1st admission if more than one):*

day mon year

22. Date of hospital discharge*(last discharge if more than one):*

day mon year

23. Primary discharge diagnosis *(from discharge summary from last hospitalization):*

24. Secondary discharge diagnosis *(from discharge summary from last hospitalization):*

a. 1st

b. 2nd

c. 3rd

d. 4th

e. 5th

f. 6th

g. 7th

h. 8th

i. 9th

j. 10th

25. Was the hospitalzation related to COPD

Yes	(1)
No	(2)
Possibly	(3)
Probably	(4)
Cannot say	(5)

26. Current status of event *(check only one):*

Resolved	(1)
Active	(2) **28.**
Unknown	(3) **28.**

27. Date resolved:

day mon year

28. Other comments on event:

E. Administrative information

29. Study Physician PIN:

30. Study Physician signature:

31. Clinical Coordinator PIN:

32. Clinical Coordinator signature:

33. Date form reviewed:

day mon year

Key this form. Fax a copy of the form to the DCC (attention: Alice Sternberg) if you feel the report needs immediate attention. Reports faxed to the DCC will be reviewed by Robert Wise, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.

mm4 - Form MM4 Room Air 6 Minute Walk with Oximetry

Date file created: 21 Apr 2017
Observations: 2489
Variables: 62

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
mm409	9 Physician approved 6 minute walk	Char	1
mm410	10 Exertional angina	Char	1
mm412	12 Vigorous exercise in past 2 hours	Char	1
mm413	13 Rescue medications available	Char	1
mm414	14 Crash cart/electronic defibrillator available	Char	1
mm415	15 4-hr bronchodilator w/in past 4 hours	Char	1
mm417	17 Patient rested for 10 minutes	Char	1
mm418	18 LOTT Radical 7 oximeter ID	Char	3
mm419	19 Probe location	Char	1
mm423	23 Borg scale at end: breathlessness	Char	3
mm424	24 Borg scale at end: overall fatigue	Char	3
mm425	25 Normal termination at 6 minutes	Char	1
mm427	27 sb visit	Char	1
mm428	28 Result of 6 minute walk oximetry at sb visit	Char	1
mm429	29 Study MD assessment of sb 6min walk oximetry	Char	1
mm430	30 Normal termination at 6 minutes	Char	1
mm434	34 Result of 6MW at follow-up visit	Char	1
mm435	35 6MW Report ID	Char	3
mm407a	7a Room air resting saturation < 80%	Char	1
mm407b	7b Myocardial infarction in past 30 days	Char	1
mm407c	7c Unstable angina in past 30 days	Char	1
mm407d	7d Pulmonary limitation precludes walking	Char	1
mm407e	7e Nonpulmonary limitation precludes walking	Char	1
mm407f	7f No contraindications to 6 minute walk	Char	1
mm408a	8a Resting heart rate > 120 beats/minute	Char	1
mm408b	8b Systolic BP > 180 mmHg	Char	1
mm408c	8c Diastolic BP > 100 mmHg	Char	1
mm408d	8d Abnormal termination of room air oximetry	Char	1
mm408e	8e No relative contraindications to 6 min walk	Char	1
mm411a	11a Exertional angina is stable	Char	1
mm411b	11b Patient took usual antiangina medication	Char	1
mm411c	11c Rescue antiangina medication available	Char	1
mm416a	16a Cane	Char	1
mm416b	16b Walker	Char	1
mm416c	16c Crutches	Char	1
mm416d	16d Leg braces	Char	1
mm416e	16e Other walking aid	Char	1
mm416f	16f No walking aid	Char	1
mm420a	20a Borg scale at start: breathlessness	Char	3
mm420b	20b Borg scale at start: overall fatigue	Char	3
mm421a	21a Radical 7 oximeter display time (hh:mm:ss)	Char	6
mm421aa	21a am/pm	Char	1
mm421b	21b Clock/watch display time (hh:mm:ss)	Char	6
mm421ba	21b am/pm	Char	1
mm421c	21c Clock/watch time when pt strtd walk, hh:mm:ss	Char	6
mm421ca	21c am/pm	Char	1
mm421d	21d Rad 7 time when pt strtd walk, hh:mm:ss	Char	6

mm4 - Form MM4 Room Air 6 Minute Walk with Oximetry

Date file created: 21 Apr 2017
Observations: 2489
Variables: 62

Variable Name	Variable Label	Type	Variable Length
mm421da	21d am/pm	Char	1
mm422a	22a Distance walked	Char	4
mm422b	22b Distance walked units	Char	1
mm426a	26a Chest pain	Char	1
mm426b	26b Intolerable dyspnea	Char	1
mm426c	26c Leg cramps	Char	1
mm426d	26d Staggering	Char	1
mm426e	26e Diaphoresis	Char	1
mm426f	26f Pale/ashen appearance	Char	1
mm426g	26g Patient refused to continue	Char	1
mm426h	26h Other reason for test termination	Char	1
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

MM - Room Air 6 Minute Walk with Oximetry

Purpose: To document room air 6 minute walk with oximetry and record data as obtained.

Data collection level: All patients (Core).

When: Visits sb, f12, f24, f36, f48, f60, and f72 or as needed (use visit code ''n'').

Administered by: Six Minute Walk Tester and Clinical Coordinator.

Instructions: This walk is done on room air only. If oxygen is needed to complete the walk safely, **stop** -- do not do the walk. Room air resting saturation must be at least 80% to do the walk. The Six Minute Walk Tester should query the patient about absolute contraindications for the walk (myocardial infarction in past 30 days, unstable angina in past 30 days) and should check for relative contraindications (resting heart rate > 120, systolic blood pressure > 180 mmHg, diastolic blood pressure > 100 mmHg, abnormal termination of resting room air oximetry). A patient with any relative contraindication must be approved by a Study Physician before proceeding with the walk; the Study Physician should review a resting EKG done in the previous 6 months. A patient with stable exertional angina should perform the walk after taking any usual (not rescue) medication. The patient's rescue anti-angina medication must be available. The patient may use his/her usual walking aids (eg, cane, walker). The patient should wear comfortable clothing and shoes appropriate for walking. The patient should not have exercised vigorously within 2 hours of beginning the walk. A light meal 2-4 hours prior to the walk is advised. The patient should rest in a chair breathing room air for 10 minutes before beginning the walk. The LOTT Radical 7 oximeter (handheld) must be used. If the Radical 7 oximeter is not functioning, call the Data Coordinating Center. Turn the Radical 7 handheld off for at least 1 minute and then back on. Note the time on the oximeter display and the time on a separate clock (eg, your watch) simultaneously and record both times. Place the Radical 7 handheld in the waist pack and place the pack around the patient's waist and attach the probe to the patient's finger. Show the patient Flash Card #7 to assess breathlessness and overall fatigue. Note the time on the same clock when the patient starts walking. Follow the instructions on Flash Card #6 for encouraging the patient at each minute during the walk. Transfer data to the LOTT laptop, print the report, and attach the report to this form. If an EKG condition is checked and this is visit sb, the patient is ineligible for LOTT. If the patient is ineligible, complete the administrative section and file the partially completed form in the file for ineligible patients. Do not key MM forms for ineligible patients.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date of 6 minute walk):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: m m 4

B. Safety checks

7. Absolute contraindications to 6 minute walk *(check all that apply)*

a. Room air resting saturation was less than 80%: (* 1) **36.**

b. Myocardial infarction in past 30 days: (* 1) **36.**

c. Unstable angina in the past 30 days: (* 1) **36.**

d. Pulmonary limitation that precludes walking *(specify):* (* 1) **36.**

_____
specify

e. Nonpulmonary patient-related limitation that precludes walking *(specify):* (* 1) **36.**

_____
specify

f. None of the above: (1)

**The patient may not do the room air 6 minute walk test.*

8. Relative contraindications to 6 minute walk *(check all that apply)*

a. Resting heart rate greater than 120 beats/minute: (*1)

b. Systolic blood pressure greater than 180 mmHg: (*1)

c. Diastolic blood pressure greater than 100 mmHg: (*1)

d. Abnormal termination of room air resting oximetry: (*1)

e. None of the above: (1)

10.

**A physician must approve the patient proceeding with the 6 minute walk.*

9. Did a physician approve the patient proceeding with the 6 minute walk:

Yes (1) No (*2)

36.

**The patient may not do the room air 6 minute walk.*

10. Does the patient have exertional angina:

Yes (1) No (2)

12.

11. Exertional angina checks

a. Is the exertional angina stable *(check with supervising physician if you are unsure of angina status):*

Yes (1)

No (*2)

36.

**Patient may not do the room air 6 minute walk.*

b. Has the patient taken their usual (not rescue) anti-angina medication:

Yes (1)

No, patient has rescue anti-angina medication only (2)

No (*3)

STOP

**Reschedule the walk; patient must have taken any usual (not rescue) anti-angina medication prescribed for the patient before proceeding with the 6 minute walk.*

c. Is the patient's rescue anti-angina medication available:

Yes (1)

No (*2)

STOP

**Reschedule the walk; patient's anti-angina rescue medication must be available.*

12. Has the patient exercised vigorously in the past 2 hours:

Yes (*1) No (2)

STOP

**Walk may not proceed until it has been at least 2 hours since the patient exercised vigorously.*

C. Room air six minute walk

13. Are rescue medications available *(oxygen, sublingual nitroglycerine, aspirin, albuterol MDI or nebulizer):*

Yes (1) No (*2)

STOP

**Do not proceed until rescue medications are available.*

14. Is a crash cart or automated electronic defibrillator available:

Yes (1) No (*2)

STOP

**Do not proceed until a crash cart or automated electronic defibrillator is available.*

15. Has the patient used a 4-hour bronchodilator (eg, albuterol) in the past 4 hours:

Yes (1) No (2)

16. What walking aids will the patient use during the walk *(check all that apply)*

a. Cane: (1)

b. Walker: (1)

c. Crutches: (1)

d. Leg braces: (1)

e. Other *(specify):* (1)

_____
specify

f. No aids: (1)

17. Has the patient rested for 10 minutes breathing room air:

Yes (1) No (*2)

**After patient has rested 10 minutes breathing room air, check Yes and proceed with testing.*

18. LOTT Radical 7 handheld oximeter ID:

___ ___ ___

19. Probe location *(check only one):*

Finger (1)
Forehead (2)
Other *(specify)* (3)

_____
specify location

_____
specify why finger and forehead were not used

20. Borg scale values at start of walk *(have patient stand up and show patient Flash Card #7)*

a. Breathlessness: ___ ___ ___•___

b. Overall fatigue: ___ ___ ___•___

21. Clock/oximeter times *(Note Radical 7 time (item 21a) and clock/watch time (item 21b) simultaneously and record both times to the nearest second; then note time on the same clock/watch when the patient starts walking and record in item 21c; these data will help you select the patient's 6 minutes of walking data on the oximetry system display)*

a. Radical 7 oximeter display time:

___ ___:___ ___:___ ___
hour minute seconds
(1) am (2) pm

b. Clock/watch time:

___ ___:___ ___:___ ___
hour minute seconds
(1) am (2) pm

c. Clock/watch time when patient starts walking:

___ ___:___ ___:___ ___
hour minute seconds
(1) am (2) pm

d. Time on Radical 7 oximeter when patient started walking *(time in item 21c adjusted by difference between the times in items 21a and 21b):*

___ ___:___ ___:___ ___
hour minute seconds
(1) am (2) pm

Do not key data recorded in this box.

Instructions: Provide instructions to patient as shown on Flash Card #6. Start the stop watch when you say "Start." The test runs for 6 minutes regardless of the patient's rest periods. Mark completed laps below. If test lasts 6 minutes, administer Borg scale for breathlessness and overall fatigue (Flash Card #7). Remind patient that 0 means no breathlessness (no fatigue) and 10 is the maximum he/she has ever felt. Measure the distance walked to the nearest meter (foot).

O = distance of 1 lap on your course
= _____ meters or feet *(circle one)*

O O O O O O O O O O

O O O O O O O O O O

O O O O O O O O O O

Distance walked in incomplete (final) lap:
_____ meters or feet *(circle one)*

Borg for breathlessness at end of walk: _____

Borg for overall fatigue at end of walk: _____

22. Total distance walked

a. Distance: ___ ___ ___ ___

b. Units:
Meters (1)
Feet (2)

23. Borg scale rating for breathlessness at end of test *(enter ''m'' if test had abnormal termination):*

___ ___ • ___

24. Borg scale rating for overall fatigue at end of test *(enter ''m'' if test had abnormal termination):*

___ ___ • ___

25. Did the test have a normal termination at 6 minutes:

Yes (1) No (2)

27.

26. Reason(s) for test termination *(check all that apply):*

a. Chest pain: (1)

b. Intolerable dyspnea: (1)

c. Leg cramps: (1)

d. Staggering: (1)

e. Diaphoresis: (1)

f. Pale or ashen appearance: (1)

g. Patient refused to continue: (1)

h. Other, specify: (1)

_____

specify

Instructions:

1. Download the data to LOTT laptop.

2. Staple the summary report to the back of this form.

D. Eligibility evaluation *(taking account of oximetry results and termination of 6 minute walk)*

27. Is this visit sb:

Yes (1) No (2)

34.

28. What was the result of the 6 minute walk oximetry at visit sb *(data must be transferred to the LOTT laptop before this item may be answered; response checked should match message in RESULTS section of oximetry report):*

6MW Eligible for LOTT *(desaturation < 80% for ≥ 1 minute was not detected, desaturation < 90% for ≥ 10 seconds was detected, and data quality was acceptable)* (1)

30.

Not 6MW Eligible for LOTT *(desaturation < 90% for ≥ 10 seconds was not detected; desaturation < 80% for ≥ 1 minute was not detected; patient is oximetry eligible for LOTT if resting oximetry is 89-93%)* (2)

30.

Ineligible for LOTT *(desaturation < 80% for ≥ 1 minute was detected)* (3)

Elig

Physician Review Needed to Determine Eligibility *(desaturation < 80% for ≥ 1 minute was not detected, desaturation < 90% for ≥ 10 seconds was detected, but data quality was unacceptable; the Study Physician must review the test session and determine if the patient should be ruled ineligible despite desaturation < 80% for ≥ 1 minute not being detected)* (4)

29. How does the Study Physician rule the patient with regard to 6 minute walk oximetry:

Eligible (1)

Ineligible (2)

Elig

30. Did the 6 minute walk terminate normally at 6 minutes *(item 25 = ''Yes'')*:

Yes (1) No (2)

35.

31. The 6 minute walk ended abnormally, and the patient has not been found ineligible with respect to the 6 minute walk (eg, the walk may have been stopped before more than a minute of saturations below 80% accumulated). The LOTT Study Physician must explain why the patient should not be considered to have exercise desaturation meeting the LOTT exclusion criterion (desaturation below 80% for at least 1 minute while walking):

_____

_____

_____

_____

_____

32. Study Physician PIN: ____ ____ ____ ____

33. Study Physician signature:

_____

Go to item 35.

E. Followup visit evaluation for need to start oxygen

34. What was the result of the 6 minute walk oximetry at the followup visit *(data will need to be transferred to the LOTT laptop before this item may be answered; response checked should match message in RESULTS section of oximetry report):*

Severe Exercise Desat Not Detected *(desaturation < 80% for ≥ 1 minute was not detected and data quality was acceptable)* (1)

Severe Exercise Desat Detected *(desaturation < 80% for ≥ 1 minute was detected; prescribe oxygen for exercise if patient is not already prescribed oxygen; if already prescribed oxygen, check adequacy of exercise dose -- complete the Ambulatory Oxygen Dose (MP) form)* (2)

Physician Review Needed to Assess Exercise Desat *(desaturation < 80% for ≥ 1 minute was not detected, but data quality was unacceptable; the Study Physician should review the test session and determine if the patient should be prescribed oxygen during exercise despite desaturation < 80% for ≥ 1 minute not being detected)* (3)

F. LOTT report ID

35. Report ID *(transcribe from upper right corner of 6MW oximetry report; write in leading zeros if needed):*

____ ____ ____

G. Administrative information

36. Six Minute Walk Tester PIN:

____ ____ ____ ____

37. Six Minute Walk Tester signature:

_____

38. Clinical Coordinator PIN: ____ ____ ____ ____

39. Clinical Coordinator signature:

_____

40. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

mo3 - Form MO3 Room Air Resting Oximetry

Date file created: 21 Apr 2017
Observations: 2581
Variables: 18

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
mo307	7 15 minute rest breathing room air	Char	1
mo309	9 Probe location	Char	1
mo310	10 Time resting oximetry session began	Char	4
mo311	11 SpO2 for test session (laptop display)	Char	3
mo312	12 Reason for terminating resting oximetry	Char	1
mo313	13 Hyperventilate or pursed lips breathing	Char	1
mo314	14 sb visit	Char	1
mo315	15 Resting saturation 88% or less	Char	1
mo316	16 Resting saturation 94% or greater	Char	1
mo317	17 Resting saturation 88% or less at FU	Char	1
mo318	18 Report ID	Char	3
mo308a	8a Handheld Rad-7 oximeter ID	Char	3
mo308b	8b Docking station Rad-7 oximeter ID	Char	3
mo310a	10 am/pm resting oximetry session began	Char	4
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

MO - Room Air Resting Oximetry

Purpose: To guide Oximetry Technician in performing room air resting oximetry and record data as obtained.

Data collection level: All patients (Core).

When: Visits sb, f12, f24, f36, f48, f60, and f72 or as needed (use visit code ''n'').

Administered by: Oximetry Technician and Clinical Coordinator.

Instructions: The LOTT Radical 7 oximeter must be used. If the LOTT Radical 7 oximeter is not working, call the Data Coordinating Center. If the patient is using oxygen, oxygen must be stopped. The patient must sit quietly breathing room air for at least 15 minutes before the resting oximetry session begins. Turn the oximeter off for at least 1 minute and turn back on. Place the probe on the patient's finger and proceed with the oximetry session.

If this is visit sb: If the resting saturation is 88% or less, the patient is ineligible. If the resting saturation is at least 89% and no greater than 93%, the patient is resting oximetry eligible. If the resting saturation is 94% or greater, the patient may be eligible; complete the 6 minute walk and evaluate the session for evidence of exercise desaturation per LOTT criteria. If you check an (IHG) condition, the patient is ineligible. Skip to the administrative information section and file the partially completed form in the file for ineligible patients. Do not key MO forms for ineligible patients. If a (C) condition is checked, the patient may be eligible; complete the 6 minute walk and evaluate the session for evidence of exercise desaturation per LOTT criteria.

If this is a followup visit: If the saturation is 88% or less, the patient meets conventional Medicare criteria for starting 24-hour oxygen and the patient should be informed of this finding. The patient should be started on 24-hour oxygen if the patient was assigned to no oxygen or if the patient was assigned to supplemental oxygen but was using oxygen for physical activity and sleep only.

All visits: Attach the resting oximetry report to this form.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date of resting oximetry):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: m o 3

B. Resting room air oxygen saturation

7. Has the patient rested 15 minutes breathing room air:

(Yes 1) (No *2)

**The patient must rest 15 minutes breathing room air before proceeding.*

8. LOTT Radical-7 oximeter ID

a. Handheld: ____ ____ ____

b. Docking station: ____ ____ ____

9. Probe location *(check only one):*

Finger (1)
Forehead (2)
Other *(specify)* (3)

_____
specify location

_____
specify why finger and forehead were not used

Instructions*: The patient should be seated, instructed not to talk, and breathe room air for 15 minutes. Attach the probe. The patient should be told not to hyperventilate and not to use pursed lips breathing during the test session.*

10. Test start time *(from oximeter display):*

____ ____:____ ____ (am 1) (pm 2)
hour minute

11. Resting SpO_2 for test session *(from Result section of laptop display or Result section of oximetry report):*

____ ____ ____
%

12. Reason for terminating resting oximetry session *(check only one):*

Normal termination by Oximetry Technician (1) → 13.

Abnormal termination by Oximetry Technician and this is visit sb (*2) → 19.

_____
specify

Abnormal termination by Oximetry Technician and this is visit f12, f24, f36, or f48 (†3) → 19.

Terminated by patient and this is visit sb (*4) → 19.

_____
specify reason

Terminated by patient and this is visit f12, f24, f36, or f48 (†5) → 19.

**The patient is ineligible for the LOTT.*

†The patient may not do the room air 6 minute walk test unless the Study Physician approves.

13. Did the patient hyperventilate or use pursed lips breathing during the resting test session:

(Yes *1) (No 2)

**Repeat session after resolving hyperventilation and/or pursed lips breathing.*

C. Eligibility evaluation

14. Is this visit sb:

(Yes 1) (No 2) → 17.

15. Is the resting saturation *(item 11)* 88% or less:

(Yes 1) (No 2) → EHg

16. Is the resting saturation *(item 11)* 94% or greater:

(Yes *1) (No †2) → C → 18.; 18.

**Patient may be eligible for LOTT; evaluate for desaturation on 6 minute walk per LOTT criteria.*

†Patient is resting oximetry eligible for LOTT.

D. Followup visit evaluation

17. Is the resting saturation *(item 11)* 88% or less:

(Yes *1) (No 2)

**The Study Physician should inform the patient that his/her resting saturation meets the conventional Medicare criterion for starting 24-hour oxygen. If the patient is not already using 24-hour oxygen, the Study Physician either should start the patient on 24-hour oxygen or refer the patient to his/her private physician.*

E. LOTT report ID

18. Report ID *(transcribe from upper right corner of oximetry report; write in leading zeros if needed):*

___ ___ ___

F. Administrative information

19. Oximetry Technician PIN:

___ ___ ___ ___

20. Oximetry Technician signature:

_____

21. Clinical Coordinator PIN:

___ ___ ___ ___

22. Clinical Coordinator signature:

_____

23. Date form reviewed:

___ ___ – ___ ___ ___ – ___ ___
day mon year

mp2 - Form MP2 Ambulatory Oxygen Dose

Date file created: 21 Apr 2017
Observations: 1254
Variables: 17

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
mp207	7 Patient in loose clothing/comfortable shoes	Char	1
mp208	8 Patient using personal ambulatory system	Char	1
mp209	9 Rested 15 minutes breathing oxygen	Char	1
mp210	10 Oximeter used	Char	1
mp211	11 Probe location	Char	1
mp212	12 Type of oxygen equipment	Char	1
mp213	13 Regulator type	Char	1
mp214	14 Time walk started	Char	4
mp215	15 Time walk ended	Char	4
mp216	16 Oxygen setting at end of walk	Char	1
mp210a	10 LOTT Rad-5 or Rad-7 ID	Char	3
mp214a	14 1=am, 2=pm	Char	1
mp215a	15 1=am, 2=pm	Char	1
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

MP - Ambulatory Oxygen Dose

Purpose: Guide Study Physician in determination of ambulatory oxygen dose for patients assigned to supplemental oxygen or control patients who have become severely hypoxemic at rest.

Data collection level: All patients (Core).

When: **Patients assigned to supplemental oxygen**: Once patient has his/her personal ambulatory oxygen system and annually thereafter; use visit codes rx, f12, f24, f36, f48, f60, f72. If needed between followup visits, use visit code n.

Control patients who agree to have oxygen treatment managed by the LOTT physician: If done at regular followup visit, use visit code f12, f24, f36, or f48; use visit code n if between followup visits.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Any oximeter may be used for this assessment. The patient should have been resting and breathing oxygen at their resting dose (setting of 2 if patient does not use oxygen at rest) for at least 15 minutes before the test begins. This assessment may be done before or after any room air 6 minute walk required at the visit. There are no requirements related to bronchodilator use, hunger status, or resting before the assessment. The patient should wear loose clothing and comfortable shoes. The patient should use his/her personal ambulatory system. The initial dose setting should be the patient's current resting dose (2 if patient does not use oxygen at rest) regardless of the patient's current ambulatory dose. Tell the patient to walk at his/her own normal pace and at a comfortable pace. Saturation is assessed after 1 minute and each minute thereafter. Increase the oxygen setting in **whole number increments** as needed to keep saturation at 90% or higher for at least 2 consecutive minutes. The walk should last at least 2 minutes and may last as long as 10 minutes. The oximetry data from the session will not be uploaded to the LOTT database.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: m p 2

B. Checks on patient condition

7. Is the patient wearing loose clothing and comfortable shoes:

Yes (1) No (*2)

**Patient should wear loose clothing and comfortable shoes, but assessment may proceed.*

8. Will the patient use his/her personal ambulatory system:

Yes (1) No (*2)

→ **9.**

_____
specify why not

**Patient should use his/her ambulatory system, but assessment may proceed.*

9. Has the patient rested at least 15 minutes breathing oxygen at the patient's resting dose (setting of 2 if patient does not use oxygen at rest):

Yes (1) No (*2) → STOP

**The patient must rest 15 minutes breathing oxygen at the patient's resting dose (2 if patient does not use oxygen at rest) before proceeding.*

C. Walk while using oxygen

10. Oximeter used *(complete only one)*

LOTT oximeter ID *(Rad 7 handheld or Rad 5):* (1)

____ ____ ____
oximeter ID

Other *(specify):* (2)

_____
specify manufacturer

11. Probe location:

Finger (1)
Forehead (2)
Other *(specify)* (3)

_____
specify location

12. Type of oxygen equipment used by patient:

Compressed gas cylinder (1)
Liquid oxygen tank (2)
Portable oxygen concentrator (3)
Other *(specify)* (4)

_____
specify oxygen equipment

13. Regulator type:

Pulse (conserver) (1)
Continuous (2)

14. Time walk started *(start patient at his/her current resting dose [2 if patient does not use oxygen at rest]):*

____ ____:____ ____ (1) (2)
hour minute am pm

15. Time walk ended *(walk ends when saturation is at least 90% for at least 2 consecutive minutes):*

____ ____:____ ____ (1) (2)
hour minute am pm

16. Oxygen setting at end of walk: ____
2-9

D. Administrative information

17. Study Physician PIN: ____ ____ ____ ____

18. Study Physician signature:

_____

19. Clinical Coordinator PIN: ____ ____ ____ ____

20. Clinical Coordinator signature:

_____

21. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

mq1 - Form MQ1 Resting Oximetry on Oxygen

Date file created: 21 Apr 2017
Observations: 13
Variables: 15

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
mq107	7 Rested 15 minutes while breathing O2	Char	1
mq108	8 Oximeter used	Char	1
mq109	9 Oximeter probe location	Char	1
mq110	10 Type of oxygen equipment used	Char	1
mq111	11 Regulator type	Char	1
mq112	12 Time session started	Char	4
mq113	13 Time session ended	Char	4
mq114	14 Oxygen setting	Char	1
mq108a	8 Oximeter ID	Char	3
mq112a	12 1=am 2=pm	Char	1
mq113a	13 1=am 2=pm	Char	1
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

MQ - Resting Oximetry on Oxygen

Purpose: Guide Study Physician in determination of resting oxygen dose for patients who have become severely hypoxemic at rest.

Data collection level: All patients (Core), as needed, if patient has become severely hypoxemic at rest.

When: As needed. Use visit code f12, f24, f36, f48, f60, or f72 if done at annual followup visit. Use visit code n otherwise.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Any oximeter may be used for this assessment. Any oxygen system may be used for this assessment. The initial dose setting should be 2 L/min regardless of the patient's current resting dose. The patient should rest breathing oxygen at 2 L/min for at least 15 minutes before the assessment starts. Saturation is assessed 1 minute after the test starts and every minute thereafter. Increase the oxygen dose by 1 L/min in whole number increments as needed to keep saturation at 89% or higher for at least 2 consecutive minutes. The testing session should last at least 2 minutes and may last as long as 10 minutes. The oximetry data from the test will not be uploaded to the LOTT database.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date of resting oximetry):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: m q 1

B. Check on resting saturation on oxygen

7. Has the patient rested at least 15 minutes breathing oxygen at a setting of 2:

(Yes 1) (No * 2) STOP

**The patient must rest 15 minutes breathing oxygen at a setting of 2 before proceeding.*

8. Oximeter used:

LOTT oximeter ID *(Rad 7 handheld or Rad 5)* (1)

Oximeter ID: ____ ____ ____

Other *(specify)* (2)

_____
specify other manufacturer

9. Probe location *(check only one):*

Finger (1)
Forehead (2)
Other *(specify)* (3)

_____
specify location

10. Type of oxygen equipment used by patient:

Compressed gas cylinder (1)
Other *(specify):* (2)

_____
specify other type

11. Regulator type:

Pulse (conserver) (1)
Continuous flow (2)

Instructions*: The patient should have been seated, instructed not to talk, and have been breathing oxygen for 15 minutes at a setting of 2. The patient should be told not to hyperventilate and not to use pursed lips breathing.*

12. Time session started *(start patient at 2 L/min):*

____ ____ : ____ ____ (1) (2)
hour minute am pm

13. Time session ended *(session ends when saturation is at least 89% for at least 2 consecutive minutes):*

____ ____ : ____ ____ (1) (2)
hour minute am pm

14. Oxygen setting at end of test: ____
2-9

C. Administrative information

15. Study Physician PIN:

____ ____ ____ ____

16. Study Physician signature:

_____

17. Clinical Coordinator PIN:

____ ____ ____ ____

18. Clinical Coordinator signature:

_____

19. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

mv1 - Form MV1 Missed or Incomplete 4-month Telephone or Annual Visit

Date file created: 21 Apr 2017
Observations: 1292
Variables: 36

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
mv107	7 Entire visit missed	Char	1
mv108a	8a Patient was ill	Char	1
mv108b	8b Patient temporarily away from area	Char	1
mv108c	8c Patient refused to return	Char	1
mv108d	8d Patient moved from area permanently	Char	1
mv108e	8e Unable to contact patient	Char	1
mv108f	8f Other reason for missed visit	Char	1
mv109a	9a Telephoned patient	Char	1
mv109b	9b Mailed reminder card	Char	1
mv109c	9c Other steps to avoid missing visit	Char	1
mv110a	10a BV: Blood Values	Char	1
mv110b	10b HA: Hospital Anxiety and Depression Scale	Char	1
mv110c	10c HI: Interim History at Annual Visit	Char	1
mv110d	10d HT: Interim History at 4-Mon Telephone Visit	Char	1
mv110e	10e MM: Room Air 6-Minute Walk w/Oximetry	Char	1
mv110f	10f MO: Room Air Resting Oximetry	Char	1
mv110g	10g MP: Ambulatory Oxygen Dose	Char	1
mv110h	10h PE: Physical Exam	Char	1
mv110i	10i PQ: Pittsburgh Sleep Quality Index	Char	1
mv110j	10j QF: SF-36v2 Health Survey	Char	1
mv110k	10k QG: St George's Respiratory Questionnaire	Char	1
mv110l	10l QW: Quality of Well-Being Scale	Char	1
mv110m	10m SP: Spirmetry	Char	1
mv110n	10n Other missed form	Char	1
mv111a	11a Patient was ill	Char	1
mv111b	11b Patient refused procedure	Char	1
mv111c	11c Procedure forgotten	Char	1
mv111d	11d Other reason form not completed	Char	1
mv112a	12a Tried to rescheduled procedure	Char	1
mv112b	12b Tried to do interview by phone	Char	1
mv112c	12c Tried to gain patient cooperation	Char	1
mv112d	12d Other attempt to complete form	Char	1
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3

LOTT

MV - Missed or Incomplete 4-month Telephone or Annual Visit

Purpose: Record reason(s) for missed or incomplete 4-month telephone visit or annual clinic visit.

When: At the close of a visit window for f04, f08, f12, f16, f20, f24, f28, f32, f36, f40, f44, f48, f52, f56, f60, f64, f68, f72, f76, and f80.

Respondent: None.

Completed by: Clinical Coordinator.

Instructions: Complete this form when a patient fails to complete a visit or specific visit procedures (resulting in missing forms) within the time window for the visit. If the f12, f24, f36, or f48 adherence promotion contact is missed, complete the AH form to document the missed adherence promotion contact.

A. Center, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: f ____ ____

6. Form & revision: m v 1

B. Reason for completion of this form

7. Was the entire visit missed:

Yes (1) No (2)

10.

C. Missed visit information

8. Reason for missed visit *(check all that apply):*

- **a.** Patient was ill: (1)
- **b.** Patient was temporarily away from area: (1)
- **c.** Patient refused to return: (1)
- **d.** Patient has permanently moved from the area: (1)
- **e.** Unable to contact patient: (1)
- **f.** Other *(specify):* (1)

_____
specify

9. Steps taken to avoid missing the visit *(check all that apply):*

- **a.** Telephoned patient: (1)
- **b.** Mailed reminder card: (1)
- **c.** Other *(specify):* (1)

_____
specify

13.

D. Incomplete visit information

10. Check form(s) not completed *(check required forms that were missed):*

- **a.** Blood Values (BV): (1)
- **b.** Hospital Anxiety and Depression Scale (HA): (1)
- **c.** Interim History at Annual Visit (HI): (1)
- **d.** Interim History at 4-Month Telephone Visit (HT): (1)
- **e.** Room Air 6-Minute Walk with Oximetry (MM): (1)
- **f.** Room Air Resting Oximetry (MO): (1)
- **g.** Ambulatory Oxygen Dose (MP): (1)
- **h.** Physical Examination (PE): (1)
- **i.** Pittsburgh Sleep Quality Index (PQ): (1)
- **j.** SF-36v2 Health Survey (QF): (1)
- **k.** St. George's Respiratory Questionnaire (QG): (1)
- **l.** Quality of Well-Being Scale (QW): (1)
- **m.** Spirometry (SP): (1)
- **n.** Other *(specify):* (1)

_____
specify

11. Reason form(s) not completed *(check all that apply):*

a. Patient was ill: (1)

b. Patient refused procedure: (1)

c. Procedure forgotten: (1)

d. Other *(specify):* (1)

_____
specify

12. Attempts made to complete form(s) *(check all that apply):*

a. Attempted to reschedule procedure: (1)

b. Attempted to collect interview data by phone from patient: (1)

c. Attempted to gain patient cooperation: (1)

d. Other *(specify):* (1)

_____
specify

E. Administrative information

13. Clinical Coordinator PIN: ____ ____ ____ ____

14. Clinical Coordinator signature:

_____

15. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

nejmdat - Analysis dataset for primary outcome paper (modified for confidentiality)

Date file created: 21 Apr 2017
Observations: 738
Variables: 126

Variable Name	Variable Label	Type	Variable Length
agerg	Age at screening for LOTT (yrs)	Num	8
anemia	1=History of anemia at screening, 0=not	Num	8
anx12	Chg in HADS anxiety scr, FU-BL, 12 mos(Exp)	Num	8
anx24	Chg in HADS anxiety scr, FU-BL, 24 mos(Exp)	Num	8
anx36	Chg in HADS anxiety scr, FU-BL, 36 mos(Exp)	Num	8
anx48	Chg in HADS anxiety scr, FU-BL, 48 mos(Exp)	Num	8
anxsb	HADS anxiety score (0-21) at BL (Exp)	Num	8
avgo2perday	Avg hours of (total) O2 use per day	Num	8
black	1=African American race, 0=not	Num	8
bmi	Body mass index (kg/m2)	Num	8
bode	BODE index (0-10) BMI,obstr,dysp,exercis	Num	8
closef04dt	Date f04 window closes convrtd to #days from RZ	Num	8
closef12dt	Date f12 window closes convrtd to #days from RZ	Num	8
closef16dt	Date f16 window closes convrtd to #days from RZ	Num	8
closef24dt	Date f24 window closes convrtd to #days from RZ	Num	8
closef36dt	Date f36 window closes convrtd to #days from RZ	Num	8
closef48dt	Date f48 window closes convrtd to #days from RZ	Num	8
curro2	1=using O2 at screening, 2=not	Num	8
cvd	1=Coronary vascular disease at screen, 0=not	Num	8
death	1=Dead asof31Aug2015,0=alive asof31Aug2015	Num	8
deathdt	Date of death convrtd to #days from RZ	Num	8
dep12	Chg in HADS depr scr, FU-BL, 12 mos (Exp)	Num	8
dep24	Chg in HADS depr scr, FU-BL, 24 mos (Exp)	Num	8
dep36	Chg in HADS depr scr, FU-BL, 36 mos (Exp)	Num	8
dep48	Chg in HADS depr scr, FU-BL, 48 mos (Exp)	Num	8
depression	1=history of depression at BL, 0=not	Num	8
depsb	HADS depression score (0-21) at BL (Exp)	Num	8
desatqul_r6b	DesatQualifyPtForLOTT:1=RestOnly,2=ExerOnly,3=Both	Num	8
distft12	6 min walk dist (ft) at 12 mos	Num	8
distft24	6 min walk dist (ft) at 24 mos	Num	8
distft36	6 min walk dist (ft) at 36 mos	Num	8
distft48	6 min walk dist (ft) at 48 mos	Num	8
distftsb	6 min walk dist (ft) at scrning	Num	8
epsgrp	Epworth sleepiness: 1=0-5, 2=6-10, 3=11-15, 4=>15	Num	8
evhomeo2yn	1=used home O2 in past, 2=never used home O2	Num	8
ex	1=had initial COPDexac, 0=never COPDexac in LOTT	Num	8
exac3mosyn	1=had COPDexac in 3 mos prior to scrning, 2=no	Num	8
exachosp1yryn	1=COPD exac hosp in yr bef scrning, 0=no	Num	8
exdesat12	1=Severe exer desat found 12 mos, 0=no	Num	8
exdesat24	1=Severe exer desat found 24 mos, 0=no	Num	8
exdesat36	1=Severe exer desat found 36 mos, 0=no	Num	8
exdesat48	1=Severe exer desat found 48 mos, 0=no	Num	8
exhosp	.=never hosp,0=noCOPDhosp,1-11=#COPD hospsInFU	Num	8
exprimary	1=death or 1st hosp forCOPD, 0=neverDuringFU	Num	8
fev12	Chg in FEV1 (mL), FU-BL, at 12 mos (Exp)	Num	8
fev24	Chg in FEV1 (mL), FU-BL, at 24 mos (Exp)	Num	8
fev36	Chg in FEV1 (mL), FU-BL, at 36 mos (Exp)	Num	8
fev48	Chg in FEV1 (mL), FU-BL, at 48 mos (Exp)	Num	8
fevsb	FEV1 (mL) at scrning (core)	Num	8

nejmdat - Analysis dataset for primary outcome paper (modified for confidentiality)

Date file created: 21 Apr 2017
Observations: 738
Variables: 126

Variable Name	Variable Label	Type	Variable Length
fu	Days from randomization to last visit	Num	8
gender	1=male, 2=female	Num	8
gerdulcer	1=history of GERD,stom ulcer at scrning,0=not	Num	8
goldlung	GOLD lung function level (0-4, spiro crit only)	Num	8
hbsmkr	1=tobacco cigarette smoker at scrning, 0=not	Num	8
hosp	1=had init hosp in LOTT, 0=never hosp in LOTT	Num	8
hypertension	1=history of hypertension at scrning, 0=not	Num	8
marital	1=nver,2=marrid,3=separatd,divrcd,ann,4=widowed	Num	8
mcs12	Chg in SF-36 MCS score, FU-BL, 12 mos (Exp)	Num	8
mcs24	Chg in SF-36 MCS score, FU-BL, 24 mos (Exp)	Num	8
mcs36	Chg in SF-36 MCS score, FU-BL, 36 mos (Exp)	Num	8
mcs48	Chg in SF-36 MCS score, FU-BL, 48 mos (Exp)	Num	8
mcssb	SF-36 MCS score at scrning (Exp)	Num	8
medicare	1=pt has Medicare coverage, 0=not	Num	8
minority	1=minority race, 0=white caucasian only	Num	8
mmrc	MMRC dyspnea score (0-4, >=1 for LOTT elig)	Num	8
nadir10	10th lowest SpO2 during scrning 6 min walk	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
nex	Number of COPD exacs during LOTT follow-up	Num	8
nhosp	Number of hosps during LOTT follow-up	Num	8
nonexhosp	.=no hosp,0=no nonCOPD hosp,1-18=no.nonCOPDhosps	Num	8
o2group	blank=rzNoO2,0=rzO2,Rx 24-hr,1=rzO2,Rx slp/exr	Num	8
o2treated3	Group per actual O2 use,def 1,NEJM ppr Tab S7	Num	8
o2treated4	Group per actual O2 use,def 2,NEJM ppr,Tab S7	Num	8
openf04dt	Date f04 window opens convrtd to #days from RZ	Num	8
openf12dt	Date f12 window opens convrtd to #days from RZ	Num	8
openf16dt	Date f16 window opens convrtd to #days from RZ	Num	8
openf24dt	Date f24 window opens convrtd to #days from RZ	Num	8
openf36dt	Date f36 window opens convrtd to #days from RZ	Num	8
openf48dt	Date f48 window opens convrtd to #days from RZ	Num	8
oxygen	1=rz to Oxygen, 0=rz to No Oxygen	Num	8
packyrs	Pack-yrs of tobacco cig smkng as of scrning	Num	8
pcs12	Chg in SF-36 PCS scr, FU-BL, at 12 mos (Exp)	Num	8
pcs24	Chg in SF-36 PCS scr, FU-BL, at 24 mos (Exp)	Num	8
pcs36	Chg in SF-36 PCS scr, FU-BL, at 36 mos (Exp)	Num	8
pcs48	Chg in SF-36 PCS scr, FU-BL, at 48 mos (Exp)	Num	8
pcssb	SF-36 PCS score at scrning (Exp)	Num	8
posfevpp	Post BD FEV1 % predicted at scrning	Num	8
posff	Post BD FEV1/FVC ratio at scrning	Num	8
posfvcpp	Post BD FVC % predicted at scrning	Num	8
pq12	Chg in PSQI score, FU-BL, at 12 mos (Exp)	Num	8
pq24	Chg in PSQI score, FU-BL, at 24 mos (Exp)	Num	8
pq36	Chg in PSQI score, FU-BL, at 36 mos (Exp)	Num	8
pq48	Chg in PSQI score, FU-BL, at 48 mos (Exp)	Num	8
pqsb	PSQI score (0-21) at scrning (Exp)	Num	8
prefevpp	Pre BD FEV1 % pred at scrning	Num	8
primary	1=had prim outcome, 0=no prim outcome event	Num	8
qg04	Chg in SGRQ total scr, FU-BL, at 4 mos	Num	8
qg12	Chg in SGRQ total scr, FU-BL, at 12 mos	Num	8

nejmdat - Analysis dataset for primary outcome paper (modified for confidentiality)

Date file created: 21 Apr 2017
Observations: 738
Variables: 126

Variable Name	Variable Label	Type	Variable Length
qg16	Chg in SGRQ total scr, FU-BL, at 16 mos	Num	8
qg24	Chg in SGRQ total scr, FU-BL, at 24 mos	Num	8
qg36	Chg in SGRQ total scr, FU-BL, at 36 mos	Num	8
qg48	Chg in SGRQ total scr, FU-BL, at 48 mos	Num	8
qgsb	SGRQ total score (0-100) at scrning	Num	8
qw04	Chg in QWB total scr, FU-BL, at 4 mos	Num	8
qw12	Chg in QWB total scr, FU-BL, at 12 mos	Num	8
qw16	Chg in QWB total scr, FU-BL, at 16 mos	Num	8
qw24	Chg in QWB total scr, FU-BL, at 24 mos	Num	8
qw36	Chg in QWB total scr, FU-BL, at 36 mos	Num	8
qw48	Chg in QWB total scr, FU-BL, at 48 mos	Num	8
qwsb	QWB total score (0-1) at scrning	Num	8
restox12	Room air resting SpO2 at 12 mos	Num	8
restox24	Room air resting SpO2 at 24 mos	Num	8
restox36	Room air resting SpO2 at 36 mos	Num	8
restox48	Room air resting SpO2 at 48 mos	Num	8
restoxsb	Room air resting SpO2 at scrning	Num	8
rz2death	Days from rz to death or 31 Aug 2015	Num	8
rz2ex	Days from rz to 1st COPD exac/last visit	Num	8
rz2exhosp	Days fr rz to 1st hosp for COPD exac/last visit	Num	8
rz2exprimary	Days fr rz to death/1st COPDhosp/last visit	Num	8
rz2hosp	Days from rz to 1st hosp/last visit	Num	8
rz2nonexhosp	Days fr rz to 1st non COPDhosp/last visit	Num	8
rz2primary	Days from rz to prim outcome event/last visit	Num	8
sacpap	9=no slp apn at BL,0=no CPAP for slp apnea,1=CPAP	Num	8
sleepapnea	1=sleep apnea hist at BL, 0=not	Num	8
vasite	1=Enrolled at VA site, 2=not	Num	8
white	1=White race, 0=not	Num	8

oe1 - Form OE1 Oxygen Equipment

Date file created: 21 Apr 2017
Observations: 371
Variables: 44

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
oe108	8 Stopped using a category of equipment	Char	1
oe111	11 Newly provided a stationary oxygen concentrator	Char	1
oe112	12. Stationary conc mfr/model	Char	1
oe114	14. Newly provided gas tank system	Char	1
oe115	Date gas syst delivrd cnvrtd to #days from RZ	Num	8
oe117	17. Regulator used w/gas tank (pulse, continuous)	Char	1
oe118	18. Mfr/model of pulse reg used w/gas tank	Char	2
oe119	19 Newly provided a liquid oxygen base unit	Char	1
oe120	20 Manufacturer and model of base unit	Char	1
oe122	22. Liquid base unit used at rest or sleep	Char	1
oe123	23. Regulator used w/liq base (pulse, continuous)	Char	1
oe124	24. Mfr/model of pulse reg used w/liq base	Char	2
oe125	25. Newly provided portable liquid gas tank	Char	1
oe127	27. Capacity of portable liq gas tank (pounds)	Char	2
oe128	28. Type reg used w/port liq tank (pulse, continuous)	Char	1
oe129	29. Mfr/model of pulse reg used w/liq tank	Char	2
oe130	30 Newly provided a portable oxygen concentrator	Char	1
oe131	31. Mfr/model of portable concentrator	Char	1
oe133	33. Type of reg used w/port conc (pulse, continuous)	Char	1
oe134	34. Mfr/model of pulse reg used w/portable conc	Char	2
oe109a	9a Stationary oxygen concentrator	Char	1
oe109b	9b Pressurized cylinders of gaseous oxygen	Char	1
oe109c	9c Liquid oxygen base unit	Char	1
oe109d	9d. Portable liquid oxygen tank	Char	1
oe109e	9e Portable oxygen concentrator	Char	1
oe110a	10a Exchanged one stationary concentrator for another	Char	1
oe110b	10b Exchanged one cylinder of gaseous oxygen for another	Char	1
oe110c	10c Exchanged one liquid oxygen tank for another	Char	1
oe110d	10d Exchanged one portable oxygen concentrator for another	Char	1
oe110e	10e None of these items have been exchanged	Char	1
oe113a	Date stat conc meter read cnvrtd to #days from RZ	Num	8
oe113b	13b. Stationary conc meter reading	Char	7
oe116a	16a. Gas cylinder mfr	Char	1
oe116b	16b. Gas cylinder model	Char	2
oe116c	16c. Gas cylinder filling pressure (psi)	Char	4
oe121a	Date liq base filled cnvrtd to #days from RZ	Num	8
oe121b	21b. Pre fill weight of base unit (pounds)	Char	4
oe121c	21c. Post fill weight of base unit (pounds)	Char	4
oe132a	Date port conc meter read cnvrtd to #days from RZ	Num	8
oe132b	32b. Portable conc meter reading	Char	7
visit	Visit code	Char	3

LOTT

OE - Oxygen Equipment

Purpose: Use this form to document the patient's LOTT oxygen supplier, details about the stationary and portable oxygen equipment that the patient will use in LOTT, rescission of types of equipment, details about new types of equipment issued, and details on selected exchanges of equipment, all in LOTT.

Data collection level: All patients (Core) randomized to supplemental oxygen.

When: Visit rz (when equipment is first issued) and as needed in followup (use visit code n).

Administered by: Clinical Coordinator or Adherence Educator.

Instructions: This form is first completed after the patient has received his/her personal oxygen equipment shortly after randomization (use visit code rz). If the patient will continue to use equipment provided prior to randomization, you must record information about the equipment that the patient will now use in LOTT; you must obtain a meter reading on any concentrator as close to randomization as possible and obtain an estimate of the weight of liquid oxygen remaining in the base unit on the day of randomization. The Clinical Coordinator or Adherence Educator will obtain some of the needed information from the patient and some from the oxygen supply company. Subsequent to randomization, most updates to the patient's oxygen equipment will come from the patient's markup of the equipment list reviewed at each in person and telephone visit and reviewed by the patient every two months when adherence information is collected from the patient by mail. A new OE form should be completed (use visit code n) in any of these situations:

(1) The patient stops using a category of equipment and returns that equipment to the supply company; the categories of equipment are: Stationary concentrator, Pressurized cylinders of gaseous oxygen, Liquid oxygen base unit, Portable liquid oxygen tank, Portable oxygen concentrator.
(2) The patient is provided equipment in a category not previously provided; the categories of equipment are: Stationary concentrator, Pressurized cylinders of gaseous oxygen, Liquid oxygen base unit, Portable liquid oxygen tank, Portable oxygen concentrator.
(3) The patient exchanges selected item(s) of equipment. Complete a new OE form if the patient gets a new stationary concentrator (even if same manufacturer/model, LOTT needs the initial meter reading), gets a new manufacturer/model/usual size cylinder of gaseous oxygen (LOTT needs the cylinder fill pressure), gets a new manufacturer/model/ usual size portable liquid oxygen tank (LOTT needs the tank capacity), or gets a new portable oxygen concentrator (even if same manufacturer/model, LOTT needs the initial meter reading). Other exchanges of equipment items do not require a new OE form to be completed.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date form was initiated):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: o e 1

B. Oxygen supply company

7. Contact information

a. Company name:

_____
specify company name

b. Contact person's name:

_____
specify contact person

c. Telephone number:

_____
specify telephone number

C. Rescission of a category of equipment previously issued in LOTT *(if this is the rz visit, answer "No" to item 8)*

8. Has the patient stopped using a category of equipment in LOTT *("stopped using" means the equipment has been returned to the company and patient no longer has that category of equipment in the home):*

Yes (1) No (2) **11.**

9. What category(s) of equipment has the patient stopped using *(check all that apply)*

a. Stationary oxygen concentrator: (1)

b. Pressurized cylinders of gaseous oxygen: (1)

c. Liquid oxygen base unit: (1)

d. Portable liquid oxygen tank for use with liquid oxygen base unit: (1)

e. Portable oxygen concentrator: (1)

D. Exchange of selected item(s) of equipment within the same category during LOTT

10. Which items has the patient exchanged *(check all that apply)*

a. Exchanged one stationary concentrator for another: (1)

b. Exchanged one manufacturer/model/usual size cylinder of gaseous oxygen for another manufacturer/model/size: (1)

c. Exchanged one manufacturer/model/usual size liquid oxygen tank for another manufacturer/model/size: (1)

d. Exchanged one portable oxygen concentrator for another: (1)

e. None of these items have been exchanged: (1)

E. Stationary concentrator

11. Was the patient newly provided a stationary oxygen concentrator?

Yes (1) No (2) **14.**

12. Manufacturer and model:

Invacare 5LPM	(1)
Invacare 10LPM	(2)
Respironics Everflow	(3)
Respironics Millennium 5LPM	(4)
Respironics Millennium M10	(5)
SeQual Integra 7	(6)
SeQual Integra 10	(7)
Other *(specify)*	(8)

_____
specify manufacturer/model

13. Initial meter reading on concentrator *(Clinical Coordinator or Aherence Educator should obtain this information from the oxygen supply company or the patient)*

a. Date read:

__ __ – __ __ – __ __
day mon year

b. Reading:

__ __ __ __ __ __ • __

F. Pressurized gaseous oxygen system

14. Was the patient newly provided a high pressure gaseous oxygen system (cylinder and regulator) or new cylinder model or size or compressor which may be used with a stationary concentrator to fill cylinders at home:

Yes (1) No (2) **19.**

15. Date delivered to patient:

__ __ – __ __ – __ __
day mon year

16. Cylinder information *(if issued more than one size cylinder, record information for cylinder size patient will likely use most of the time)*

a. Cylinder manufacturer:

Luxfer (1)
Other *(specify):* (2)

_____
specify cylinder manufacturer

b. Cylinder model:

M004 (01)
M006 (02)
M006A (03)
M007 (04)
M009 (05)
M011 (06)
MD15 (07)
M018 (08)
M022 (09)
ME24 (10)
M060 (11)
M00M (12)
M265 (13)
M04T (14)
M05T (15)
M06F (16)
M06T (17)
M08D (18)
M08T (19)
M11T (20)
M14T (21)
M15T (22)
M16T (23)
M21T (24)
M23A (25)
Other *(specify)* (26)

_____
specify cylinder model

c. Cylinder filling pressure:

____ ____ ____ ____
psi

17. Type of regulator used with cylinder *(check only one):*

Pulse (conserver) (1)
Continuous flow (2)

19.

18. Manufacturer and model of pulse (conserver) regulator:

CR-50 (01)
Cypress 511 (02)
Easy Pulse (03)
EX3000 (04)
Impulse Elite A (05)
Impulse Elite B (06)
Mini O2 (07)
O2 On Demand II (08)
O2 Express (09)
OPC 830 (10)
Oxyclip (11)
Oxymatic 401 (12)
Oxymatic 411 (13)
PD 1000 (14)
PD 4000 (15)
Sequoia 302 (16)
Sequoia 311 (17)
Venture (18)
Other *(specify)* (19)

_____
specify manufacturer/model

G. Liquid oxygen base unit

19. Was the patient newly provided a liquid oxygen base unit:

Yes (1) No (2)

25.

20. Manufacturer and model of base unit:

Helios (1)
Spirit (2)
Other *(specify)* (3)

_____
specify manufacturer/model

21. Initial fill of base unit *(Clinical Coordinator or Adherence Educator should obtain this information from the oxygen supply company or the patient)*

a. Date filled:

____ ____–____ ____ ____–____ ____
day mon year

b. Pre fill weight: ____ ____ ____ • ____ pounds

c. Post fill weight: ____ ____ ____ • ____ pounds

22. Is the liquid oxygen base unit used at rest or during sleep:

Yes (1) No (2)

25.

23. Type of regulator used with base unit for rest or during sleep *(check only one):*

Pulse (conserver) (1)
Continuous flow (2)

25.

24. Manufacturer and model of regulator:

CR-50 (01)
Cypress 511 (02)
Easy pulse (03)
EX3000 (04)
Impulse Elite A (05)
Impulse Elite B (06)
Mini O2 (07)
O2 On Demand II (08)
O2 Express (09)
OPC 830 (10)
Oxyclip (11)
Oxymatic 401 (12)
Oxymatic 411 (13)
PD 1000 (14)
PD 4000 (15)
Sequoia 302 (16)
Sequoia 311 (17)
Venture (18)
Other *(specify)* (19)

_____
specify manufacturer/model

H. Liquid oxygen portable tank

25. Was the patient newly provided a portable liquid oxygen tank to use with the liquid oxygen base unit or a new model/capacity liquid oxygen tank:

Yes (1) No (2)

30.

26. Manufacturer and model of portable liquid oxygen tank:

_____
specify manufacturer/model

27. Capacity of portable liquid oxygen tank:

____ • ____ pounds

28. Type of regulator used with portable liquid oxygen tank *(check only one):*

Pulse (conserver) (1)
Continuous flow (2)

30.

29. Manufacturer and model of regulator:

CR-50 (01)
Cypress 511 (02)
Easy pulse (03)
EX3000 (04)
Impulse Elite A (05)
Impulse Elite B (06)
Mini O2 (07)
O2 On Demand II (08)
O2 Express (09)
OPC 830 (10)
Oxyclip (11)
Oxymatic 401 (12)
Oxymatic 411 (13)
PD 1000 (14)
PD 4000 (15)
Sequoia 302 (16)
Sequoia 311 (17)
Venture (18)
Other *(specify)* (19)

_____
specify manufacturer/model

I. Portable oxygen concentrator

30. Was the patient newly provided a portable oxygen concentrator:

(Yes 1) (No 2)

35.

31. Manufacturer and model:

Evergo	(1)
Excel	(2)
Inogen One	(3)
SeQual Eclipse	(4)
Other *(specify)*	(5)

_____
specify manufacturer/model

32. Initial meter reading

a. Date read:

____ ____–____ ____ ____–____ ____
day mon year

b. Reading:

____ ____ ____ ____ ____ ____ • ____

33. Type of regulator used with portable oxygen concentrator *(check only one):*

Pulse (conserver)	(1)
Continuous flow	(2)

35.

34. Manufacturer and model of regulator:

CR-50	(01)
Cypress 511	(02)
Easy pulse	(03)
EX3000	(04)
Impulse Elite A	(05)
Impulse Elite B	(06)
Mini O2	(07)
O2 On Demand II	(08)
O2 Express	(09)
OPC 830	(10)
Oxyclip	(11)
Oxymatic 401	(12)
Oxymatic 411	(13)
PD 1000	(14)
PD 4000	(15)
Sequoia 302	(16)
Sequoia 311	(17)
Venture	(18)
Other *(specify)*	(19)

_____
specify manufacturer/model

J. Administrative information

35. Clinical Coordinator or Adherence Educator PIN:

____ ____ ____ ____

36. Clinical Coordinator or Adherence Educator signature:

_____

37. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

of2 - Oxygen Equipment in Use Listing

Date file created: 21 Apr 2017
Observations: 999
Variables: 19

Variable Name	Variable Label	Type	Variable Length
concentrator	Stationary conc mfr/model (coded per oe112)	Char	5
cylfillpress	Gas tank filling pressure (psi)	Char	4
cylmanufact	Gas tank mfr (coded per oe116a)	Char	5
cylmodel	Gas tank model (coded per oe116b)	Char	5
cylregmfrmodel	Mfr/model gas tank reg (coded per oe118)	Char	5
cylregtype	Gas tank reg (pulse, continuous, coded per oe117)	Char	5
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
liqbasemfrmodel	Mfr/model of liq base unit (coded per oe120)	Char	5
liqbaseregmfrmodel	Liq base unit reg mfr/model (coded per oe124)	Char	5
liqbaseregtype	Liq base unit reg type (coded per oe123)	Char	5
liqportregmfrmodel	Liq port tank reg mfr/model (coded per oe129)	Char	5
liqportregtype	Liq port tank reg type (coded per oe128)	Char	5
liqportsize	Liq port tank capacity (pounds)	Char	5
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
pconcmfrmodel	Portable conc mfr/model (coded per oe131)	Char	5
pconcregmfrmodel	Port conc reg mfr/model (coded per oe134)	Char	5
pconcregtype	Port conc reg (pulse/continuous (coded per oe133)	Char	5
visit	Visit code	Char	5

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LOTT keyed ( )

Long Term Oxygen Treatment Trial (LOTT)

Oxygen Equipment in Use

A. RCC, patient, and date information

1. RCC: zzz

2. Date generated: 2/11/2009

3. Patient ID: za001

4. Patient code: alex

5. Date mailed to patient _____

B. Oxygen supply company and equipment information

Listed below is the oxygen supply company and equipment that we believe you are using. Please review this information and mark any corrections needed.

If no corrections are needed, please check the No corrections box at the end of the listing.

		Corrections
Oxygen company name:	roberts	_____
Portable oxygen concentrator		
Manufacturer/model:	Evergo	_____
Regulator type:	Pulse (conserver)	_____
Regulator manufacturer/model:	Oxyclip	_____

No corrections needed: ( )

Date reviewed by patient: _____

Thank you! Please return to your LOTT center.

C. Administrative information *(clinic use only)*

6. Date reviewed at clinic: _____

7. Clinical Coordinator PIN: _____

LOTT

keyed ( )

Long Term Oxygen Treatment Trial (LOTT)

Oxygen Equipment in Use

A. RCC, patient, and date information

1. RCC: [redacted]
2. Date generated: [redacted]
3. Patient ID: [redacted]
4. Patient code: [redacted]
5. Date mailed to patient _____

B. Oxygen supply company and equipment information

Listed below is the oxygen supply company and equipment that we believe you are using. Please review this information and mark any corrections needed.

If no corrections are needed, please check the No corrections box at the end of the listing.

		Corrections
Oxygen company name:	lincare healthcare solutions	_____
Liquid oxygen base unit (reservoir)		
Manufacturer/model of base unit:	Helios	_____
Regulator type:	Continuous flow	_____
Regulator manufacturer/model:	Not applicable	_____
Liquid oxygen portable tank		
Manufacturer/model/capacity of portable tank:	helios, 1.0 pounds	_____
Regulator type:	Continuous flow	_____
Regulator manufacturer/model:	Not applicable	_____

No corrections needed: ( )

Date reviewed by patient: _____

Thank you! Please return to your LOTT center.

C. Administrative information *(clinic use only)*

6. Date reviewed at clinic: _____
7. Clinical coordinator PIN: _____
8. Clinical coordinator signature: _____

LOTT

keyed ( )

Long Term Oxygen Treatment Trial (LOTT)

Oxygen Equipment in Use

A. RCC, patient, and date information

1. RCC: [redacted]
2. Date generated: [redacted]
3. Patient ID: [redacted]
4. Patient code: [redacted]
5. Date mailed to patient _____

B. Oxygen supply company and equipment information Listed below is the oxygen supply company and equipment that we believe you are using. Please review this information and mark any corrections needed.

If no corrections are needed, please check the No corrections box at the end of the listing.

		Corrections
Oxygen company name:	apria care	_____
Stationary concentrator:		
Manufacturer/model:	airsep visionaire	_____
Tanks (cylinders) of gaseous oxygen		
Tank manufacturer/size/fill pressure:	catalina cylinders/unknown/2000 psi	_____
Regulator type:	Continuous flow	_____
Regulator manufacturer/model:	Not applicable	_____

No corrections needed: ( )

Date reviewed by patient: _____

Thank you! Please return to your LOTT center.

C. Administrative information *(clinic use only)*

6. Date reviewed at clinic: _____
7. Clinical coordinator PIN: _____
8. Clinical coordinator signature: _____

oxim6mw - 6 Minute Walk Oximetry Data

Date file created: 21 Apr 2017
Observations: 402411
Variables: 7

Variable Name	Variable Label	Type	Variable Length	Format
filenum	File number in original LOX file name	Num	3	
hr	Heart rate (beats per min)	Num	8	
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5	
oximtime	Time datapoint was obtained (per oximeter clock)	Num	8	TIME
spo2	SpO2 (%)	Num	8	
testdate	Test date cnvrtd to #days from RZ	Num	8	
visit	Visit code	Char	3	

oximrest - Resting Oximetry Data

Date file created: 21 Apr 2017
Observations: 899280
Variables: 7

Variable Name	Variable Label	Type	Variable Length	Format
filenum	File number (report ID) in original file name	Char	3	
hr	Heart rate (beats/min, numeric)	Num	8	
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5	
oximtime	Oximeter time of data acquisition (per oximeter clock)	Num	8	TIME
spo2	SpO2 (%, numeric)	Num	8	
testdate	Test date cnvrtd to #days from RZ	Num	8	
visit	Visit code	Char	3	

pe1 - Form PE1 Physical Examination

Date file created: 21 Apr 2017
Observations: 2575
Variables: 18

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
pe107	7 Visit sb	Char	1
pe110	10 Resting radial pulse	Char	3
pe111	11 Pretibial pitting edema	Char	1
pe108a	8a Weight	Char	4
pe108b	8b Units of weight measurement	Char	1
pe109a	9a Systolic blood pressure	Char	3
pe109b	9b Diastolic blood pressure	Char	3
pe112a	12a Decreased intensity of breath sounds	Char	1
pe112b	12b Prolongation of expiration	Char	1
pe112c	12c Rales or crackles	Char	1
pe112d	12d Rhonchi	Char	1
pe112e	12e Wheezes	Char	1
pe112f	12f Other	Char	1
pe112g	12g None of the above	Char	1
visit	Visit code	Char	3

LOTT

PE - Physical Examination

Purpose: Record physical exam findings.
Data collection level: All patients (Core).
When: Visits sb, f12, f24, f36, f48, f60, f72.
Administered by: Clinical Coordinator, Physical Exam Assessor, or Study Physician at site's discretion. Clinical Coordinator must review the completed form.
Respondent: Patient.
Instructions: Weight should be measured with shoes off and after items have been removed from pockets. Blood pressure may be measured with the patient supine or sitting; the patient should relax for 5 minutes before measurement is taken. Count the pulse for 30 seconds and multiply by 2 to obtain beats per minute. Pretibial edema should be assessed **with the socks rolled down (clear hose is OK)**. Report edema of the worst leg. Press on the skin with moderate pressure and assess the pitting.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date of exam):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: p e 1

B. Findings

7. Is this visit sb:

Yes (1) No (2)

9.

8. Weight

a. Measurement: ____ ____ ____ • ____

b. Units:
Pounds (1)
Kilograms (2)

9. Blood pressure *(patient should relax 5 minutes supine or sitting before measurement is taken)*

a. Systolic: ____ ____ ____ mmHg

b. Diastolic: ____ ____ ____ mmHg

10. Resting radial pulse *(count for 30 seconds and multiply by 2):*

____ ____ ____ beats/minute

11. Pretibial pitting edema *(roll down socks, press on legs with moderate pressure, report edema of worst leg; check only one):*

None or trace (1)
More than trace (2)

12. Chest and lung abnormalities *(check all that apply)*

a. Decreased intensity of breath sounds: (1)
b. Prolongation of expiration: (1)
c. Rales or crackles: (1)
d. Rhonchi: (1)
e. Wheezes: (1)
f. Other *(specify):* (1)

_____
specify abnormality

g. None of the above: (1)

C. Administrative information

13. PIN of certified staff member completing the exam:

____ ____ ____ ____

14. Signature of certified staff member completing the exam:

_____

15. Clinical Coordinator PIN: ____ ____ ____ ____

16. Clinical Coordinator signature:

_____

17. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

pq1 - Form PQ1 Pittsburgh Sleep Quality Index

Date file created: 21 Apr 2017
Observations: 2237
Variables: 38

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
pq109	9 Time usually go to bed	Char	4
pq110	10 Minutes taken to fall asleep	Char	3
pq111	11 Time usually wake up	Char	4
pq112	12 Hours of sleep per night	Char	2
pq114	14 Rate overall sleep quality	Char	1
pq115	15 Taken medicine to help you sleep	Char	1
pq116	16 Trouble staying awake while driving	Char	1
pq117	17 Problem getting things done	Char	1
pq118	18 Have a bed partner or roommate	Char	1
pq109a	9 am=1 pm=2	Char	1
pq111a	11 am=1 pm=2	Char	1
pq113a	13a Cannot get to sleep within 30 minutes	Char	1
pq113b	13b Wake up in middle of night or early	Char	1
pq113c	13c Get up to go to bathroom	Char	1
pq113d	13d Cannot breathe comfortably	Char	1
pq113e	13e Cough or snore loudly	Char	1
pq113f	13f Feel too cold	Char	1
pq113g	13g Feel too hot	Char	1
pq113h	13h Have bad dreams	Char	1
pq113i	13i Have pain	Char	1
pq113j	13j Other reason	Char	1
pq119a	19a Loud snoring	Char	1
pq119b	19b Long pauses between breaths	Char	1
pq119c	19c Legs twitching or jerking	Char	1
pq119d	19d Episodes of disorientation or confusion	Char	1
pq119e	19e Other restlessness during sleep	Char	1
psqi_c1	PSQI component 1 = subjective sleep quality (0-3)	Num	8
psqi_c2	PSQI component 2 = sleep latency (0-3)	Num	8
psqi_c3	PSQI component 3 = sleep duration (0-3)	Num	8
psqi_c4	PSQI component 4 = habitual sleep efficiency (0-3)	Num	8
psqi_c5	PSQI component 5 = sleep disturbances (0-3)	Num	8
psqi_c6	PSQI component 6 = use of sleeping medicine (0-3)	Num	8
psqi_c7	PSQI component 7 = daytime dysfunction (0-3)	Num	8
psqi_tot	PSQI total score (0-21)	Num	8
visit	Visit code	Char	3

PQ - Pittsburgh Sleep Quality Index©

Purpose: To obtain information about the patient's sleep quality.
Data collection level: Expanded.
When: Visits sb, f12, f24, f36, f48, f60, f72.
Administered by: Self-administered, but Clinical Coordinator must be available to answer questions and review completed forms.
Respondent: Patient. If patient has a room mate or bed partner, that person responds to the last few questions.
Instructions: The Clinical Coordinator completes page 1 of this form; the patient completes pages 2-6. A label (with patient ID, patient code and visit code) should be affixed to the upper right corner of pages 2-6. The patient should meet with the Clinical Coordinator, be instructed in completion of the form, and then should complete the form. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by the Clinical Coordinator and re-attached to pages 2-6.
Reference: Buysse DJ, Reynolds CF III, Monk TH, Berman SR, Kupfer DJ: The Pittsuburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Research* 1989;28:193-213.

A. Clinic, visit, and patient identification

1. RCC ID: _____ _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____ _____

3. Patient code: _____ _____ _____ _____

4. Visit date *(date patient completed the form)*:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____ _____

6. Form & revision: **p q 1**

B. Administrative information

(To be completed by Clinical Coordinator after questionnaire is completed)

7. Clinical Coordinator
- **a**. PIN: _____ _____ _____ _____
- **b**. Signature:

_____

8. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

161
Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Pittsburgh Sleep Quality Index©

(Items 1-8 are reserved for clinic use)

The following questions relate to your usual sleep habits during the past month *only*. Your answers should indicate the most accurate replay for the *majority* of days and nights in the past month. Please answer all questions.

9. During the past month, when have you usually gone to bed at night?

Usual bed time: ____ ____:____ ____ ($_{am}^{1}$) ($_{pm}^{2}$)

10. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

Number of minutes: ____ ____ ____

11. During the past month, when have you usually gotten up in the morning?

Usual getting up time: ____ ____:____ ____ ($_{am}^{1}$) ($_{pm}^{2}$)

12. During the past month, how many hours of *actual sleep* did you get at night *(this may be different than the number of hours you spend in bed)*?

Hours of sleep per night: ____ ____

For each of the remaining questions, check the one best response. Please answer *all* questions.

13. During the past month, how often have you had trouble sleeping because you ...

	Circle one			
	Not during the past month	**Less than once a week**	**Once or twice a week**	**Three or more times a week**
a. Cannot get to sleep within 30 minutes	0	1	2	3
b. Wake up in the middle of the night or early morning	0	1	2	3
c. Have to get up to use the bathroom	0	1	2	3
d. Cannot breathe comfortably	0	1	2	3
e. Cough or snore loudly	0	1	2	3
f. Feel too cold	0	1	2	3
g. Feel too hot	0	1	2	3
h. Had bad dreams	0	1	2	3
i. Have pain	0	1	2	3
j. Other reason, please describe _____ _____	0 *(no other reason in the past month)*	1	2	3

14. During the past month, how would you rate your sleep quality overall:

Circle One

Very good 0

Fairly good 1

Fairly bad 2

Very bad 3

15. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep:

Circle One

Not during the past month 0

Less than once a week 1

Once or twice a week 2

Three or more times a week 3

16. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity:

Circle One

Not during the past month 0

Less than once a week 1

Once or twice a week 2

Three or more times a week 3

17. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done:

Circle One

No problem at all 0

Only a very slight problem 1

Somewhat of a problem 2

A very big problem 3

18. Do you have a bed partner or roommate:

Circle One

No bed partner or roommate 0

STOP; Thank you! ↵

Partner/roommate in other room 1

Partner in same room, but not same bed 2

Partner in same bed 3

19. If you have a roommate or bed partner, ask him/her how often in the past month you have had ...

	Circle one			
	Not during the past month	**Less than once a week**	**Once or twice a week**	**Three or more times a week**
a. Loud snoring	0	1	2	3
b. Long pauses between breaths while asleep	0	1	2	3
c. Legs twitching or jerking while you sleep	0	1	2	3
d. Episodes of disorientation or confusion during sleep	0	1	2	3
e. Other restlessness while you sleep; please describe _____ _____	0	1	2	3

Thank you!

qf1 - Form QF1 SF-36 v2 Health Survey

Date file created: 21 Apr 2017
Observations: 2238
Variables: 50

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
mcs	SF-36v2 mental component summary score	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
pcs	SF-36v2 physical component summary score	Num	8
qf109	9 In general, health is	Char	1
qf110	10 Rate health compared to one year ago	Char	1
qf114	14 Health/emotions interfere with social activities	Char	1
qf115	15 How much bodily pain in past 4 weeks	Char	1
qf116	16 Did pain interfere with normal work	Char	1
qf118	18 Problems interfered w/social activities	Char	1
qf111a	11a Limit vigorous activities	Char	1
qf111b	11b Limit moderate activities	Char	1
qf111c	11c Limit lifting/carrying groceries	Char	1
qf111d	11d Limit climbing several stair flights	Char	1
qf111e	11e Limit climbing one stair flight	Char	1
qf111f	11f Limit bending, kneeling, stooping	Char	1
qf111g	11g Limit walking more than a mile	Char	1
qf111h	11h Limit walking hundred yards	Char	1
qf111i	11i Limit walking one hundred yards	Char	1
qf111j	11j Limit bathing/dressing self	Char	1
qf112a	12a Cut down work time-physical health problems	Char	1
qf112b	12b Accomplished less than liked	Char	1
qf112c	12c Limited activities-health problem	Char	1
qf112d	12d Difficulty doing work/activities-health problem	Char	1
qf113a	13a Cut down work time-emotional problems	Char	1
qf113b	13b Accomplished less than liked-emotional problems	Char	1
qf113c	13c Did activities less carefully-emotional problems	Char	1
qf117a	17a Did you feel full of life	Char	1
qf117b	17b Have you been very nervous	Char	1
qf117c	17c Have you felt down in dumps	Char	1
qf117d	17d Have you felt calm and peaceful	Char	1
qf117e	17e Did you have a lot of energy	Char	1
qf117f	17f Have you felt downhearted	Char	1
qf117g	17g Did you feel worn out	Char	1
qf117h	17h Have you been happy	Char	1
qf117i	17i Did you feel tired	Char	1
qf119a	19a Seem to get sick easier than other people	Char	1
qf119b	19b Healthy as anybody I know	Char	1
qf119c	19c Expect health to get worse	Char	1
qf119d	19d Health is excellent	Char	1
visit	Visit code	Char	3
wgenhlth	SF-36v2 general health score (Ware)	Num	8
wmenhlth	SF-36v2 mental health score (Ware)	Num	8
wpain	SF-36v2 pain score (Ware)	Num	8
wphyfunc	SF-36v2 physical functioning score (Ware)	Num	8
wrolemot	SF-36v2 role emotional score (Ware)	Num	8
wrolephy	SF-36v2 role physical score (Ware)	Num	8
wsocfunc	SF-36v2 social functioning score (Ware)	Num	8

qf1 - Form QF1 SF-36 v2 Health Survey

Date file created: 21 Apr 2017
Observations: 2238
Variables: 50

Variable Name	Variable Label	Type	Variable Length
wvital	SF-36v2 vitality score (Ware)	Num	8

QF – SF-36 v2™ Health Survey

Keyed: ( )

Purpose: To obtain the patient's views of his/her health and well-being.
Data collection level: Expanded.
When: Visits sb, f12, f24, f36, f48, f60, f72.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and review the completed form.
Respondent: Patient, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A below and attach a label to each of pages 2-7.
Visit sb: The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-7. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-7 and the Clinical Coordinator should complete section B below. **Visits f12, f24, f36, f48:** Pages 2-7 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and to bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be attached to pages 2-7 and the Clinical Coordinator should complete section B below. Fill in item 4 with the date the patient wrote in item 20. If the patient did not write in a date, use the date of the study visit for the visit date.

A. Center, visit, and patient identification

1. RCC ID: _____ _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____ _____

3. Patient code: _____ _____ _____ _____

4. Visit date *(date patient completed the form)*:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____ _____

6. Form & revision: **q f 1**

B. Administrative information

(To be completed by Clinical Coordinator after questionnaire is completed)

7. Clinical Coordinator
a. PIN: _____ _____ _____ _____
b. Signature: _____

8. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Affix label here

Patient ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Your Health and Well-Being

(Items 1-8 are reserved for clinic use)

Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

9. In general, would you say your health is:

	Circle one
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

10. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

Affix label here

Patient ID: __ __ __ __ __ __

Pt code: __ __ __ __ __

Visit code: __ __ __

11. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	Circle one		
	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports:	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:	1	2	3
c. Lifting or carrying groceries:	1	2	3
d. Climbing several flights of stairs:	1	2	3
e. Climbing one flight of stairs:	1	2	3
f. Bending, kneeling, or stooping:	1	2	3
g. Walking more than a mile:	1	2	3
h. Walking several hundred yards:	1	2	3
i. Walking one hundred yards:	1	2	3
j. Bathing or dressing yourself:	1	2	3

Affix label here

Patient ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

12. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Circle one				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Cut down on the amount of time you spent on work or other activities:	1	2	3	4	5
b. Accomplished less than you would like:	1	2	3	4	5
c. Were limited in the kind of work or other activities:	1	2	3	4	5
d. Had difficulty performing the work or activities (for example, it took extra effort):	1	2	3	4	5

13. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Circle one				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Cut down on the amount of time you spent on work or other activities:	1	2	3	4	5
b. Accomplished less than you would like:	1	2	3	4	5
c. Did work or other activities less carefully than usual:	1	2	3	4	5

Affix label here

Patient ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

14. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Circle one

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

15. How much bodily pain have you had during the past 4 weeks?

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

16. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

Affix label here

Patient ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

17. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

	Circle one				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt downhearted and depressed?	1	2	3	4	5
g. Did you feel worn out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
i. Did you feel tired?	1	2	3	4	5

18. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

Circle one

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

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Affix label here

Patient ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

19. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Circle one				
	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

20. Date completed:

_____

Thank you for completing these questions!

Please bring this completed survey with you to your scheduled LOTT study visit.

qg2 - Form QG2 The St Georges Respiratory Questionnaire

Date file created: 21 Apr 2017
Observations: 3844
Variables: 59

Variable Name	Variable Label	Type	Variable Length
act	SGRQ activities score	Num	8
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
imp	SGRQ impact score	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
qg209	9 Coughed over past 4 weeks	Char	1
qg210	10 Brought up phlegm over past 4 weeks	Char	1
qg211	11 Shortness of breath over past 4 weeks	Char	1
qg212	12 Wheezing episodes over past 4 weeks	Char	1
qg213	13 No of severe respiratory attacks	Char	1
qg214	14 Length of worst attack	Char	1
qg215	15 No of good days/week over past 4 weeks	Char	1
qg216	16 Wheeze worse in the morning	Char	1
qg217	17 Describe respiratory condition	Char	1
qg218	18 If ever had a job	Char	1
qg219	19 Short of breath when sitting/lying still	Char	1
qg220	20 Short of breath when getting washed/dressed	Char	1
qg221	21 Short of breath when walking in house	Char	1
qg222	22 Short of breath when walking outside on level	Char	1
qg223	23 Short of breath when walking up stairs	Char	1
qg224	24 Short of breath when walking up hills	Char	1
qg225	25 Short of breath when playing sports/games	Char	1
qg226	26 Hurts to cough	Char	1
qg227	27 Cough makes me tired	Char	1
qg228	28 Breathless when I talk	Char	1
qg229	29 Short of breath when I bend over	Char	1
qg230	30 Cough/breathing disturbs sleep	Char	1
qg231	31 Get exhausted easily	Char	1
qg232	32 Cough/breathing is embarrassing	Char	1
qg233	33 Lung problem is nuisance to family/friends	Char	1
qg234	34 I panic when cannot get my breath	Char	1
qg235	35 I feel not in control of lung problem	Char	1
qg236	36 I do not expect lung problem to get better	Char	1
qg237	37 I am frail/invalid because of lung problem	Char	1
qg238	38 Exercise is not safe for me	Char	1
qg239	39 Everything seems too much of an effort	Char	1
qg240	40 Treatment for lung problem	Char	1
qg241	41 Treatment does not help me very much	Char	1
qg242	42 Embarrassed using medication in public	Char	1
qg243	43 Medication side effects are unpleasant	Char	1
qg244	44 Treatment interferes with my life a lot	Char	1
qg245	45 Take long time to wash or dress	Char	1
qg246	46 Cannot bathe/shower, or take a long time	Char	1
qg247	47 Walk slower than other people/stop to rest	Char	1
qg248	48 Housework takes long time/stop to rest	Char	1
qg249	49 Walk slowly/stop up 1 flight of stairs	Char	1
qg250	50 Stop/slow down when walk fast or hurry	Char	1
qg251	51 Difficult to do gardening, golf, etc	Char	1
qg252	52 Difficult to carry heavy loads, jog, etc	Char	1

qg2 - Form QG2 The St Georges Respiratory Questionnaire

Date file created: 21 Apr 2017
Observations: 3844
Variables: 59

Variable Name	Variable Label	Type	Variable Length
qg253	53 Difficult to do heavy manual work, run, etc	Char	1
qg254	54 Cannot play sports or games	Char	1
qg255	55 Cannot go out for entertainment/recreation	Char	1
qg256	56 Cannot go out to shop	Char	1
qg257	57 Cannot do housework	Char	1
qg258	58 Cannot move far from bed or chair	Char	1
qg259	59 How respiratory problems affect me	Char	1
sgrqtot	SGRQ total score	Num	8
symp	SGRQ symptoms score	Num	8
visit	Visit code	Char	3

QG - The St. George's Respiratory Questionnaire

Purpose: To learn more about how the patient's breathing troubles him/her and affects his/her life.
Data collection level: All patients (Core).
When: Visits sb, f04, f12, f16, f24, f36, f48, f60, f72.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and review completed questionnaires.
Respondent: Patient without help from spouse or family.
Instructions: **All visits**: The Clinical Coordinator completes page 1 of this form; the patient completes pages 2-10. A label (with patient ID, patient code, and visit code) should be affixed to the upper right corner of pages 2-10. **Visit sb:** The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should be given pages 2-10 to complete. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by the Clinical Coordinator and re-attached to pages 2-10. **Visits f04, f16**: Pages 2-10 should be mailed to the patient 2 weeks before the target date for the visit by mail with instructions to complete the form at home and to return the form to the clinic by mail in the stamped, addressed envelope provided. When the form is received at the clinic, the Clinical Coordinator should review the form for completeness and obtain responses for missing items by telephone (1 attempt). If the patient did not write a date in item 60, use the date the form was mailed to the patient. Page 1 should be completed by the Clinical Coordinator and re-attached to pages 2-10. **Visits f12, f24, f36, f48**: Pages 2-10 should be mailed to the patient 2 weeks prior to the scheduled LOTT clinic visit with instructions to complete the form at home and to bring the completed form to the next LOTT clinic visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the clinic visit. If the patient did not write in a date in item 60, use the date of the clinic visit for the visit date. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be completed by the Clinical Coordinator and re-attached to pages 2-10.

A. Clinic, visit, and patient identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date patient completed the form)*:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **q g 2**

B. Administrative information

(To be completed by Clinical Coordinator staff after questionnaire is completed)

7. Clinical Coordinator
a. PIN: ____ ____ ____ ____
b. Signature:

_____

8. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

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Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

The St. George's Respiratory Questionnaire

(Items 1-8 are reserved for clinic use.)

This questionnaire is designed to help us learn more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully.
Do not spend too long deciding about your answers.

Part 1 – Four Week Description

Please describe how often your respiratory problems have affected you over the past 4 weeks. Please circle one answer for each question.

9. Over the past 4 weeks, I have coughed:

Circle One

Almost every day. 1

Several days a week. 2

A few days a month. 3

Only with respiratory infections. 4

Not at all. 5

10. Over the past 4 weeks, I have brought up phlegm (sputum):

Almost every day. 1

Several days a week. 2

A few days a month. 3

Only with respiratory infections. 4

Not at all. 5

LOTT

179
Affix label here

Pt ID: ___ ___ ___ ___ ___

Pt code: ___ ___ ___ ___

Visit code: ___ ___ ___

11. Over the past 4 weeks, I have had shortness of breath:

Circle One

Almost every day. 1

Several days a week. 2

A few days a month. 3

Only with respiratory infections. 4

Not at all. 5

12. Over the past 4 weeks, I have had wheezing attacks:

Almost every day. 1

Several days a week. 2

A few days a month. 3

Only with respiratory infections. 4

Not at all. 5

13. How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks:

More than 3 times. 1

3 times. 2

2 times. 3

1 time. 4

None of the time. 5

Go to 15.

180
Affix label here

Pt ID: ___ ___ ___ ___ ___

Pt code: ___ ___ ___ ___

Visit code: ___ ___ ___

14. How long did the worst respiratory attack last:

Circle One

A week or more. 1

3 or more days. 2

1 or 2 days.. 3

Less than a day. 4

15. Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had:

No good days. 1

1 or 2 good days. 2

3 or 4 good days. 3

Nearly every day is good. 4

Every day is good. 5

16. If you wheeze, is it worse when you get up in the morning:

No. 1

Yes. 2

Don't have a wheeze. 3

LOTT

181
Affix label here

Pt ID: ___ ___ ___ ___ ___

Pt code: ___ ___ ___ ___

Visit code: ___ ___ ___

Part 2

Section 1

17. How would you describe your respiratory condition:

Circle One

The most important problem I have. 1

Causes me quite a lot of problems. 2

Causes me a few problems. 3

Causes me no problem. 4

18. If you have ever held a job:

My respiratory problems made me stop working altogether. 1

My respiratory problems interfere (interfered) with my job or made me change my job.. 2

My respiratory problems do (did) not affect my job. 3

Never held a job. 4

Section 2

These are questions about what activities usually make you feel short of breath these days. For each item, please circle either 1 for True or 2 for False.

		Circle One	
		TRUE	**FALSE**
19.	Sitting or lying still:	1	2
20.	Washing yourself or dressing:	1	2
21.	Walking in the house:	1	2
22.	Walking outside on level ground:	1	2

Circle One

LOTT

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Affix label here

Pt ID: ___ ___ ___ ___ ___

Pt code: ___ ___ ___ ___

Visit code: ___ ___ ___

	TRUE	FALSE
23. Walking up a flight of stairs:	1	2
24. Walking up hills:	1	2
25. Playing sports or other physical activities:	1	2

Section 3

These are more questions about your cough and shortness of breath these days. For each item, please circle either 1 for True or 2 for False.

	Circle One TRUE	FALSE
26. Coughing hurts:	1	2
27. Coughing makes me tired:	1	2
28. I am short of breath when I talk:	1	2
29. I am short of breath when I bend over:	1	2
30. My coughing or breathing disturbs my sleep:	1	2
31. I become exhausted easily:	1	2

Section 4

These are questions about other effects that your respiratory problems may have on you these days. For each item, please circle 1 for True or 2 for False.

	Circle One TRUE	FALSE
32. My coughing or breathing is embarrassing in public:	1	2
33. My respiratory problems are a nuisance to my family, friends, or neighbors:	1	2
34. I get afraid or panic when I cannot catch my breath:	1	2
35. I feel that I am not in control of my respiratory problems:	1	2

LOTT

Affix label here 183	
Pt ID:	__ __ __ __ __
Pt code:	__ __ __ __
Visit code:	__ __ __

		Circle One TRUE	FALSE
36.	I do not expect my respiratory problems to get any better:	1	2
37.	I have become frail or an invalid because of my respiratory problems:	1	2
38.	Exercise is not safe for me:	1	2
39.	Everything seems too much of an effort:	1	2

Section 5

These are questions about your treatment and medication (including oxygen, inhalers and pills).

		Circle One YES	NO
40.	Are you receiving any treatment for your respiratory problems:	1	2 → **Go to 45.**

Please circle 1 for True or 2 for False.

		Circle One TRUE	FALSE
41.	My treatment does not help me very much:	1	2
42.	I get embarrassed using my medication in public:	1	2
43.	I have unpleasant side effects from my medication:	1	2
44.	My treatment interferes with my life a lot:	1	2

LOTT

184
Affix label here

Pt ID: ___ ___ ___ ___ ___

Pt code: ___ ___ ___ ___

Visit code: ___ ___ ___

Section 6

These are questions about how your activities might be affected by your respiratory problems. For each question, please circle 1 for True or 2 for False.

		Circle One TRUE	FALSE
45.	I take a long time to get washed or dressed:	1	2
46.	I cannot take a bath or shower, or I take a long time to do it:	1	2
47.	I walk slower than other people my age, or I stop to rest:	1	2
48.	Jobs such as household chores take a long time, or I have to stop to rest:	1	2
49.	If I walk up one flight of stairs, I have to go slowly or stop:	1	2
50.	If I hurry or walk fast, I have to stop or slow down:	1	2
51.	My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl or play golf:	1	2
52.	My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim:	1	2
53.	My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast or play competitive sports:	1	2

LOTT

Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Section 7

We would like to know how your respiratory problems usually affect your daily life. Please circle either 1 for True or 2 for False.

		Circle One TRUE	FALSE
54.	I cannot play sports or do other physical activities:	1	2
55.	I cannot go out for entertainment or recreation:	1	2
56.	I cannot go out of the house to do the shopping:	1	2
57.	I cannot do household chores:	1	2
58.	I cannot move far from my bed or chair:	1	2

Section 8

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these, they are just to remind you of ways your shortness of breath may affect you.)

Going for walks or walking the dog

Doing activities or chores at home or in the garden

Sexual intercourse

Going to a place of worship, or a place of entertainment

Going out in bad weather or into smoky rooms

Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

_____

_____

_____

59. Now please circle the response (one only) that you think best describes how your respiratory problems affect you:

Circle One

It does not stop me doing anything I would like to do. 1

It stops me doing one or two things I would like to do. 2

It stops me doing most of the things I would like to do. 3

It stops me doing everything I would like to do. 4

60. Date completed:

_____

Thank you for completing this questionnaire.
Please check to be sure you have answered all questions.
Please return your completed questionnaire to your LOTT clinic.

qw2 - Form QW2 Quality of Well-Being Scale Self Administered V1.04

Date file created: 21 Apr 2017
Observations: 3843
Variables: 263

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
qw250	50 Symptoms not mentioned	Char	1
qw268	68 Would you say your health is	Char	1
qw269	69 Rate general health now	Char	1
qw270	70 State of health over last 3 days	Char	3
qw209a	9a Blind or severely impaired in both eyes	Char	1
qw209b	9b Blind or severely impaired in one eye	Char	1
qw209c	9c Speech problems such as stuttering	Char	1
qw209d	9d Missing or paralyzed hands, feet, arms	Char	1
qw209e	9e Missing or paralyzed fingers or toes	Char	1
qw209f	9f Any deformity of face, fingers, hand	Char	1
qw209g	9g General fatigue, tiredness, or weakness	Char	1
qw209h	9h Problem with unwanted weight gain or loss	Char	1
qw209i	9i Problem with being under or over weight	Char	1
qw209j	9j Problems chewing food adequately	Char	1
qw209k	9k Any hearing loss or deafness	Char	1
qw209l	9l Noticeable skin problems	Char	1
qw209m	9m Eczema or burning/itching rash	Char	1
qw210a	10a Dentures	Char	1
qw210b	10b Oxygen tank	Char	1
qw210c	10c Prosthesis	Char	1
qw210d	10d Eye glasses or contact lenses	Char	1
qw210e	10e Hearing aide	Char	1
qw210f	10f Magnifying glass	Char	1
qw210g	10g Neck, back, or leg brace	Char	1
qw211a	11a Vision problems - no days	Char	1
qw211b	11b Vision problems - yesterday	Char	1
qw211c	11c Vision problems - 2 days ago	Char	1
qw211d	11d Vision problems - 3 days ago	Char	1
qw212a	12a Eye pain - no days	Char	1
qw212b	12b Eye pain - yesterday	Char	1
qw212c	12c Eye pain - 2 days ago	Char	1
qw212d	12d Eye pain - 3 days ago	Char	1
qw213a	13a Headache - no days	Char	1
qw213b	13b Headache - yesterday	Char	1
qw213c	13c Headache - 2 days ago	Char	1
qw213d	13d Headache - 3 days ago	Char	1
qw214a	14a Dizziness - no days	Char	1
qw214b	14b Dizziness - yesterday	Char	1
qw214c	14c Dizziness - 2 days ago	Char	1
qw214d	14d Dizziness - 3 days ago	Char	1
qw215a	15a Difficulty hearing - no days	Char	1
qw215b	15b Difficulty hearing - yesterday	Char	1
qw215c	15c Difficulty hearing - 2 days ago	Char	1
qw215d	15d Difficulty hearing - 3 days ago	Char	1
qw216a	16a Stuffy nose - no days	Char	1
qw216b	16b Stuffy nose - yesterday	Char	1

qw2 - Form QW2 Quality of Well-Being Scale Self Administered V1.04

Date file created: 21 Apr 2017
Observations: 3843
Variables: 263

Variable Name	Variable Label	Type	Variable Length
qw216c	16c Stuffy nose - 2 days ago	Char	1
qw216d	16d Stuffy nose - 3 days ago	Char	1
qw217a	17a Sore throat - no days	Char	1
qw217b	17b Sore throat - yesterday	Char	1
qw217c	17c Sore throat - 2 days ago	Char	1
qw217d	17d Sore throat - 3 days ago	Char	1
qw218a	18a Tooth ache - no days	Char	1
qw218b	18b Tooth ache - yesterday	Char	1
qw218c	18c Tooth ache - 2 days ago	Char	1
qw218d	18d Tooth ache - 3 days ago	Char	1
qw219a	19a Sore lips - no days	Char	1
qw219b	19b Sore lips - yesterday	Char	1
qw219c	19c Sore lips - 2 days ago	Char	1
qw219d	19d Sore lips - 3 days ago	Char	1
qw220a	20a Coughing - no days	Char	1
qw220b	20b Coughing - yesterday	Char	1
qw220c	20c Coughing - 2 days ago	Char	1
qw220d	20d Coughing - 3 days ago	Char	1
qw221a	21a Short of breath - no days	Char	1
qw221b	21b Short of breath - yesterday	Char	1
qw221c	21c Short of breath - 2 days ago	Char	1
qw221d	21d Short of breath - 3 days ago	Char	1
qw222a	22a Chest pain - no days	Char	1
qw222b	22b Chest pain - yesterday	Char	1
qw222c	22c Chest pain - 2 days ago	Char	1
qw222d	22d Chest pain - 3 days ago	Char	1
qw223a	23a Upset stomach - no days	Char	1
qw223b	23b Upset stomach - yesterday	Char	1
qw223c	23c Upset stomach - 2 days ago	Char	1
qw223d	23d Upset stomach - 3 days ago	Char	1
qw224a	24a Difficulty with bowels - no days	Char	1
qw224b	24b Difficulty with bowels - yesterday	Char	1
qw224c	24c Difficulty with bowels - 2 days ago	Char	1
qw224d	24d Difficulty with bowels - 3 days ago	Char	1
qw225a	25a Painful urination - no days	Char	1
qw225b	25b Painful urination - yesterday	Char	1
qw225c	25c Painful urination - 2 days ago	Char	1
qw225d	25d Painful urination - 3 days ago	Char	1
qw226a	26a Bladder control problems - no days	Char	1
qw226b	26b Bladder control problems - yesterday	Char	1
qw226c	26c Bladder control problems - 2 days ago	Char	1
qw226d	26d Bladder control problems - 3 days ago	Char	1
qw227a	27a Genital pain - no days	Char	1
qw227b	27b Genital pain - yesterday	Char	1
qw227c	27c Genital pain - 2 days ago	Char	1
qw227d	27d Genital pain - 3 days ago	Char	1
qw228a	28a Broken bone - no days	Char	1
qw228b	28b Broken bone - yesterday	Char	1
qw228c	28c Broken bone - 2 days ago	Char	1

qw2 - Form QW2 Quality of Well-Being Scale Self Administered V1.04

Date file created: 21 Apr 2017
Observations: 3843
Variables: 263

Variable Name	Variable Label	Type	Variable Length
qw228d	28d Broken bone - 3 days ago	Char	1
qw229a	29a Pain in neck or back - no days	Char	1
qw229b	29b Pain in neck or back - yesterday	Char	1
qw229c	29c Pain in neck or back - 2 days ago	Char	1
qw229d	29d Pain in neck or back - 3 days ago	Char	1
qw230a	30a Pain in hips or side - no days	Char	1
qw230b	30b Pain in hips or side - yesterday	Char	1
qw230c	30c Pain in hips or side - 2 days ago	Char	1
qw230d	30d Pain in hips or side - 3 days ago	Char	1
qw231a	31a Pain in joints - no days	Char	1
qw231b	31b Pain in joints - yesterday	Char	1
qw231c	31c Pain in joints - 2 days ago	Char	1
qw231d	31d Pain in joints - 3 days ago	Char	1
qw232a	32a Swelling of ankles - no days	Char	1
qw232b	32b Swelling of ankles - yesterday	Char	1
qw232c	32c Swelling of ankles - 2 days ago	Char	1
qw232d	32d Swelling of ankles - 3 days ago	Char	1
qw233a	33a Fever, chills - no days	Char	1
qw233b	33b Fever, chills - yesterday	Char	1
qw233c	33c Fever, chills - 2 days ago	Char	1
qw233d	33d Fever, chills - 3 days ago	Char	1
qw234a	34a Loss of consciousness - no days	Char	1
qw234b	34b Loss of consciousness - yesterday	Char	1
qw234c	34c Loss of consciousness - 2 days ago	Char	1
qw234d	34d Loss of consciousness - 3 days ago	Char	1
qw235a	35a Difficulty with balance - no days	Char	1
qw235b	35b Difficulty with balance - yesterday	Char	1
qw235c	35c Difficulty with balance - 2 days ago	Char	1
qw235d	35d Difficulty with balance - 3 days ago	Char	1
qw236a	36a Trouble sleeping - no days	Char	1
qw236b	36b Trouble sleeping - yesterday	Char	1
qw236c	36c Trouble sleeping - 2 days ago	Char	1
qw236d	36d Trouble sleeping - 3 days ago	Char	1
qw237a	37a Feeling nervous - no days	Char	1
qw237b	37b Feeling nervous - yesterday	Char	1
qw237c	37c Feeling nervous - 2 days ago	Char	1
qw237d	37d Feeling nervous - 3 days ago	Char	1
qw238a	38a Feeling upset - no days	Char	1
qw238b	38b Feeling upset - yesterday	Char	1
qw238c	38c Feeling upset - 2 days ago	Char	1
qw238d	38d Feeling upset - 3 days ago	Char	1
qw239a	39a Excessive worry - no days	Char	1
qw239b	39b Excessive worry - yesterday	Char	1
qw239c	39c Excessive worry - 2 days ago	Char	1
qw239d	39d Excessive worry - 3 days ago	Char	1
qw240a	40a Little control over life - no days	Char	1
qw240b	40b Little control over life - yesterday	Char	1
qw240c	40c Little control over life - 2 days ago	Char	1
qw240d	40d Little control over life - 3 days ago	Char	1

qw2 - Form QW2 Quality of Well-Being Scale Self Administered V1.04

Date file created: 21 Apr 2017
Observations: 3843
Variables: 263

Variable Name	Variable Label	Type	Variable Length
qw241a	41a Feeling lonely - no days	Char	1
qw241b	41b Feeling lonely - yesterday	Char	1
qw241c	41c Feeling lonely - 2 days ago	Char	1
qw241d	41d Feeling lonely - 3 days ago	Char	1
qw242a	42a Feeling frustrated - no days	Char	1
qw242b	42b Feeling frustrated - yesterday	Char	1
qw242c	42c Feeling frustrated - 2 days ago	Char	1
qw242d	42d Feeling frustrated - 3 days ago	Char	1
qw243a	43a Hangover - no days	Char	1
qw243b	43b Hangover - yesterday	Char	1
qw243c	43c Hangover - 2 days ago	Char	1
qw243d	43d Hangover - 3 days ago	Char	1
qw244a	44a Decrease of sexual interest - no days	Char	1
qw244b	44b Decrease of sexual interest - yesterday	Char	1
qw244c	44c Decrease of sexual interest - 2 days ago	Char	1
qw244d	44d Decrease of sexual interest - 3 days ago	Char	1
qw245a	45a Confusion - no days	Char	1
qw245b	45b Confusion - yesterday	Char	1
qw245c	45c Confusion - 2 days ago	Char	1
qw245d	45d Confusion - 3 days ago	Char	1
qw246a	46a Thoughts or images in mind - no days	Char	1
qw246b	46b Thoughts or images in mind - yesterday	Char	1
qw246c	46c Thoughts or images in mind - 2 days ago	Char	1
qw246d	46d Thoughts or images in mind - 3 days ago	Char	1
qw247a	47a Take medications - no days	Char	1
qw247b	47b Take medications - yesterday	Char	1
qw247c	47c Take medications - 2 days ago	Char	1
qw247d	47d Take medications - 3 days ago	Char	1
qw248a	48a Medically prescribed diet - no days	Char	1
qw248b	48b Medically prescribed diet - yesterday	Char	1
qw248c	48c Medically prescribed diet - 2 days ago	Char	1
qw248d	48d Medically prescribed diet - 3 days ago	Char	1
qw249a	49a Loss of appetite - no days	Char	1
qw249b	49b Loss of appetite - yesterday	Char	1
qw249c	49c Loss of appetite - 2 days ago	Char	1
qw249d	49d Loss of appetite - 3 days ago	Char	1
qw250ab	50ab 1st symptom - yesterday	Char	1
qw250ac	50ac 1st symptom - 2 days ago	Char	1
qw250ad	50ad 1st symptom - 3 days ago	Char	1
qw250bb	50bb 2nd symptom - yesterday	Char	1
qw250bc	50bc 2nd symptom - 2 days ago	Char	1
qw250bd	50bd 2nd symptom - 3 days ago	Char	1
qw251a	51a Any part of day in hospital - no days	Char	1
qw251b	51b Any part of day in hospital - yesterday	Char	1
qw251c	51c Any part of day in hospital - 2 days ago	Char	1
qw251d	51d Any part of day in hospital - 3 days ago	Char	1
qw252a	52a Help with personal care - no days	Char	1
qw252b	52b Help with personal care - yesterday	Char	1
qw252c	52c Help with personal care - 2 days ago	Char	1

qw2 - Form QW2 Quality of Well-Being Scale Self Administered V1.04

Date file created: 21 Apr 2017
Observations: 3843
Variables: 263

Variable Name	Variable Label	Type	Variable Length
qw252d	52d Help with personal care - 3 days ago	Char	1
qw253a	53a Drive a motor vehicle - no days	Char	1
qw253b	53b Drive a motor vehicle - yesterday	Char	1
qw253c	53c Drive a motor vehicle - 2 days ago	Char	1
qw253d	53d Drive a motor vehicle - 3 days ago	Char	1
qw254a	54a Used public transportation - no days	Char	1
qw254b	54b Used public transportation - yesterday	Char	1
qw254c	54c Used public transportation - 2 days ago	Char	1
qw254d	54d Used public transportation - 3 days ago	Char	1
qw255a	55a Not drive due to health - no days	Char	1
qw255b	55b Not drive due to health - yesterday	Char	1
qw255c	55c Not drive due to health - 2 days ago	Char	1
qw255d	55d Not drive due to health - 3 days ago	Char	1
qw256a	56a Trouble climbing stairs - no days	Char	1
qw256b	56b Trouble climbing stairs - yesterday	Char	1
qw256c	56c Trouble climbing stairs - 2 days ago	Char	1
qw256d	56d Trouble climbing stairs - 3 days ago	Char	1
qw257a	57a Avoid walking - no days	Char	1
qw257b	57b Avoid walking - yesterday	Char	1
qw257c	57c Avoid walking - 2 days ago	Char	1
qw257d	57d Avoid walking - 3 days ago	Char	1
qw258a	58a Limp or use cane - no days	Char	1
qw258b	58b Limp or use cane - yesterday	Char	1
qw258c	58c Limp or use cane - 2 days ago	Char	1
qw258d	58d Limp or use cane - 3 days ago	Char	1
qw259a	59a Trouble bending over - no days	Char	1
qw259b	59b Trouble bending over - yesterday	Char	1
qw259c	59c Trouble bending over - 2 days ago	Char	1
qw259d	59d Trouble bending over - 3 days ago	Char	1
qw260a	60a Trouble lifting - no days	Char	1
qw260b	60b Trouble lifting - yesterday	Char	1
qw260c	60c Trouble lifting - 2 days ago	Char	1
qw260d	60d Trouble lifting - 3 days ago	Char	1
qw261a	61a Limitations in movements - no days	Char	1
qw261b	61b Limitations in movements - yesterday	Char	1
qw261c	61c Limitations in movements - 2 days ago	Char	1
qw261d	61d Limitations in movements - 3 days ago	Char	1
qw262a	62a Spend day in bed - no days	Char	1
qw262b	62b Spend day in bed - yesterday	Char	1
qw262c	62c Spend day in bed - 2 days ago	Char	1
qw262d	62d Spend day in bed - 3 days ago	Char	1
qw263a	63a Spend day in wheelchair - no days	Char	1
qw263b	63b Spend day in wheelchair - yesterday	Char	1
qw263c	63c Spend day in wheelchair - 2 days ago	Char	1
qw263d	63d Spend day in wheelchair - 3 days ago	Char	1
qw264a	64a Someone controlled wheelchair - no days	Char	1
qw264b	64b Someone controlled wheelchair - yesterday	Char	1
qw264c	64c Someone controlled wheelchair - 2 days ago	Char	1
qw264d	64d Someone controlled wheelchair - 3 days ago	Char	1

qw2 - Form QW2 Quality of Well-Being Scale Self Administered V1.04

Date file created: 21 Apr 2017
Observations: 3843
Variables: 263

Variable Name	Variable Label	Type	Variable Length
qw265a	65a Work limited due to health - no days	Char	1
qw265b	65b Work limited due to health - yesterday	Char	1
qw265c	65c Work limited due to health - 2 days ago	Char	1
qw265d	65d Work limited due to health - 3 days ago	Char	1
qw266a	66a Social activities limited - no days	Char	1
qw266b	66b Social activities limited - yesterday	Char	1
qw266c	66c Social activities limited - 2 days ago	Char	1
qw266d	66d Social activities limited - 3 days ago	Char	1
qw267a	67a Change plans due to health - no days	Char	1
qw267b	67b Change plans due to health - yesterday	Char	1
qw267c	67c Change plans due to health - 2 days ago	Char	1
qw267d	67d Change plans due to health - 3 days ago	Char	1
qwb_1	QWB score on yesterday	Num	8
qwb_2	QWB score 2 days ago	Num	8
qwb_3	QWB score 3 days ago	Num	8
qwb_ave	QWB average daily score	Num	8
qwb_tot	QWB total score over 3 days	Num	8
visit	Visit code	Char	3

QW - Quality of Well-Being Scale, Self Administered V1.04©

Purpose: To assess the patient's health problems in the last 3 days.
Data collection level: All patients (Core).
When: Visits sb, f04, f12, f16, f24, f36, f48, f60, f72.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and review completed forms.
Respondent: Patient without help from spouse or family.
Instructions: Clinical Coordinator completes page 1 of this form; the patient completes pages 2-12. A label (with patient ID, patient code, and appropriate visit code) should be affixed to the upper right corner of pages 2-12. **Visit sb:** The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete the form. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by the Clinical Coordinator and re-attached to pages 2-12. **Visits f04, f16**: Pages 2-12 should be mailed to the patient 2 weeks before the target date for the visit by mail, with instructions to complete the form at home and to return the completed form to the clinic by mail in the stamped, addressed envelope provided. When the form is received at the clinic, the Clinical Coordinator should review the form for completeness and obtain any missing items by telephone (1 attempt). If the patient did not write a date in item 71, use the date the form was mailed to the patient. Page 1 should be completed by the Clinical Coordinator and re-attached to pages 2-12. **Visits f12, f24, f36, f48:** Pages 2-12 should be mailed to the patient 2 weeks prior to the scheduled LOTT clinic visit with instructions to complete the form at home and to bring the completed form to the next LOTT clinic visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the clinic visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be completed by the Clinical Coordinator and re-attached to pages 2-12. Use the date the form was completed for the visit date. If the patient did not write in a date in item 71, use the date of the clinic visit for the visit date. For items 11-67, checked responses should be keyed as "1", otherwise they should be left blank.

A. Clinic, visit, and patient identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date patient completed the form)*:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **q w 2**

B. Administrative information

(To be completed by Clinical Coordinator after questionnaire is completed)

7. Clinical Coordinator
a. PIN: ____ ____ ____ ____
b. Signature: _____

8. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

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Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

QWB-SA - Quality of Well-Being Scale, Self Administered V1.04

This survey asks about health problems that you have experienced in the last 3 days, not including today. Please answer all questions. Thank you.

(Items 1-8 are reserved for clinic use.)

9. Please indicate whether you currently experience each of the following health symptoms or problems.

Do you have...

	Circle One YES	NO
a. Blindness or severely impaired vision in both eyes?	1	2
b. Blindness or severely impaired vision in only one eye?	1	2
c. Speech problems such as stuttering, or being unable to speak clearly?	1	2
d. Missing or paralyzed hands, feet, arms, or legs?	1	2
e. Missing or paralyzed fingers or toes?	1	2
f. Any deformity of the face, fingers, hand or arm, foot or leg, or back (e.g. severe scoliosis)?	1	2
g. General fatigue, tiredness, or weakness?	1	2

Do you have...

	Circle One YES	NO
h. A problem with unwanted weight gain or weight loss?	1	2
i. A problem with being under or over weight?	1	2
j. Problems chewing your food adequately?	1	2
k. Any hearing loss or deafness?	1	2
l. Any noticeable skin problems, such as bad acne or large burns or scars on face, body, arms, or legs?	1	2
m. Eczema or burning/itching rash?	1	2

10. Which of the following health aides do you use/have?

	Circle One YES	NO
a. Dentures?	1	2
b. Oxygen tank?	1	2
c. Prosthesis?	1	2
d. Eye glasses or contact lenses?	1	2
e. Hearing aide?	1	2
f. Magnifying glass?	1	2
g. Neck, back, or leg brace?	1	2

LOTT

Affix label here 196

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

For the following list of problems, indicate which days (if any) over the past 3 days, not including today, you had the problem. If you have not had the symptom in the past 3 days, do not leave the question blank, please check "no days". If you have experienced the symptom in the past 3 days, please check which of the days you had it; if you experienced it on more than one of the days, check all days that apply.

For example, if you had a headache yesterday and the day before that:

Did you have:	No days	Yesterday	2 days ago	3 days ago
A headache?		✓	✓	

Over the past 3 days, did you have: (please check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
11. Any problems with your vision not corrected with glasses or contact lenses (such as double vision, distorted vision, flashes, or floaters)?				
12. Any eye pain, irritation, discharge, or excessive sensitivity to light?				
13. A headache?				
14. Dizziness, earache, or ringing in your ears?				
15. Difficulty hearing, or discharge, or bleeding from an ear?				
16. Stuffy or runny nose, or bleeding from the nose?				

LOTT

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Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Over the past 3 days, did you have: (please check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
17. A sore throat, difficulty swallowing, or hoarse voice?				
18. A tooth ache or jaw pain?				
19. Sore or bleeding lips, tongue, or gums?				
20. Coughing or wheezing?				
21. Shortness of breath or difficulty breathing?				
22. Chest pain, pressure, palpitations, fast or skipped heart beat, or other discomfort in the chest?				
23. An upset stomach, abdominal pain, nausea, heartburn, or vomiting?				
24. Difficulty with bowel movements, diarrhea, constipation, rectal bleeding, black tar-like stools, or any pain or discomfort in the rectal area?				
25. Pain, burning, or blood in urine?				
26. Loss of bladder control, frequent night-time urination, or difficulty with urination?				

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Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Over the past 3 days, did you have: (please check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
27. Genital pain, itching, burning, or abnormal discharge, or pelvic cramping or abnormal bleeding? (does not include normal menstruation)				
28. A broken arm, wrist, foot, leg, or any other broken bone (other than in the back)?				
29. Pain, stiffness, cramps, weakness, or numbness *in the neck or back*?				
30. Pain, stiffness, cramps, weakness, or numbness *in the hips or sides*?				
31. Pain, stiffness, cramps, weakness, or numbness *in any of the joints or muscles of the hand, feet, arms, or legs*?				
32. Swelling of ankles, hands, feet or abdomen?				
33. Fever, chills, or sweats?				
34. Loss of consciousness, fainting, or seizures?				
35. Difficulty with your balance, standing, or walking?				

LOTT

199

Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

The following symptoms are about your feelings, thoughts, and behaviors.

Please check which days (if any) over the past 3 days, not including today, you have had...	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
36. Trouble falling asleep or staying asleep?				
37. Spells of feeling nervous or shaky?				
38. Spells of feeling upset, downhearted, or blue?				
39. Excessive worry or anxiety?				
40. Feelings that you had little or no control over events in your life?				
41. Feelings of being lonely or isolated?				
42. Feelings of frustration, irritation, or close to losing your temper?				
43. A hangover?				
44. Any decrease of sexual interest or performance?				
45. Confusion, difficulty understanding the written or spoken word, or significant memory loss?				
46. Thoughts or images you could not get out of your mind?				

200
Affix label here
Pt ID: __ __ __ __ __
Pt code: __ __ __ __
Visit code: __ __ __

Please check which days (if any) over the past 3 days, not including today, you have had...	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
47. To take any medication including over-the-counter remedies (aspirin/Tylenol, allergy medications, insulin, hormones, estrogen, thyroid, prednisone)?				
48. To stay on a medically prescribed diet for health reasons?				
49. A loss of appetite or over-eating?				

50. In the last 3 days did you have any symptoms, health complaints, or pains that have not been mentioned? (circle one)

YES 1 **NO** 2 → **51.**

If yes, what were they and on which days did you have them?

	b. Yesterday	c. 2 days ago	d. 3 days ago
a.			
b.			

201
Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Over the last 3 days: (please check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
51. Did you spend any part of the day or night as a patient in a hospital, nursing home, or rehabilitation center?				
52. Because of any impairment or health problem, did you need help with your personal care needs, such as eating, dressing, bathing, or getting around your home?				
53. Which days did you drive a motor vehicle?				
54. Which days did you use public transportation such as a bus, subway, Medi-van, train, or airplane?				
55. Which days did you either not drive a motor vehicle or not use public transportation because of your health, or need help from another person to use?				

LOTT

202
Affix label here
Pt ID: __ __ __ __ __
Pt code: __ __ __ __
Visit code: __ __ __

Over the last 3 days did you... (please check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
56. Have trouble climbing stairs or inclines or walking off the curb?				
57. Avoid walking, have trouble walking, or walk more slowly than other people your age?				
58. Limp or use a cane, crutches, or walker?				
59. Avoid or have trouble bending over, stooping, or kneeling?				
60. Have any trouble lifting or carrying everyday objects such as books, a briefcase, or groceries?				
61. Have any other limitations in physical movements?				
62. Spend all or most of the day in a bed, chair, or couch because of health reasons?				
63. Spend all or most of the day in a wheelchair?	Go to 65			
64. **If in a wheelchair**, on which days did someone else control its movement?				

203
Affix label here

Pt ID: __ __ __ __ __

Pt code: __ __ __ __

Visit code: __ __ __

Over the last 3 days did you... (please check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
65. Because of any physical or emotional health reasons, on which days did you avoid, need help with, or were limited in doing some of your usual activities, such as work, school or housekeeping?				
66. Because of physical or emotional health reasons, on which days did you avoid or feel limited in doing some of your usual activities, such as visiting family or friends, hobbies, shopping, recreational, or religious activities?				
67. On which days did you have to change any of your plans or activities because of your health? (Consider only activities that you did not report in the last 2 questions.)				

204
Affix label here
Pt ID: __ __ __ __ __
Pt code: __ __ __ __
Visit code: __ __ __

68. Would you say that your health is:

Circle One

Excellent 1
Very Good 2
Good 3
Fair 4
Poor 5

69. Compared to a year ago, how would you rate your health in general now:

Circle One

Much better now than a year ago 1
Somewhat better now than one year ago 2
About the same as a year ago 3
Somewhat worse than a year ago 4
Much worse than a year ago 5

70. Think about a scale of 0 to 100, with zero being the least desirable state of health that you could imagine and 100 being perfect health. What number, from 0 to 100 would you give to the state of your health, on average, over the last 3 days? (Please circle one)

0 10 20 30 40 50 60 70 80 90 100

71. Date completed:

_____

Thank you for completing this questionnare.

Please bring this completed questionnaire with you to your scheduled LOTT clinic visit.

rg3 - Form RG3 Registration

Date file created: 21 Apr 2017
Observations: 1759
Variables: 38

Variable Name	Variable Label	Type	Variable Length
bmi	Body mass index (kg/m**2)	Num	8
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
htcm	Standing height (cm) at visit sb (only ht measure)	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
rg307	7 Signed informed consent	Char	1
rg314	14 Age at last birthday	Char	2
rg315	15 Patient 40 or older	Char	1
rg316	16 Highest educational level	Char	1
rg317	17 Marital status	Char	1
rg318	18 Annual household income	Char	1
rg319	19 Current residence	Char	1
rg320	20 Living arrangement	Char	1
rg322	22 Short of breath when hurrying	Char	1
rg323	23 Short of breath walking up hill	Char	1
rg324	24 Yes to item 22 or 23	Char	1
rg325	25 Breathlessness	Char	1
rg326	26 Ever smoked cigarettes	Char	1
rg327	27 Age started smoking	Char	2
rg328	28 Age last smoked cigarettes	Char	2
rg329	29 No. years not smoked cigarettes	Char	2
rg330	30 Cigarettes/day, on average	Char	3
rg331	31 Pack-years of cigarette smoking	Char	3
rg332	32 At least 10 pack-years of cigarette smoking	Char	1
rg333	33 Acute care hospital in past 30 days	Char	1
rg334	34 30+ days since took antibiotics for COPD exacerbation	Char	1
rg335	35 Patient takes systemic corticosteroids for COPD	Char	1
rg336	36 30+ days since systemic corticosteroids started/increased	Char	1
rg337	37 Prescribed supplemental O2 currently	Char	1
rg338	38 Patient agrees to equipment removal	Char	1
rg339	39 Procedure causing pulmonary instability	Char	1
rg340	40 Participation in another intervention trial	Char	1
rg309a	9a Medicare A & B coverage	Char	1
rg309b	9b Veterans Affairs/VHA	Char	1
rg309c	9c Other coverage	Char	1
rg309d	9d No coverage	Char	1
visit	Visit code	Char	3
wtkg	Weight (kg)	Num	8

LOTT

RG - Registration

Purpose: To document consent, assign Patient ID and code, verify insurance, obtain demographics, check selected eligibility criteria, and obtain height and weight.

Data collection level: All patients (Core).

When: sb.

Administered by: Clinical Coordinator.

Respondent: Patient.

Instructions: This is the first LOTT form completed for a patient; it may be completed only after the patient has signed the LOTT consent statement. Once the patient has signed the consent, assign an ID number and code to the patient by removing the RG form label from the next available visit sb label sheet and affixing it in item 8c (if re-screening a patient, enter the original assigned ID and code in items 8a and 8b and then assign a new ID and code). Use Flash Cards #1-5 and #8 as instructed. Measure height with shoes off. If height cannot be measured, measure arm span (from tips of the middle fingers with arms maximally outstretched with subject as upright as possible). Measure weight with shoes off and after items have been removed from pockets. If an (Lung) condition is checked, skip to the Administrative information section leaving the remaining items blank. The RG form must be keyed first; other forms may not be keyed until this form has been keyed. Key the RG form regardless of whether the patient is eligible or ineligible. If the patient is eligible, a page of lung function predicted values (specific for the patient's age, gender, and height and using the equations of Hankinson et al) will print when this form is keyed to the database. **Randomization must occur within 60 days of the date in item 4 or the patient must re-start screening.**

A. Center, patient and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: s b ____

6. Form & revision: r g 3

B. Consent and ID assignment

7. Patient signed the consent for *(check only one)*:

Core data collection only (1)
Core and Expanded data collection (* 2)
Neither Core nor Expanded (+ 3)
STOP

** Expanded data collection adds the HA, NO, PQ, QF forms, A1AT blood test, and serum banking to CORE data collection.*

+ Patient must sign the consent for Core/Expanded data collection prior to continuing with screening. Do not proceed until patient signs the consent statement.

8. Has the Registration (RG) form previously been keyed to the LOTT data system for this patient:

Yes (* 1) No (2)
8c.

** Record the previously assigned ID and code in items 8a and 8b and then assign a new ID and code in item 8c.*

a. Patient ID number on previously keyed RG form:

____ ____ ____ ____ ____

b. Patient code on previously keyed RG form:

____ ____ ____ ____

c. Place ID label below and record Patient ID in item 2 and Patient code in item 3.

LOTT (RG form)

Patient ID:
Patient code:

C. Insurance

9. How will costs of procedures, treatment and visits required for LOTT be covered *(check at least 1 and all that apply):*

a. Patient has Medicare Part A and Part B through traditional Medicare or Medicare Advantage (HMO, PPO, Medicare Choice, etc.): (1)

b. Veterans Affairs/Veterans Health Administration: (1)

c. Other resource willing to cover the costs of procedures, treatment, and visits required by LOTT: (1)

d. None of the above: (1)

Elig

D. Demographic information

10. Gender:

Male (1)
Female (2)

11. Ethnic category *(show the patient Flash Card #1 and ask the patient to pick the category that best describes him/her; check only one):*

Hispanic or Latino or Spanish origin (1)
Not Hispanic, not Latino, not Spanish origin (2)

12. Racial category *(show the patient Flash Card #2 and ask to pick the category or categories that best describe him/her; check all that apply)*

a. American Indian or Alaska Native: (1)

b. Asian: (1)

c. Black or African American: (1)

d. Native Hawaiian or other Pacific Islander: (1)

e. White: (1)

f. Unknown or not reported: (1)

13. Date of birth:

__ __ – __ __ __ – __ __ __ __
day month year

Record 4-digit year for date of birth.

14. Age at last birthday: __ __
years

15. Is the patient age 40 or older:

Yes (1) No (2)

Elig

16. Highest educational level achieved by patient *(show the patient Flash Card #3 and ask the patient to pick the category that best describes him/her; check only one):*

Did not complete high school (1)
Completed high school (2)
Some college or post high school education or training (3)
Bachelor's degree or higher (4)

17. Marital status of the patient *(show patient Flash Card #4 and ask the patient to pick the category that best describes him/her; check only one):*

Single, never married (1)
Married or living in marriage-like relationship (2)
Separated, divorced, or annulled (3)
Widowed (4)

18. Combined income before taxes of all members of patient's household *(show the patient Flash Card #5 and ask the patient to pick the category that best describes his/her combined household income before taxes; check only one):*

Less than $15,000 (1)
$15,000 - $29,999 (2)
$30,000 - $49,999 (3)
$50,000 or more (4)
Refused (5)

19. What best describes your current residence *(check only one):*

Private house, apartment, condominium, mobile home (1)
Retirement home (2) **21.**
Assisted living facility (3) **21.**
Nursing home (4) **21.**
Rehabilitation facility (5) **21.**
Other *(specify):* (6) **21.**

_____
specify

20. What best describes your current living arrangement *(check only one):*

Live alone (1)
Live with at least one other person (2)

21. Zip code of current residence:

____ ____ ____ ____ ____

E. MMRC dyspnea score

22. Are you short of breath when hurrying on the level:

Yes (1) No (2)

23. Are you short of breath when walking up a slight hill:

Yes (1) No (2)

24. Is Yes checked for at least one of items 22 and 23:

Yes (1) No (2) → Elig

25. Which category best describes your breathlessness *(show the patient LOTT Flash Card #8 and ask the patient which rating best describes his/her breathlessness; check only one):*

Not troubled by breathlessness except during strenuous exercise (0) → Elig
Troubled by shortness of breath when hurrying on the level or when walking up a slight hill (1)
Walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level (2)
Stops for breath after walking about 100 yards or after a few minutes of walking on the level (3)
Too breathless to leave house or breathless when dressing or undressing (4)

F. Tobacco cigarette smoking exclusion

26. Have you ever smoked tobacco cigarettes regularly *(regularly means more than 20 packs of cigarettes in a lifetime or more than 1 cigarette a day for at least a year):*

Yes (1) No (2) → Elig

27. How old were you when you first started regular cigarette smoking:

____ ____

28. How old were you when you last smoked tobacco cigarettes *(enter current age if still smoking):*

____ ____

29. Between the time you started regularly smoking tobacco cigarettes and the time you last smoked, for how many years did you ever quit smoking *(enter 00 if you have never quit smoking or quit for less than 6 months):*

____ ____
years

30. On average over the entire time you smoked tobacco cigarettes, about how many cigarettes did you smoke per day *(there are 20 cigarettes in a standard U.S. pack of cigarettes):*

____ ____ ____

31. Pack-years of tobacco cigarette smoking *([item 28-item 27+1-item 29]*[item 30/20]):*

____ ____ ____

32. Is the response to item 31 at least 10:

Yes (1) No (2) → Elig

G. Other exclusions (based on patient self report -- these questions will be asked again prior to randomization; at this time, get the patient's self report; if such a history is detected later in screening, the exclusion will be applied then).

33. Has the patient been discharged from an acute care hospital (for any reason) in the past 30 days:

Yes (1) → Elig No (2)

34. Have at least 30 days elapsed since the patient last took antibiotics for a COPD exacerbation:

Yes (1) No (2) → Elig

35. Has the patient ever taken systemic corticosteroids for COPD:

Yes (1) No (2) → 37.

36. Have at least 30 days elapsed since the prescription for systemic corticosteroids was initiated or was last increased:

Yes (1) No (2) → Elig

37. Is the patient prescribed supplemental (home) oxygen currently (stationary system and/or portable system) for any reason:

Yes (1) No (2) → 39.

38. Does the patient agree to have the equipment removed from the home if the patient is randomized to the no oxygen group:

Yes (1) No (2) → Elig

39. Does the patient report having any procedure in the past 6 months that is likely to cause instability of pulmonary status *(eg, thoracotomy, sternotomy, major cardio-pulmonary intervention such as lung resection, open heart surgery, etc):*

Yes (1) → Elig No (2)

40. Does the patient report participation in another intervention study:

Yes (1) → Elig No (2)

H. Measurements

41. Height or arm span *(measure height if the patient can stand and has no condition that precludes height measurement; otherwise, measure arm span):*

a. Type of measurement:
- Height (1)
- Arm span (2)

b. Measurement: ____ ____ ____ • ____

c. Units:
- Centimeters (1)
- Inches (2)

42. Weight

a. Measurement: ____ ____ ____ • ____

b. Units:
- Pounds (1)
- Kilograms (2)

I. Administrative information

43. Clinical Coordinator PIN: ____ ____ ____ ____

44. Clinical Coordinator signature:

_____

45. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

rr4 - Form RR4 Eligibility Review

Date file created: 21 Apr 2017
Observations: 1716
Variables: 44

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
rr407	7 Patient known to be ineligible	Char	1
rr408	8 Signed contract not to smoke near oxygen	Char	1
rr410	10 Any disease expected to cause death w/in 6mos	Char	1
rr411	11 Any disease affecting compliance in next 6mos	Char	1
rr412	12 Supplemental oxygen since starting LOTT	Char	1
rr413	13 Meds for COPD exacerbation prescribed	Char	1
rr414	14 Participating in another intervention study	Char	1
rr415	15 Thoracotomy, sternotomy, ... in past 6 mos	Char	1
rr416	16 Prescribed home O2 at screening start	Char	1
rr417	17 Used O2 equipment in past 4 days	Char	1
rr418	18 MD will cancel O2 if randomized to no O2	Char	1
rr419	19 MD will remove O2 equipment if randomized to no O2	Char	1
rr421	21 Ineligible condition in items 7-20b	Char	1
rr422	22 Data collection level	Char	1
rr423	23 Stops in Randomization Task	Char	1
rr424	24 Study MD approves patient for randomization	Char	1
rr425	25 Ready for delivery of oxygen equipment	Char	1
rr426	26 Patient consents to randomization	Char	1
rr409a	9a Radiologic evidence of emphysema	Char	1
rr409b	9b Disease process dominated by COPD	Char	1
rr409c	9c Non-COPD lung disease affecting oxygenation	Char	1
rr420a	20a Clinic will change O2 companies if needed	Char	1
rr420b	20b Patient feels well today	Char	1
rr427a	27a Reason covered in 7-26	Char	1
rr427b	27b Exacerbation w/ antibiotics/inc corticosteroids	Char	1
rr427c	27c Prescribed O2 since screening start	Char	1
rr427d	27d Resting oxygen saturation <=88%	Char	1
rr427e	27e Resting oxygen saturation >=94% w/o desat	Char	1
rr427f	27f Desaturation below 80% for 1min/6min walk	Char	1
rr427g	27g Other reason - resting room air oximetry	Char	1
rr427h	27h Other reason - room air 6 min walk	Char	1
rr427i	27i Post BD FEV1 predicted >=71%/no evidence EMP	Char	1
rr427j	27j Post BD FEV1/FVC >=0.70	Char	1
rr427k	27k Epworth Sleepiness Scale > 15	Char	1
rr427l	27l Unwilling to stop O2	Char	1
rr427m	27m Unable to stop O2	Char	1
rr427n	27n MD unwilling to stop O2	Char	1
rr427o	27o Required data are missing	Char	1
rr427p	27p Required tests outside window	Char	1
rr427q	27q Other reason for ineligibility	Char	1
visit	Visit code	Char	3

LOTT

RR - Eligibility Review

Purpose: To review eligibility just prior to randomization or to document the reason for ineligibility.

Data collection level: All patients (Core).

When: Visit rz (within 60 days of initiating screening).

Administered by: Study Physician and Clinical Coordinator.

Instructions: This form must be completed for each patient who was eligible upon completion of the Registration (RG) form. Hence, it will be completed for patients who proceed to randomization and for patients found to be ineligible after completion of the Registration (RG) form. If an Exc condition is checked, skip to item 27. **For patients whom you expect to randomize**: This form must be completed on the day of randomization. The patient must affirm consent orally before the randomization task is run. The patient should be present in the clinic when the treatment assignment is generated. The clinic and patient should be prepared to make arrangements for delivery of home oxygen equipment immediately if the patient is randomized to supplemental oxygen and does not have oxygen equipment in the home. If the patient is randomized to no oxygen, the clinic and patient should be ready to arrange for removal of any oxygen equipment in the home.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date completed):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: r z ____

6. Form & revision: r r 4

B. Known ineligibility

7. Is the patient known to be ineligible:

( ) Yes (1) ( ) No (2)

27. ⌊

C. Exclusions not covered on other forms

8. Has the patient signed a contract not to smoke while using oxygen:

( ) Yes (1) ( ) No (2) Elig ⌊

9. COPD judgment questions

a. In your judgment (Study Physician), is there radiologic evidence of emphysema:

( ) Yes (1) ( ) No (2)

b. In your judgment (Study Physician), are the patient's dyspnea and disease process dominated by COPD:

( ) Yes (1) ( ) No (2) Elig ⌊

c. In your judgment (Study Physician), does the patient have any non-COPD lung disease that affects oxygenation or survival:

( ) Yes (1) ⌊ ( ) No (2) Elig

10. In your judgment (Study Physician), does the patient have any disease or condition that is expected to cause death within the next 6 months:

( ) Yes (1) ⌊ ( ) No (2) Elig

11. In your judgment (Study Physician), does the patient have any disease or condition that is expected to cause inability to perform the procedures for the trial or comply with therapy for the trial within the next 6 months:

( ) Yes (1) ⌊ ( ) No (2) Elig

D. Eligibility check on day of randomization
(these questions must be answered on the day of randomization)

12. Has the patient been newly prescribed supplemental oxygen since initiating screening for LOTT:

Yes (1) → Elig; No (2)

13. Has the patient had a COPD exacerbation that required antibiotics or new or increased systemic corticosteroids since initiating screening for LOTT:

Yes (1) → Elig; No (2)

14. Is the patient participating in another intervention study:

Yes (1) → Elig; No (2)

15. Has the patient had a thoracotomy, sternotomy, major cardiopulmonary intervention or other procedure in the 6 months prior to screening or since initiating screening that is likely to cause instability of pulmonary status:

Yes (1) → Elig; No (2)

16. Was the patient prescribed home oxygen for any reason when he/she started screening:

Yes (1); No (2) → **20b.**

17. Has the patient used the oxygen equipment in the past 4 days:

Yes (1) → Elig; No (2)

18. Does the clinic have written agreement from the prescribing practitioner to cancel the oxygen prescription if the patient is randomized to no oxygen:

Yes (1); No (2) → Elig

19. Does the patient agree to removal of the oxygen equipment from the home if randomized to no oxygen:

Yes (1); No (2) → Elig

20. Other criteria

a. Does the clinic have the logistics in place to change oxygen companies if needed if the patient is randomized to supplemental oxygen *(eg, to a company that agrees to waive cost-sharing obligations):*

Yes (1); No (2) → Elig

b. Is the patient feeling well today:

Yes (1); No (2) → Elig

21. Is an ineligibility condition checked in items 7-20b or are any of items 7-20b missing *(ie, marked as m, d, n, r, ?, etc)* or is patient known to be ineligible:

Yes (*1) → Elig; No (2)

**If Yes, patient is ineligible; skip to item 27.*

22. What is the patient's data collection level *(check only one):*

Core (1)
Expanded (2)

**NOTE: Key visit sb forms RG, BC (if consent for banking was obtained), BV, DC, EP, HB, ID, MM, MO, PE, QG, QW, and SP (these are Core Data Collection forms) and HA, NO, PQ, and QF if the patient consented to Expanded Data Collection. Run the Randomization Task on the LOTT data system.*

23. Were any STOPS or Ineligible conditions other than missing Form RR identified by the Randomization Task:

Yes (*1) Elig
No (2)
Task not run because patient is known to be ineligible (3)
27.

**If Yes, patient is ineligible; skip to item 27.*

24. Does the Study Physician approve randomizing the patient to either treatment group:

Yes (1) No (*2) Elig

**If No, patient is ineligible; skip to item 27.*

25. Are the patient and clinic prepared to arrange for delivery and receipt of home oxygen equipment immediately (or restart of equipment already in the home) if patient is randomized to supplemental oxygen:

Yes (1) No (*2) Elig

**If No, patient is ineligible; skip to item 27.*

26. Does the patient still consent to randomization:

Yes (*1) No (†2)
28. Elig

**Go to item 27 and complete this form. Then key this form and run the Randomization Task on the LOTT data system to randomize the patient.*

†Complete items 27 and 30-32 and key this form. This form must be keyed to document the reason(s) for ineligibility for LOTT.

E. Reasons for ineligibility

Note: Complete this section for ineligible patients only

27. Reason(s) for ineligibility *(check all that apply)*

a. Reason covered in items 8-26: (1)

b. Exacerbation requiring antibiotics or new or increased systemic corticosteroids since starting screening: (1)

c. Prescription of supplemental oxygen since starting screening: (1)

d. Resting oxygen saturation 88% or less: (1)

e. Resting oxygen saturation 94% or greater and desaturation below 90% for ≥ 10 seconds not detected during 6 minute walk: (1)

f. Desaturation below 80% for at least 1 minute during 6 minute walk: (1)

g. Other reason related to resting room air oximetry *(specify):* (1)

_____
specify

h. Other reason related to room air 6 minute walk *(specify):* (1)

_____
specify

i. Post BD FEV_1 percent predicted 71% or higher and no radiologic evidence of emphysema: (1)

j. Post BD FEV_1/FVC 0.70 or higher: (1)

k. Epworth Sleepiness Scale score greater than 15: (1)

l. Patient unwilling to stop oxygen: (1)

m. Patient unable to stop oxygen: (1)

n. Prescribing physician unwilling to cancel oxygen prescription: (1)

o. Missing required data and patient or clinic cannot obtain needed data: (1)

p. Required tests outside window and patient or clinic cannot repeat the tests: (1)

q. Other *(specify):* (1)

_____
specify

Go to item 30.

F. Administrative information

28. Study Physician PIN: ____ ____ ____ ____

29. Study Physician signature:

_____

30. Clinical Coordinator PIN: ____ ____ ____ ____

31. Clinical Coordinator signature:

_____

32. Date form reviewed:
(Note re: patient proceeding to randomization: This form must be reviewed on the day of randomization; if it was initiated prior to the randomization day, update it and re-review it on the day of randomization and key the revised date of review):

____ ____–____ ____ ____–____ ____
day mon year

sp4 - Form SP4 Spirometry

Date file created: 21 Apr 2017
Observations: 2222
Variables: 40

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
goldlung	GOLD score (0-4; based on spiro criteria only)	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
posfev	Post BD FEV1 (L)	Num	8
posfevpp	Post BD FEV1 percent predicted (Hankinson)	Num	8
posff	Post BD FEV1/FVC ratio	Num	8
posfvc	Post BD FVC (L)	Num	8
posfvcpp	Post BD FVC percent predicted (Hankinson)	Num	8
predfev	Predicted FEV1 (L) (Hankinson)	Num	8
predfvc	Predicted FVC (L) (Hankinson)	Num	8
prefev	Pre BD FEV1 (L)	Num	8
prefevpp	Pre BD FEV1 percent predicted (Hankinson)	Num	8
preff	Pre BD FEV1/FVC ratio	Num	8
prefvc	Pre BD FVC (L)	Num	8
prefvcpp	Pre BD FVC percent predicted (Hankinson)	Num	8
sp411	11 Spirometry equipment meets ATS standards	Char	1
sp412	12 Race for pulmonary function	Char	1
sp413	13 Time spirometry session began	Char	4
sp414	14 Used 3+ puffs short-acting BD in last 4 hrs	Char	1
sp407a	7a Used theophylline in past 24 hrs	Char	1
sp407b	7b Time last used theophylline	Char	4
sp407ba	7b Time last used theophylline (am/pm)	Char	1
sp408a	8a Used 24hr bronchodilator in past 24 hrs	Char	1
sp408b	8b Time last used 24hr bronchodilator	Char	4
sp408ba	8b Time last used 24hr bronchodilator (am/pm)	Char	1
sp409a	9a Used 12hr bronchodilator in past 12 hrs	Char	1
sp409b	9b Time last used 12hr bronchodilator	Char	4
sp409ba	9b Time last used 12hr bronchodilator (am/pm)	Char	1
sp410a	10a Used 4hr bronchodilator in past 4 hrs	Char	1
sp410b	10b Time last used 4hr bronchodilator	Char	4
sp410ba	10b Time last used 4hr bronchodilator (am/pm)	Char	1
sp413a	13 Time spirometry session began (am/pm)	Char	1
sp415c	15c Number of short-acting BD puffs in last 4 hrs	Char	1
sp416c	16c sb visit	Char	1
sp417a	17a Session meets ATS quality standards	Char	1
sp417b	17b Session meets ATS standards for repeatability	Char	1
sp417c	17c Yes for 17a and 17b	Char	1
sp417d	17d Physician believes spirometry acceptable	Char	1
visit	Visit code	Char	3

LOTT

Spirometry

Purpose: To record spirometry results.

Data collection level: Core or Expanded, depending on visit.

When: Screening visit sb (all patients, Core) and followup visits f12, f24, f36, f48, f60, f72 (Expanded).

Administered by: Spirometry Technician and Clinical Coordinator.

Instructions: LOTT does not require patients to hold bronchodilator before completing spirometry. If the patient has used 3 or more puffs of short-acting bronchodilator in the past 4 hours, skip pre BD spirometry and proceed with post BD spirometry without administration of any additional bronchodilator. Otherwise, complete pre BD spirometry. Once pre BD spirometry is complete, administer bronchodilator for post BD testing: Administer 4 puffs albuterol (90 mcg/puff) if the patient has not used any short-acting BD in the previous 4 hours. Administer 2 puffs albuterol (90 mcg/puff) if the patient has used 1 or 2 puffs short-acting BD in the previous 4 hours. Wait 15 minutes and complete post BD spirometry. Note: Ignore recent use of 12- and 24-hour bronchodilator; recent use of 12- or 24-hour bronchodilator does not suffice for post BD testing for LOTT. Spirometry should be performed with the patient in a sitting position and with the patient wearing nose clips. Show the patient Flashcard #9 and ask the patient which choice best describes his/her race/ethnicity. Transcribe the measured values from the pulmonary function laboratory report. The report should be marked with the patient's study ID and code and stapled to the back of this form. Use LOTT predicted values (predicted values of Hankinson et al, 1999); obtain the appropriate values from the patient's chart of predicted values. Use a calculator for all calculations. If this is screening visit sb and an (EXC) condition is checked, the patient is ineligible for LOTT. If the patient is ineligible, complete the administrative section and file the form in the file for ineligible patients. Do not key SP forms for ineligible patients.

A. Clinic, visit, and patient information

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Visit date *(date of spirometry):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: s p 4

B. Medication use *(ask these questions before initiating LOTT spirometry and before administering albuterol for LOTT post-BD testing)*

7. Theophylline use in the past 24 hours

a. Has the patient used theophylline in the past 24 hours:

( ) Yes (1) ( ) No (2) → **8.**

b. Time of last theophylline use:

____ ____ : ____ ____ ( ) am (1) ( ) pm (2)
hour minute

8. 24-hour bronchodilator use in the past 24 hours

a. Has the patient used a 24-hour bronchodilator (eg, tiotropium) in the past 24 hours:

( ) Yes (1) ( ) No (2) → **9.**

b. Time of last 24-hour bronchodilator use:

____ ____ : ____ ____ ( ) am (1) ( ) pm (2)
hour minute

9. 12-hour bronchodilator use in the past 12 hours

a. Has the patient used a 12-hour bronchodilator (eg, salmeterol) in the past 12 hours:

( ) Yes (1) ( ) No (2) → **10.**

b. Time of last 12-hour bronchodilator use:

____ ____ : ____ ____ ( ) am (1) ( ) pm (2)
hour minute

10. 4-hour bronchodilator use in the past 4 hours

a. Has the patient used a 4-hour bronchodilator (eg, albuterol) in the past 4 hours:

(Yes 1) (No 2)

11.

b. Time of last 4-hour bronchodilator use:

____ ____:____ ____ (am 1) (pm 2)

hour minute

C. Spirometry

11. Does the spirometry equipment meet ATS standards:

(Yes †1) (No *2)

STOP

†Complete pre and post BD spirometry.

**Spirometry equipment must meet ATS standards for quality. Do not complete spirometry until equipment meeting ATS standards is obtained.*

12. Race/ethnicity for pulmonary function *(show patient LOTT Flash Card #9 and ask the patient which choice best describes his/her race/ethnicity):*

Caucasian	(1)
African-American	(2)
Mexican or Mexican-American	(3)
Other	(4)
Refused	(5)

13. Time spirometry session began:

____ ____:____ ____ (am 1) (pm 2)

hour minute

14. Has the patient taken 3 or more puffs of short-acting bronchodilator in the last 4 hours *(this question is asked before administering BD for LOTT post-BD testing):*

(Yes *1) (No 2)

16.

**Skip pre BD testing and proceed with post BD testing without administering additional bronchodilator.*

15. Pre BD values

a. FVC: ____ • ____ ____ liters-BTPS

b. FEV_1: ____ • ____ ____ liters-BTPS

c. How many puffs of short-acting bronchodilator has the patient taken in the last 4 hours:

None (no puffs)	(*1)
1 or 2 puffs	(†2)

**Administer 4 puffs albuterol (90 mcg/puff) and wait 15 minutes.*

†Administer 2 puffs albuterol (90 mcg/puff) and wait 15 minutes.

16. Post BD values

a. FVC: ____ • ____ ____ liters-BTPS

b. FEV_1: ____ • ____ ____ liters-BTPS

c. Is this visit sb:

(Yes 1) (No 2)

17.

d. Post BD FEV_1/FVC *(item 16b/item 16a):*

____ • ____ ____

e. Is item 16d less than 0.70:

(Yes 1) (No 2)

Elig

f. Predicted FEV_1 *(obtain from LOTT chart for patient):*

____ • ____ ____ liters-BTPS

g. FEV_1 % predicted *([item 16b/item 16f]x100):*

____ ____ % ____

h. Is item 16g less than or equal to 70%:

(Yes *1) (No †2)

C

**Patient is eligible for LOTT with respect to FEV_1 % predicted.*

†Patient must have radiologic evidence of emphysema to be eligible for LOTT.

17. ATS standards

a. Did the session meet ATS standards for quality:

(Yes 1) (No 2)

b. Did the session meet ATS standards for repeatability:

(Yes 1) (No 2)

c. Was Yes checked for both items 17a and 17b:

(Yes 1) (No *2)

18.

**Repeat spirometry if possible. If not possible, proceed to item 17d.*

d. Since the spirometry did not meet ATS standards for both quality and repeatability and since it cannot be repeated or repeating did not improve quality and/or repeatability, the LOTT Study Physician must review the spirometry. Does the LOTT Study Physician believe the spirometry measures are acceptable and reflective of the patient's condition:

(Yes 1) (No 2)

Elig

e. Study Physician PIN: ____ ____ ____ ____

f. Study Physician signature:

_____

D. Administrative information

18. Spirometry Technician PIN:

____ ____ ____ ____

19. Spirometry Technician signature:

_____

20. Clinical Coordinator PIN:

____ ____ ____ ____

21. Clinical Coordinator signature:

_____

22. Date form reviewed:

____ ____–____ ____ ____–____ ____

day mon year

tc1 - Form TC1 Post Randomization Initiation or Cancellation of Home Oxygen

Date file created: 21 Apr 2017
Observations: 165
Variables: 22

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
tc107	7 Cancellation of home O2 prescription	Char	1
tc108	Date O2 script canceled cnvrtd to #days from RZ	Num	8
tc110	10 O2 use prescribed or resumed	Char	1
tc111	Date O2 script strted/resumd cnvrtd to #days from RZ	Num	8
tc113	13 Who is prescribing home O2	Char	1
tc109a	9a Patient request	Char	1
tc109b	9b Safety concerns	Char	1
tc109c	9c Patient recovered from severe desaturation	Char	1
tc109d	9d Other reason	Char	1
tc112a	12a Resumption of assigned O2 randomization	Char	1
tc112b	12b Patient has severe resting hypoxemia	Char	1
tc112c	12c Patient has severe exercise desaturation	Char	1
tc112d	12d Meets criteria for O2 during exercise	Char	1
tc112e	12e Meets criteria for O2 during sleep	Char	1
tc112f	12f Other reason for O2 initiation/resumption	Char	1
tc114a	14a Prescription for O2 at rest	Char	1
tc114b	14b Prescription for O2 during exercise	Char	1
tc114c	14c Prescription for O2 during sleep	Char	1
visit	Visit code	Char	3

LOTT

TC - Post Randomization Initiation or Cancellation of Home Oxygen

Purpose: To report prescription (initial or resumed) or cancellation of home oxygen, post randomization.

Data collection level: All patients (Core).

When: As needed after randomization. Use visit code n. If you need to complete more than one TC form on the same date, use visit code n for the first and visit code n2 for the second.

Administered by: Clinical Coordinator.

Instructions: This form is used to report post randomization changes in home oxygen prescription status (eg, initiation, resumption or cancellation of home oxygen post randomization). It is not used to report initiation of oxygen because of randomization to the supplemental oxygen group, nor is it used to report changes in oxygen flow prescription. It is not used to report hiatus in oxygen use due to patient travel. It is not used to report oxygen use while hospitalized, but it is used to report prescription of home oxygen after a hospitalization that included oxygen use while hospitalized.

A. Center, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____

6. Form & revision: t c 1

B. Change in treatment being reported

7. Is cancellation of the home oxygen prescription being reported:

Yes (1) No (2)

→ **10.**

8. Date home oxygen prescription was canceled *(estimate if necessary):*

____ ____–____ ____ ____–____ ____
day mon year

9. Why is the home oxygen prescription being canceled *(check all that apply)*

a. Due to patient request *(specify reason for patient request):* (1)

_____
specify

b. Due to safety concerns *(specify reason):* (1)

_____
specify

c. Patient has recovered from severe resting hypoxemia and/or severe exercise desaturation: (1)

d. Other reason *(specify reason):* (1)

_____
specify

10. Is initial prescription or resumption of home oxygen being reported:

Yes (1) No (2)

→ **15.**

11. Date home oxygen was prescribed *(if home oxygen is being resumed, enter date of most recent prescription; estimate if necessary):*

____ ____–____ ____ ____–____ ____
day mon year

12. Why was home oxygen initiated or resumed *(check all that apply)*

a. Patient was randomized to oxygen and home oxygen is being resumed after having been canceled: (1)

b. Patient has severe resting hypoxemia *(resting saturation < 89%):* (1)

c. Patient has severe exercise desaturation *(saturation < 80% for over one minute during 6MW):* (1)

d. Patient meets conventional Medicare criteria for oxygen during exercise and patient and/or physician requests prescription: (1)

e. Patient meets conventional Medicare criteria for oxygen during sleep and patient and/or physician requests prescription: (1)

f. Other reason *(specify reason):* (1)

_____
specify

13. Who is prescribing the home oxygen *(check only one):*

LOTT Study Physician (1)
Other healthcare provider (2)

14. Is the home oxygen prescription for

	Yes	No
a. Oxygen at rest:	(1)	(2)
b. Oxygen during exercise:	(1)	(2)
c. Oxygen during sleep:	(1)	(2)

C. Administrative information

15. Clinical Coordinator PIN:

____ ____ ____ ____

16. Clinical Coordinator signature:

_____

17. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

valids - Valids file (census file)

Date file created: 21 Apr 2017
Observations: 1759
Variables: 14

Variable Name	Variable Label	Type	Variable Length
birthdt	Birth date cnvrtd to #days frm RZ/scr	Num	8
black	1=Black or African American	Char	1
death	1=Dead asof31Aug2015,0=alive asof31Aug2015	Num	8
deathdt	Death date cnvrtd to #days frm RZ/scr	Num	8
desatqul_r6b	DesatQualifyPtForLOTT:1=RestOnly,2=ExerOnly,3=Both	Num	8
eligdt	Scr date as # days frm scr (ie, 0, nonrz pts)	Num	8
enrolldt	RZ date as #days frm RZ (ie, 0, rz pts)	Num	8
gender	Gender: 1=male, 2=female	Char	1
minority	1=minority race, 0=white caucasian only	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
rcc	1 if patient enrolled at an RCC, 0 otherwise	Num	8
trtgrp	LOTT treatment group: LTOT or NoLTOT	Char	6
va	1 if patient enrolled at VA site, 0 otherwise	Num	8
white	1=White	Char	1

xz2 - Form XZ2 Documentation of RZ and RZ Day Adherence Promotion Contact (Both Grps)

Date file created: 21 Apr 2017
Observations: 738
Variables: 25

Variable Name	Variable Label	Type	Variable Length
form	Form abbreviation and revision number	Char	3
formdate	item 4 cnvrtd to #days from RZ	Num	8
newlott	New LOTT ID (5 digit numeric patient id number)	Char	5
visit	Visit code	Char	3
xz207	7 Staff member PIN who gave treatment assignment	Char	4
xz209	9 Rate readiness to use oxygen as prescribed	Char	2
xz210	10 Rate importance of using oxygen	Char	2
xz213	13 Rate confidence in ability to use oxygen	Char	2
xz216	16 Delivery of oxygen equipment scheduled	Char	1
xz217	Date of delivery cnvrtd to #days from RZ	Num	8
xz218	18 Dose determination appointment made	Char	1
xz220	20 Rate understanding of role in study	Char	2
xz222	22 Patient has O2 equipment in home	Char	1
xz223	23 Visit w01 telephone appointment made	Char	1
xz225	25 Visit f12 scheduled	Char	1
xz208a	8a Treatment assignment	Char	1
xz208b	8b Oxygen prescription	Char	1
xz221a	21a Relief	Char	1
xz221b	21b Disappointment	Char	1
xz221c	21c Concern about future health	Char	1
xz221d	21d Worry about breathing problems	Char	1
xz221e	21e Feels shortchanged	Char	1
xz221f	21f Not sure of feelings	Char	1
xz221g	21g Other	Char	1
xz221h	21h Patient does not express any feelings	Char	1

LOTT

XZ - Documentation of Randomization and Randomization Day Adherence Promotion Contact (Both Groups)

Purpose: To document/guide activities of the randomization day, after the treatment assignment has been generated.
Data collection level: All patients (Core).
When: Visit rz.
Administered by: Clinical Coordinator and Adherence Educator.
Respondent: Patient.
Instructions: Complete this form after the patient's treatment assignment has been generated and the patient has been informed of his/her assignment. **Supplemental oxygen patients**: Provide adherence promotion contact; objectives include: (1) Review oxygen prescription with patient (24/7 if patient has resting hypoxemia; with physical activity and sleep if patient has normal saturation at rest but desaturates on exercise); (2) Establish rapport with the patient by assisting the patient in identifying their feelings about oxygen use, including ambivalence and expected barriers/solutions to oxygen use at home and away from home; (3) Determine the patient's level of readiness to use supplemental oxygen; assess and explore how important the patient believes oxygen use is and how confident the patient feels about using oxygen; (4) Educate the patient about equipment choices and safe operation of the equipment; (5) Check the patient's level of understanding of the treatment and study protocol; (6) Arrange for delivery of oxygen equipment if not already in the home and initiate the Oxygen Equipment (OE) form; (7) Schedule the visit for ambulatory dose assessment. **Control patients**: Provide adherence promotion contact; objectives include: (1) Establish rapport with the patient by assisting the patient in identifying their feelings about not being assigned to the oxygen group, including ambivalence and expected barriers/solutions to living with COPD without supplemental oxygen; (2) Check the patient's level of understanding of the treatment and study protocol, including the need to report oxygen use and to recognize when oxygen would be appropriate; (3) Make arrangements to have any oxygen equipment in the home removed; (4) Schedule the 1 week followup adherence promotion contact. **All patients**: Schedule the f12 visit. **Note**: Only items 1-10, 13, and 16-31 are keyed.

A. Center, patient, and visit identification

1. RCC ID: ____ ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____ ____

3. Patient code: ____ ____ ____ ____

4. Date of visit:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: r z ____

6. Form & revision: x z 2

B. Checks

7. PIN of staff member who informed the patient of his/her treatment assignment:

____ ____ ____ ____

8. Treatment assignment

a. Treatment group:
Supplemental oxygen (1)
No supplemental oxygen (2)

20. ____

b. Oxygen prescription:
24-hour oxygen (1)
Oxygen during physical activity and sleep (2)

C. Supplemental oxygen patient adherence promotion contact

(Adherence Educator administers this section - see instruction box for topics to cover; any barriers/solutions to oxygen use mentioned during discussions should be listed in Section H. For questions 9, 10, and 13, if patient responds with fraction, eg, 6.5, seek a whole number response by asking if more 6 or more 7.)

9. On a scale of 0 to 10 where 0 means Not at all ready and 10 means Very ready, how ready are you today to use oxygen all of the time *(as much as prescribed):*

____ ____
00-10

10. On a scale of 0 to 10 where 0 means Not at all important and 10 means Very important, how important is using oxygen to you:

____ ____
00-10

If item 10 is 5 or greater:

11. Why did you give yourself a ____ *[quote number response to item 10]* instead of a 2 or 3:

_____

_____

_____

If item 10 is 4 or less:

12. What would it take to get you to a 6 or 7 instead of a ____ *[quote number response to item 10]*:

_____

_____

_____

13. On a scale of 0 to 10 where 0 means Not at all confident and 10 means Very confident, how confident are you today that you can use oxygen all the time *(as much as prescribed):*

____ ____
00-10

If item 13 is 5 or greater:

14. Why did you give yourself a ____ *[quote number response to item 13]* instead of a 2 or 3:

_____

_____

If item 13 is 4 or less:

15. What would it take to get you to a 6 or 7 instead of a ____ *[quote number response to item 13]*:

_____

_____

Ask the patient what problems he/she foresees to using supplemental oxygen and list those problems in Section H. Ask the patient "How do you think you might handle [mention one barrier at a time]" and list solutions in Section H.

D. Oxygen equipment and appointment for dose determination

(Clinical Coordinator or Adherence Educator may administer this section)

16. Was delivery of oxygen equipment scheduled:

Yes (1)

No, patient already has stationary and portable oxygen systems at home (2)

18.

No *(specify why not)* (3)

18.

_____
specify why not

17. Date scheduled for equipment delivery:

____ ____–____ ____ ____–____ ____
day mon year

18. Was an appointment made for walking oxygen dose determination *(visit rx):*

Yes (1)

No *(specify why not)* (2)

25.

_____
specify why not

19. Date and time scheduled for walking oxygen dose determination *(visit rx)*

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Time:

____ ____:____ ____ (1) (2)
hour minute am pm

Go to item 25.

E. No supplemental oxygen patient adherence promotion contact

(Adherence Educator administers this section - see instruction box for topics to cover; any barriers/solutions to living with COPD without supplemental oxygen mentioned during discussions should be listed in Section H)

20. Ask the patient to describe his/her role in the study and rate the patient's understanding of his/her role in the study (ie, the role of the control group patient), where 0 denotes Poor understanding and 10 denotes Excellent understanding:

____ ____
00-10

21. Ask the patient to describe his/her feelings about assignment to the no oxygen group. What feelings does the patient report *(check all that apply)*

a. Relief: (1)
b. Disappointment: (1)
c. Concern about future health: (1)
d. Worry about breathing problems: (1)
e. Feels shortchanged: (1)
f. Not sure of feelings: (1)
g. Other *(specify):* (1)

_____
specify

h. Patient does not express any feelings: (1)

Discuss with the patient what he/she sees as barriers and solutions to living with COPD without supplemental oxygen. Ask the patient what problems he/she foresees to living with COPD without supplemental oxygen and list those problems in Section H. Ask the patient ''How do you think you will handle [mention one barrier at a time]?'' and list solutions in Section H.

22. Does the patient have oxygen equipment in the home:

Yes (*1) No (2)

**Remind the patient of his/her agreement to have the equipment removed. Contact the prescribing physician and request cancellation of the prescription.*

23. Was an appointment made for the 1-week followup telephone adherence promotion contact *(visit w01):*

Yes (1) No (2)
→ 25.

24. Date and time scheduled for 1-week followup telephone adherence promotion contact *(visit w01)*

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Time:

____ ____:____ ____ (1) (2)
hour minute am pm

F. Annual followup visit

25. Was visit f12 scheduled:

Yes (1) No (2)
→ 27.

26. Date and time scheduled for visit f12

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Time:

____ ____:____ ____ (1) (2)
hour minute am pm

G. Administrative information

27. Adherence Educator PIN:

____ ____ ____ ____

28. Adherence Educator signature:

_____

29. Clinical Coordinator PIN:

____ ____ ____ ____

30. Clinical Coordinator signature:

_____

31. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

H. Barriers and solutions *(these discussions may elicit barriers and provide opportunities to explore solutions; please list below)*

32.	Barriers	Solutions

I. Notes *(record any notes about today's discussion that will be helpful for your next contact with this patient)*

33. Notes: