

# Endpoints Ascertainment Procedure Supplements

Version 1.1

January 23, 2015

### **Endpoints Ascertainment Procedure Supplements**

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#### Supplement 1. Example Event Summary Form (ESF) for Pulmonary Diagnosis

EVENT ID: X0 SPIROMICS ID: X0000010	00000010010 Gender: F	1 Age a Baselir 55	0	<b>Height</b> 161.00	Predicted BMI PEF 27.9
Event Date ICD-9 Discha 786.50	12/28/2009 <b>rge Codes:</b> 486	Date of arr 493.20	rival: [mm/dd/yyyy] 99.21	Date of disch	narge: [mm/dd/yyyy]
100.00	100	100.20	00.21		

#### ER, hospital or observation:

#### **Doctor's diagnosis**

Reason in doctor's notes that this event may be exacerbation of COPD: Reason in doctor's notes that event may be exacerbation of asthma:

#### Signs and symptoms

Any of the following signs or symptoms at the time of the event:

New onset or increase in cough: New onset or increase in sputum production New onset or increase in sputum purulence New onset or increase in wheezing New onset or increase in dyspnea Crackles / rales Wheezing or rhonchi

#### History

History of any of the following: Asthma Emphysema Chronic obstructive pulmonary disease (COPD)

#### Tests

Any of the following signs on chest x-ray or chest CT at any time during this event? Hyperinflation Flattened diaphragms Emphysema Infiltrate/consolidation Pulmonary edema Pleural effusion Sputum or respiratory fluid culture results

**Prior PFTS:** Percent predicted FEV<sub>1</sub>:

FEV1/FVC:

#### Peak flows

Date of first PEF(R) taken after hospital/ED arrival: (mm/dd/yyyy) First PEF recording (L/min) Worst PEF recording (L/min) during this hospitalization

## TREATMENTS / MEDICATIONS

Antibiotics Inhaled short-acting beta-agonists (i.e., albuterol, xopenex) Inhaled short-acting anticholinergics (i.e., atrovent, ipratropium) Inhaled long-acting beta agonists Inhaled long-acting anticholinergics Inhaled corticosteroids Systemic corticosteroid (oral or IV) CPAP or BiPap Mechanical Ventilation

No/NR 0 Yes 1

## Supplement 2. Morbidity and Mortality Committee – Principles of Mortality Adjudication

The Morbidity and Mortality Committee will designate cause of death by probable cause. Causes of death will be grouped by general categories, e.g. Respiratory, Cardiovascular, Cancer, or Other. If a cause of death cannot be ascertained, the cause of death will be classified as Unknown. The general principles used in this classification are listed:

- 1. All diagnoses of cancer should be corroborated by the primary medical record. If the primary medical record cannot be obtained to confirm the diagnosis, this should be affirmatively stated in the documentation, and the committee will determine a diagnosis based on their best judgment.
  - a. Patients who die with an uncured cancer will be designated as dying from the cancer. For example, a patient with documented gastric cancer who dies of gastrointestinal hemorrhage will be classified to have died from gastric cancer. A patient who dies from neutropenic sepsis while undergoing chemotherapy for lymphoma will be classified as dying from lymphoma.
  - b. Based on the medical information, patients who have cancers that are not expected to result in death from complications of the disease or treatment such as localized skin or urogenital cancer may be considered to die of other causes.
- 2. Death certificates should be obtained in all cases. If they cannot be obtained, it should be affirmatively stated in the documentation.
- 3. If medical records are inadequate and cannot be obtained as affirmatively stated in the documentation, a cause of death will be adjudicated based on the best available evidence of record. If a probable cause of death cannot be adjudicated, it will be classified as unknown.
- 4. The primary cause of death should be attributed to the disorder that causes the patient to present for medical treatment. This should be distinguished from terminal events that are the immediate cause of death.
  - For example, if a patient is admitted to the hospital with a COPD exacerbation, from which they do not fully recover, and the patient subsequently develops complications such as pneumonia, respiratory failure, renal failure, sepsis, cardiac arrhythmia or myocardial infarction, the primary cause of death will be attributed to COPD.
  - For example, if a patient undergoes surgery for cancer and dies from complications of the surgery or during the immediate post-operative period, the primary cause of death will be attributed to cancer, even if the cancer was potentially curable by the surgery.
  - For example, if a patient is admitted to the hospital with pneumonia and develops complications such as respiratory failure, gastrointestinal bleeding, etc. the cause of death will be attributed to pneumonia. If it is unclear if a patient is admitted with a COPD exacerbation or pneumonia, the cause of death will be based on the hospital admission chest radiograph. If pneumonia is present

on the admitting chest radiograph (or within 48 hours of presentation), the cause of death will be designated pneumonia. If pneumonia is present only on subsequent chest radiographs (beyond 48 hours after presentation), the cause of death will be designated as COPD.

- If a patient is admitted to hospice care for a designated chronic terminal condition (e.g. COPD, CHF), then the terminal condition will be the designated cause of death.
- 5. Included within cardiovascular causes of death will be two subcategories, "sudden death" and "sudden cardiac death." Sudden Death is defined as death that occurs within 24 hours of being observed alive and without evidence of a deteriorating medical condition. Sudden Cardiac Death is defined as death that occurs within 1 hour of being observed alive and without evidence of a deteriorating medical condition. If the interval between death and last being observed alive is greater than 24 hours, and there is no other known cause of death, the cause of death will be classified as "Unknown." The diagnosis of myocardial infarction will require pathologic evidence, or evidence of medical record including electrocardiographic tracings, blood enzyme measurements, and compatible clinical findings.
- 6. In cases of out of hospital death, the site coordinator or site physician should interview family or witnesses to ascertain the following information:
  - When was the person last known to be alive?
  - When was the person found to be deceased?
  - What were the events surrounding the death?
  - Did the decedent have any symptoms or change in health status that preceded the death? Special reference should be made to dyspnea, febrile illnesses, chest pain, abdominal pain, syncope, seizures, paralysis and change in mental status.
  - Were there recent medical visits or recent changes in medication?
  - Was an autopsy performed?
  - Permission to obtain medical records should be requested from next-of-kin.

## **Supplement 3. Scanning and Redacting**

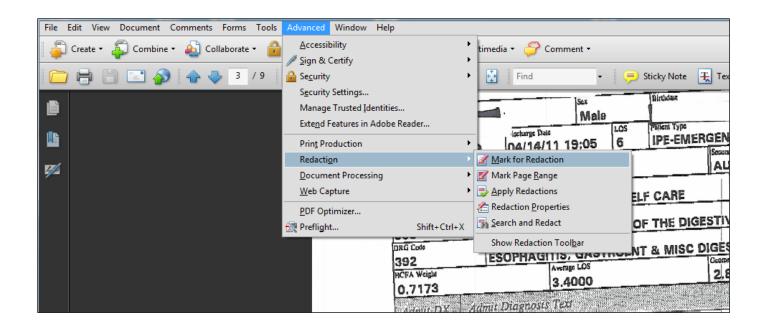
The GIC will provide each site with a document scanner and Adobe Acrobat Professional Version 9.5 or higher to create PDFs of your electronic files. This ensures the proper level of file security.

Place all documents for each event, including the Medical Record Shipping Cover Letter, in Table 1 order and scan using the scanner set to black and white document and save as a PDF in a secure location. Open the case with Adobe Acrobat Professional 9.5 or higher. You will need to right-click on the document and choose "Open With" and "Adobe Acrobat 9.5" to access full functionality. Double-clicking on the PDF will only open the document in Adobe Reader.

Once the file is open with Adobe Pro, insert a header (found in the Document tab menu) with the appropriate Event ID from the Event ID Tracking Report in the upper right-hand corner. This header should appear on every page of the document.

## Redaction

To redact, open the medical record case with Adobe Acrobat Professional 9.5 or higher. Select Mark for Redaction.



This will bring up one of two redaction cursors (image courtesy of Rick Borstein).

While reading through the file, left click, hold and drag the text or image cursor over the text you want to redact so it is enclosed in a blue shadowed box. Release the cursor and a red redaction box will remain to indicate your selection. If you don't see a red box, the text is not selected for redaction and you may need to go back and click on Mark for Redaction again. To correct the area selected, use CTRL-Z to delete the red redaction box. If the text cursor is making it hard to select specific text, hold down the CTRL key to force the + image cursor.

CPT Code & M	odifier(s) CPT Texa Date	Provider
\$3239 \$5380 \$3259 74022 76705 96374 99285	Upper GI endoscopy, esophegus/stomach/duodenum/jajunum: with Colonoscopy, flexible, proximal to spienic flexure: with biopsy, Upper GI endoscopy, esophagus, stomach, duodenum or jujunum: with Rediologic examination, ebdomen: complete acute abdomen series, Ultrasound, ebdominel, real time with image documentation: limited Therapeutic, prophylactic or diagnostic injection: intravenous push. Emergency dept visit for eval & mgmt of a patient, roquiring 3	
	\$3239 \$5380 \$3259 74022 76705 96374	3239 Upper GI endoscopy, esophegus/stomach/duodenum/jajunum: with   16380 Colonoscopy, flexible, proximal to spienic flexure: with biopsy,   13259 Upper GI endoscopy, esophagus, stomach, duodenum or jujunum: with   14022 Radiologic examination, abdomen: complete acute abdomen series,   16705 Ultrasound, abdominel, real time with image documentation: limited   16374 Therapautic, prophylactic or diagnostic injection: intravenous push.   19285 Emergency dept visit for eval & mgmt of a patient, requiring 3

Once the entire document has been reviewed and text for redaction selected, go back to Advanced and choose Apply Redactions. A dialog box opens warning that redactions are permanent. Click Yes to complete the redactions.

File	Edit Vie	w Document	Comments	Forms	Tools	Advanced	Window	Help						
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When this is complete, a second dialog box opens up asking if you want to complete other functions, just click on No. Save the file – Adobe will ask if you want to replace the current file. Click Yes.

Each page of the scanned medical records or death certificates must be checked and the following items redacted:

Participant and family member names and/or initials, addresses, and telephone numbers Participant birth date and Social Security number Hospital and healthcare system names, facility initials, street addresses, and telephone numbers Institutional letterheads and/or logos All healthcare staff names, initials, provider numbers, pager and extension numbers Medical record numbers Health plan ID numbers Account numbers Lab, test, or procedure accession numbers, order numbers, or exam numbers Dictation job and confirmation numbers Electronic mail addresses Web addresses or URLs, IP addresses

The following items should *not* be redacted:

Participant age, gender Admit and Discharge dates Healthcare staff titles or departments (i.e., MD, RT, Cardiology) On death certificates, do not blind causes of death

# **Supplement 4. Tables 1-3**

Table 1. Documents to be obtained if available for all deaths occurring while hospitalized OR if an ED visit or hospitalization has occurred in the setting of relevant diagnoses (Tables 2 and 3).

-	
1	Coding summary with ICD-9 or ICD-10 codes
2	Admission History and Physical
3	Discharge Summary (#2 and #3 maybe one note for ED visits)
4	General labs (blood)
5	Microbiology labs (blood, sputum, tracheal and bronchial fluid)
6	Procedure or surgical reports
7	Spirometry report
8	Echo report
9	Pulse oximetry report
10	Arterial blood gas report
11	Discharge medication report
12	Chest X-ray report
13	Chest CT scan report
14	Pulmonary angiography
15	V/Q Lung scan
16	Autopsy or Medical examiner report
17	12-lead EKG reports and cardiac enzyme lab reports for MI and CAD cases only

Diagnoses requiring abstraction	
Acute upper respiratory infection	465.X
Acute bronchitis	466.X
Viral Pneumonia	480.X
Pneumococcal pneumonia	481.X
Other bacterial pneumonia	482.X
Pneumonia due to other specified organism	483.X
Bronchopneumonia, organism unspecified	485.X
Pneumonia, organism unspecified	485.X 486.X
Influenza	480.X 487.X
Influenza	467.A 488.X
Bronchitis	
Chronic bronchitis 491	490.X
	491.X
With acute exacerbation 491.21	400 X
Emphysema	492.X
Asthma 493	493.X
Unspecified 493.0	
With status asthmaticus 493.1	
With acute exacerbation 493.2	404 37
Bronchiectasis	494.X
COPD	496.X
Pneumonitis due to solids and liquids	507.X
Empyema	510.X
Pleurisy	511.X
Pneumothorax	512.X
Abscess of lung and mediastinum	513.X
Pulmonary congestion and hypostasis (includes pulmonary edema NOS)	514.X
Other diseases of lung including but not exclusive to:	518.X
Acute pulmonary edema of lung, unspecified 518.4	
Pulmonary insufficiency following trauma and surgery 518.5	
Acute respiratory failure 518.81	
Heart Failure	428.X
Additional diagnoses or procedures if listed on coding	Mechanical Ventilation not in the setting of a
summary or reported by patient where additional records are	surgical procedure
needed	Lung Transplantation, or any hospitalization
	where the patient reports they were treated for
	a respiratory problem
For abstraction but not adjudication	
Lung cancer	162.X or 163.X
Diabetes	249.X 250.X
Venous thrombosis (DVT)	453.X
Pulmonary embolus	415.X
Osteoporosis	733.X
Hip Fracture	820.X 821.X
Myocardial Infarction	410.X, 411.X
Coronary artery disease	414.X
Stroke or transient ischemic attack	433.X, 434.X, 435.X
	, , ,

Table 2. ICD-9-CM codes and diagnoses that require attainment of additional records (see Table 1).

Diagnoses requiring abstraction	
Acute upper respiratory infections of multiple and	J06.X
unspecified sites	
Influenza due to identified avian influenza virus	J09.X
Influenza due to identified influenza virus	J10.X
Influenza, virus not identified	J11.X
Viral pneumonia	J12.X
Pneumonia due to Streptococcus pneumonia	J13.X
Pneumonia due to Haemophilus influenza	J14.X
Bacterial pneumonia, not elsewhere classified	J15.X
Pneumonia due to other infectious organisms, not	J16.X
elsewhere classified	
Pneumonia in disease classified elsewhere	J17.X
Pneumonia, organism unspecified	J18.X
Acute bronchitis	J20.X
Acute bronchiolitis	J21.X
Unspecified acute lower respiratory infection	J22.X
Bronchitis, not specified as acute or chronic	J40.X
Simple and mucopurulent chronic bronchitis	J41.X
Unspecified chronic bronchitis	J42.X
Emphysema	J43.X
Other chronic pulmonary disease which includes but is not	J44.X
exclusive to:	
COPD with acute lower respiratory infection (J44.0)	
excluding influenza	
COPD with acute exacerbation (J44.1)	
Other specified COPD (J44.8) Asthma	J45.X
	J45.X J46.X
Status asthmaticus (includes acute severe asthma) Bronchiectasis	J40.X J47.X
Respiratory conditions due to inhalation of chemicals,	J47.A J68.X
gases, fumes and vapors	J08.A
Pneumonitis due to solids and liquids	J69.X
Respiratory conditions due to other external agents	J70.X
Adult respiratory distress syndrome	J80.X
Pulmonary edema	J81.X
Abscess of lung and mediastinum	J85.X
Pyothorax	J86.X
Pleural effusion, not elsewhere classified	J90.X
Pleural effusion in conditions classified elsewhere	J90.X J91.X
Pneumothorax	J93.X
Other pleural conditions	J95.A J94.X
Postprocedural respiratory disorders, not elsewhere	J94.A J95.X
classified	375.23
Respiratory failure, not elsewhere classified	J96.X
Other respiratory disorders	J98.X
Heart Failure	150.X
	1.0.0.11

Table 3. ICD-10-CM codes and diagnoses that require attainment of additional records (see Table 1).

Additional diagnoses or procedures if listed on coding summary or reported by patient where additional records are needed	Mechanical Ventilation not in the setting of a surgical procedure
	Lung Transplantation, or any hospitalization where the patient reports they were treated for a
	respiratory problem
For abstraction but not adjudication	
Lung cancer	C33.X, C34.X, C38.4
Diabetes	E1X.X
Venous thrombosis	I80.X, I81.X, I82.X
Pulmonary embolus	I26.X
Osteoporosis	M80.X, M81.X, M82.X
Hip fracture	S72.X
Myocardial infarction	I20.X, I21.X, I22.X, I23.X, I24.X
Coronary artery disease	I25.X
Stroke or transient ischemic attack	I63, I64, G45.X

## Supplement 5. File Transfer to the GIC

FileZilla FTP will be used for secure transfer of completed medical record files to the GIC. Please follow host institution protocol for downloads. We strongly recommend having your IT safely download and configure FileZilla for your secure network and the number of users you want.



Once FileZilla is installed, open and click on File, then Site Manager.

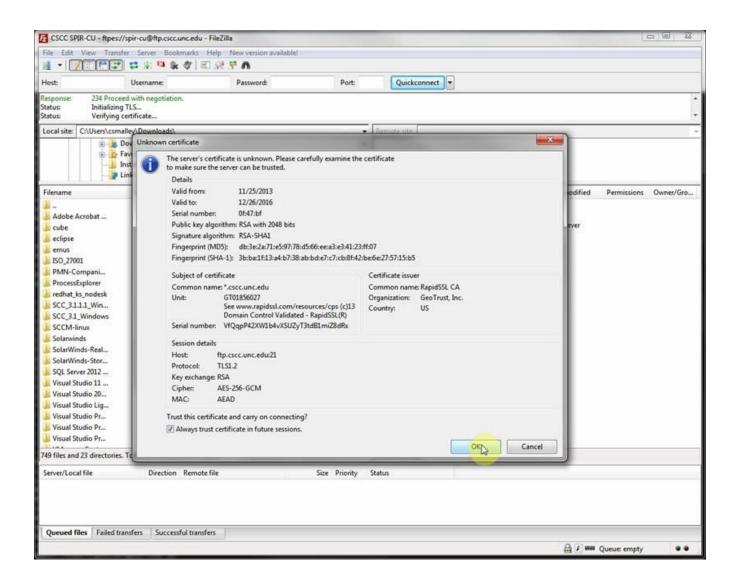
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Exit			CTRL+Q		-						
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SCC_3.1.1.1_Win	F	ile folder	9/6/2013	10:55:36							
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SCCM-linux	F	ile folder	8/6/2013	9:35:47 AM							
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This brings up the Site Manager screen. For the first time in, click on the New Site button and type in a name for the ftp connection to the GIC (ex. "CSCC SPIR-CU"). Then on the right-hand side, enter or select the information as shown below for Host, Protocol, and Encryption. Your site's unique User name

and Password will be sent securely under separate cover. Then click on Connect. The next time you come in to FileZilla, you can just select the GIC site name on the left-hand My Sites panel to connect.

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Carlos and Carlos and Carlos								-	Queue: empty	
									queue: empty	

The first time you sign on, you will get an "Unknown certificate" screen. If the common name is "\*.cscc.unc.edu" then you can check the Always Trust check box and click OK to connect.



Once you are connected, in the left panel navigate to the location of files for transfer on your system. The right-hand panel shows files sitting on our ftp server. Click and drag files from the left panel over to the right panel to copy files over to the GIC ftp server.

CSCC SPIR-CU - 1	ftpes://spir-cu@ftp.c	cscc.unc.edu - F	ileZilla						e	- 0 - X
the second s	Transfer Server I		elp New version availa	ible!						
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When you're finished transferring files, click the "X" to break the connection or click on "Server" and then "Disconnect". A script goes through every 30 minutes or so and moves the files from the server into the GIC system, so if you've copied a file over and then don't see it, it has probably been moved.

# Supplement 6. Support Contact List

Policy Questions	Betsy Carretta	<u>besty.carretta@unc.edu</u> (919) 962-2190
Medical Record Questions	Michele Inishi	<u>minishi@email.unc.edu</u> (919) 962-3440
Case Query/Receipt Questions	Nell Malone	<u>dlmalone@email.unc.edu</u> (919) 966-9518