Updated Manual 3c

This table summarizes changes of Manual 3c as of 08/19/2021

Section in Manual 3c	Description of Changes in Manual
Appendix II, pg. 17	• Removed hospital name from the “List of Items for Blinding”

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

Manual 3c

Stroke Cohort Surveillance Procedures Manual of Operations

Version 1.0
08/19/2021

Sponsored by: http://www.nhlbi.nih.gov/
National Heart, Lung, and Blood Institute of the National Institutes of Health

FOREWORD

This manual, entitled Stoke Cohort Surveillance Procedures, is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described. Detailed Manuals of Operation for specific procedures, including those for surveillance, follow-up, clinic visits, reading centers and central laboratories can be found on the ARIC website https://sites.cscc.unc.edu/aric/.

Manual 3c Stroke Cohort Surveillance Procedures

Table of Contents

1.0 STROKE COHORT SURVEILLANCE

1.1 Introduction

Potential clinical stroke events are identified and then validated for cohort participants only. The procedure for identification, investigation, and classification of these events is outlined below. More information on the stroke classification system can be found in Rosamond, 1999.

1.2 Identification of Stroke Events

There are two ways of identifying cohort stroke events. As the field centers are abstracting CEL forms they identify those cohorts with a stroke code listed on their hospital discharge form (see Table 1.1 '**ICD-9 and ICD-10 Stroke Codes'**) and/or one of the following keywords listed in their discharge summary or mentioned during the admission: stroke, TIA, cerebrovascular disease, cerebral hemorrhage, cerebral infarction, subarachnoid hemorrhage, cerebral embolus, paralysis, aphasia, diplopia, lacunar (syndrome infarction), dysarthria, cerebral angiography, carotid endarterectomy, CT/MRI scan showing cerebrovascular findings, or Neuro ICU care. Note, for hospital discharges in 1997 and beyond, ICD9 code 437 and 438 were dropped from the stroke eligible target codes. This was based on experience investigating and validating stroke events from 1987-1996 that showed the percent of validated cases from these code groups to be minimal (<2%). Similarly in 2020, ICD-10 codes I65, I66 & I67 were removed due to the production of minimal valid cases.

Death certificates listings are also reviewed for the presence of an underlying cause of death suggestive of stroke. Stroke deaths without additional hospitalization data are not investigated further. Classification of non-linked stroke deaths (not linked to a hospitalization within 28 days) is classified on the basis of underlying cause of death code only (ICD10 codes I60-I69).

In order to verify that the field centers have not missed any stroke events using the above method, the Coordinating Center sends out a list of cohort hospitalizations that appear to be stroke events based on their CEL form. The field centers investigate the events listed and determine if there should be a stroke form for the event.

Table 1.1 ICD-9 and ICD-10 Stroke Codes

ICD-9 Code	ICD-9 Classification	ICD-10 Code	ICD-10 Classification
430	Subarachnoid hemorrhage	I60	Subarachnoid hemorrhage
431	Intracerebral hemorrhage	I61	Intracerebral hemorrhage
432	Other intracerebral hemorrhage	I62	Other nontraumatic intracranial hemorrhage
433	Occlusion of precerebral arteries	I63	Cerebral infarction
434	Occlusion of cerebral arteries	I63	Cerebral infarction
435	Transient ischemic attack	~~I65~~	~~Occlusion of precerbral arteries not resulting in infarction~~
		~~I66~~	~~Occulsion and stenosis of cerebral arteries not resulting in infarction~~
		G45	Transient cerebral ischemic attacks and related syndromes (Not relevant death classification. Do not include in algorithm)
436	Acute, ill-defined CVD	Na	Na
437	Other ill-defined CVD	I64	Stroke, not specified as hemorrhage or infarction
~~438~~	~~Late effects of CVD~~	~~I67~~	~~Other CVD~~
		~~I69~~	~~Sequelae of CVD~~

Important Notes:

I63 includes occlusion and stenosis of cerebral and precerebral arteries resulting in infarction

~~I65 includes embolism and narrowing not resulting in infarction~~

Excluded is ICD-10 code I68, cerebrovascular disease in diseases classified elsewhere (cerebral amyloid angiopathy, cerebral arteritis in infectious and parasitic diseases)

1.3 Investigation

If a cohort event meets the above criteria, the field center sends appropriate sections of their hospital records to the stroke abstractors as per section 1.3.1. Specially trained abstractors then reviews these records and completes the Stroke Form (STR). These data are then entered into the data entry system at Minneapolis. Approximately every month, these data are retrieved at the CC and run through a series of data check programs.

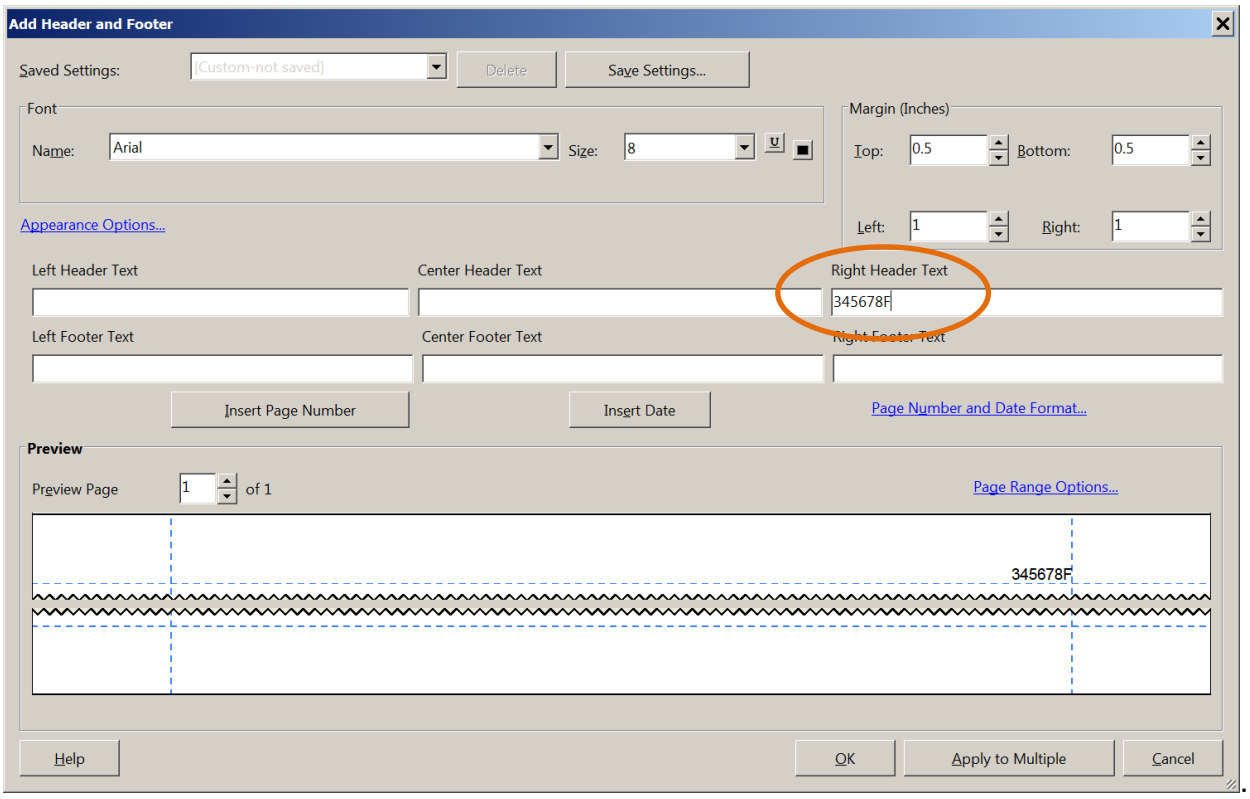
1.3.1 Procedures for Sending Hospital Record Documents to CC

For the cohort stroke events, field centers should upload selected electronic sections of the medical record in PDF format via LiquidFiles on a regular basis (without CC's request).

Include in the PDF file is one of the following, ranked in priority:

- ✓ Discharge summary
- ✓ Progress note of last physician and cardiac consultation
- ✓ Progress note of last physician and history and physical

Each document should be blinded using a black china marker or the redacting tool (see appendix II). Use the "Checklist for Hospital Event Materials" as the first page of the PDF document. The event IDs should be added to each page of the document using a 'header' in the PDF.



When a significant number of medical records have been prepared, they are put in numeric order and sent to the CC via LiquidFiles.

If CC requires hospital records for materials not sent for a particular patient's event, such as cases of hospitalizations to determine possible linkages, these are also prepared and sent in a similar fashion.

1.4 Diagnosis

All potential stroke hospitalizations are automatically assigned a stroke diagnosis by the computerized stroke algorithm (Appendix I). The computerized stroke algorithm classifies stroke events based on the data from the STR form and the DTH form if the event is a death. The possible computer stroke classifications are as follows: definite or probable subarachnoid hemorrhage (SAH); definite or probable brain hemorrhage (IPH); definite or probable brain infarction, thrombotic (TIB); definite or probable brain infarction, non-carotid embolic (EIB); possible stroke of undetermined type; undocumented fatal stroke; out of hospital death stroke; or no stroke. Undocumented fatal strokes and out of hospital death strokes do not require a STR form. In the rare case where a stroke event meets the criteria for two different diagnoses, the following hierarchy is used:

Definite IPH
Definite SAH
Definite EIB
Definite TIB
Probable IPH
Probable SAH
Probable EIB
Probable TIB
Possible stroke of undetermined type

A stroke event summary form (S-ESF) is produced for each stroke event that includes information on the number of major/minor symptoms, any stroke procedures, all discharge diagnosis codes, and the computer classification of the event. The S-ESF and selected hospital materials for the stroke event are sent to one member of the Stroke-Mortality and Morbidity Classification Committee (S-MMCC) for classification (see full description of procedures in section 1.4.1). The S-MMCC reviewer fills out a Stroke Final Diagnosis Form (SDX). The S-MMCC reviewer can either cite exclusionary conditions such as major head trauma, neoplasm, CNS infection, etc., or classify the stroke event in one of the following categories: definite or probable subarachnoid hemorrhage; definite or probable brain hemorrhage; definite or probable brain infarction, thrombotic; definite or probable brain infarction, non-carotid embolic; possible stroke of undetermined type; or other (no stroke) if no exclusionary conditions were met. Event summary forms are not produced for the following three event types: 1) Events where the STR form indicates that neurological symptoms did not last more than 24 hours or there were no new neurological symptoms prior to or during the hospital

admission; 2) Out of hospital stroke deaths not linked to a hospitalization; or 3) hospitalized events with no medical chart available. These events are automatically classified without physician review as “no stroke”.

1.4.1 Procedures for Stroke Reviews

All eligible Cohort events (those that have charts and neurological signs and symptoms) are reviewed for a stroke classification. The Stroke Data Management Program (MGP) generates the MMCC Event Summary Forms (ESFs) and lists for both original reviews and required adjudications for the classification of stroke.

The steps are to:

A. **Check Documents at Arrival at CSCC:** Upon arrival of documents at the CSCC via LiquidFiles, the PDF should be checked for ID number to make sure it matches the number labeled on the file. Once the file has been checked, it can be moved to the MMCC Scanned Materials folder where the MGP will search for it. Queries for materials not received are generated in the MGP and sent to the field centers.

B. **Assigning Reviews:** The review packet is created during the MGP and loaded into CDART using a CSV file. The CSV file is also used to make reviewer assignments. The reviewer code and date assigned are completed and then the CSV file is loaded to CDART. The original reviewer is assigned to the X1 sequence number, a different reviewer is assigned to the X3 sequence number for adjudication. An email is sent to the reviewer with the CDART link and the date that reviews are expected to be completed.

C. **Adjudicated Stroke Events**: Adjudication is required if the original reviewer disagrees with the computer diagnosis (variable called “COMPDIAG”, listed on the sheet “Listing of ESF for Original Review). The reviewer’s answers are compared to the computer diagnosis during the MGP. The event for adjudication is sent to the stroke adjudicator with sequence number X3.

1.5 Classification

The one S-MMCC reviewer and the computer algorithm determine final classification of stroke events. If there are discrepancies between these two sources, the final event classification is determined by a second reviewer (stroke adjudicator). An event is considered classified if one of the following situations occurs:

- If the reviewer has not cited any exclusionary conditions and the computer algorithm diagnosis agrees with the reviewer's diagnosis, the event is classified as such.

- If the reviewer does cite exclusionary conditions and the computer algorithm diagnosis is no stroke, the event is classified as no stroke.

- If the S-MMCC reviewer and the computer algorithm disagree, the adjudicator's classification is taken as the final classification.

2.0 STROKE CERTIFICATION

2.1 Certification of Stroke Medical Records Abstractors

Beginning in April 2015 certification of medical records for stroke was implemented. These procedures were approved by the ARIC Surveillance Committee March 2015. Training for certification is conducted by the stroke clinician and lead stroke abstractor**.**

Training includes the following:

- Studying the form and the QxQ, learning about stroke (types, pathology, etc)
- Abstracting records (about 20)
- Abstracting various diagnostic reports (about 50)

The trainees work is reviewed and discussed together as a group and questions are answered over multiple sessions with the lead stroke abstractor and lead stroke clinician

Abstractors are certified on the basis of their abstraction of two certification charts. There is a no *a-priori* rules for passing established (such as 90% of items). Instead the results are reviewed to determine competency. A correct answer to most of the items is expected, but is not sufficient for to be considered certified. For example, 95% correct responses while missing a major deficit and an MR diagnosis would not be considered certified.

To maintain certification in stroke, it is recommended that an abstractor abstract one stroke event per week for the first 4 months, and then one every other month after that. The lead stroke abstractor in Minnesota would select 3 cases for the annual recertification training.

2.2 Certification of Stroke MMCC Reviewers

The Stroke Mortality and Morbidity Classification Committee meets either in person or by conference call to conduct annual recertification training. Topics for discussion during these training sessions include update on changes in ICD coding rules, innovations in diagnostic testing, review of quality control data, update on form changes, and group discussion of changes to case law. As a part of recertification, a standard set of cases are distributed to all members prior to the meeting. Committee members are asked to complete the SDX form as they normally would do and send them to the coordinating center. The data from the SDX forms are summarized in table form and distributed for discussion during the re-certification process. Each case is reviewed in detail with special discussion among the reviewers on any

disagreement in diagnosis. In addition, special cases may be selected and presented and discussed in detail.

3.0 QUALITY CONTROL (QC)

Twice each year, the CC generates a set of QC reports. In addition, occasional monitoring visits from the CC to each site, and central training for abstractors and MMCC reviewers are held once every 1-3 years to assure data quality.

3.1 Quality Control for Stroke Medical Abstraction

Each stroke abstractor selects one event every other month for one of their colleague abstractors to re-abstract. A phantom ID for the re-abstraction must be assigned, using the PTM form.

The variables selected for comparison between the abstractor and re-abstractor includes these items from the stroke (STR) form: Items 14, 16, 18, 19a, 20, 21, 22, 23, 26, 29a, 29c, 29d, 29g1, 29g2, 29i, 29j, 30e, 30f, 35a, 36a,38a, 40a, 41a, 41c, 42a, 42b, 42c, 43a, 44a, 45a, 46c, 48d, 48e, 49d, 50d, 51d, 52d, 53c, 53d

3.2 Quality Control for MMCC Reviews

Quality control of MMCC reviewers is conducted via calculation of disagreement rates for cohort events that require review by two MMCC members. Further, for those events where the MMCC reviewers disagree, the event is sent to the adjudicator and disagreement rates between the reviewers and adjudicator are calculated.

MMCC QC Tables and Graphs includes:

- Disagreement Rates for Stroke Classification between Original Physician Review and Computer Diagnosis by year

- Comparison between Computerized Diagnosis and Original Physician Review Diagnosis (9 Levels, 5 Levels, & 2 Levels)

- Comparison between Computerized Diagnosis and Original Physician Review Diagnosis (9 Levels, 5 Levels, & 2 Levels) by Reviewer

- Disagreement Rates for Stroke Classification between Adjudicator (for cases that go to adjudication) and original physician review Diagnosis by year

- Comparison between Adjudicator and Original Physician Review Diagnosis (9 Levels, 5 Levels, & 2 Levels)

- Comparison between Adjudicator and Original Physician Review Diagnosis (9 Levels, 5 Levels, & 2 Levels) by Reviewer

4.0 SUGGESTED READINGS

ARIC Investigators. The ARIC Study: Design and Objectives. Am J Epidemiology 1989; 127:682-702.

Rathore S, Hinn A, Cooper L, Taylor, Rosamond W. Characterization of incident stroke signs and symptoms: Findings from the Atherosclerosis Risk in Community. Stroke 2002; 33(27): 2718-2721.

Rosamond W, Folsom A, Chambless L, Wang C, McGovern P, Howard G, Copper L, Shahar E. Stroke incidence and survival among middle-aged adults: Nine year follow-up of the Atherosclerosis Risk in Communities (ARIC) study. Stroke 1999; 30:736-743.

APPENDICES

APPENDIX I. COMPUTERIZED STROKE CLASSIFICATION ALGORITHM

I. Subarachnoid Hemorrhage (SAH)

ARIC Definition of Definite SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the four below:

1. Meets criteria (a) and (b) below:
    a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
    b. Bloody (not traumatic) tap or xanthochromic spinal fluid, OR
2. Demonstration by CT or MRI of a blood clot in Fissure of Sylvius, between the frontal lobes, in basal cisterns or within a ventricle with no associated intraparenchymal hematoma, OR
3. Demonstration at surgery of bleeding saccular aneurysm, OR
4. Demonstration at autopsy of recent bleeding of a saccular aneurysm

ARIC Definition of Probable SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet either criterion (1) or criteria (2) and (3) below:

1. a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
    b. Spinal tap was either not done or was traumatic, or missing, OR
2. One or more of the following symptoms or signs occurred within minutes or a few hours after onset:
    a. Severe headache at onset, or severe headache when first conscious after hospital admission;
    b. Depression of state of consciousness;
    c. Evidence of meningeal irritation;
    d. Retinal (subhyaloid) hemorrhages; AND
3. Bloody (not traumatic) tap or xanthochromic spinal fluid.

II. Brain Hemorrhage (IPH)

ARIC Definition of Definite IPH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the three below:

1. Demonstration of definite intracerebral hematoma by CT or MRI, e.g. an area of increased density, such as seen with blood, OR
2. Demonstration at autopsy or surgery of intracerebral hemorrhage, OR
3. Evidence in the patient's clinical record that meet criteria (a), (b), (c), and (d) below:
    a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

        Major:

        - hemiparesis involving two or more body parts
        - homonymous hemianopia
        - aphasia

        Minor:

        - diplopia
        - vertigo or gait disturbance
        - dysarthria or dysphagia or dysphonia
        - unilateral numbness involving two or more body parts, AND

    b. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND
    c. Cerebral angiography demonstrates an avascular mass effect and no evidence of aneurysm or arteriovenous malformation, AND
    d. No CT / MRI was performed or the CT / MRI was technically inadequate.

ARIC Definition of Probable IPH: Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #3 that lasted at least 24 hours or until the patient died, AND
2. Decreased level of consciousness or coma that lasted at least 24 hours or until the patient died, AND
3. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND

3. No CT / MRI was performed or the CT / MRI was technically inadequate.

III. Thrombotic Brain Infarction (TIB)

ARIC Definition of Definite TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of nonhemorrhagic infarct in brain, OR
2. Evidence in the patient's clinical record that meet criteria (a) and (b) below:
    a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

        Major:

        - hemiparesis involving two or more body parts
        - homonymous hemianopia
        - aphasia

        Minor:

        - diplopia
        - vertigo or gait disturbance
        - dysarthria or dysphagia or dysphonia
        - unilateral numbness involving two or more body parts, AND

    b. CT or MRI shows "infarct" or an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage.

ARIC Definition of Probable TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND

2. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
3. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

IV. Noncarotid Embolic Brain Infarction (EIB)

ARIC Definition of Definite EIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of:
    a. An infarcted area (bland or hemorrhagic) in the brain, AND
    b. A source of emboli in a vessel of any organ, or an embolus in the brain, OR
2. Evidence in the patient's clinical record that meet criteria (a), (b), and (c) below:
    a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

Major:
- hemiparesis involving two or more body parts
- homonymous hemianopia
- aphasia

Minor:
- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts, AND

b. Establishment of a likely source for cerebral embolus, e.g.: valvular heart disease (including prosthetic heart valve), atrial fibrillation or flutter, MI, cardiac or arterial operation or procedure, cardiac myxoma, bacterial endocarditis, AND

c. CT or MRI shows an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage

ARIC Definition of Probable EIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND
2. An identifiable source for the cerebral embolus as specified in definite #2b, AND
3. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
4. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

V. Possible Stroke of Undetermined Type

ARIC Definition:
Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus one major or two minor neurological signs listed below:

Major:
- hemiparesis involving two or more body parts
- homonymous hemianopia
- aphasia

Minor:
- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts
- severe headache at onset or severe headache when first conscious after hospital admit

- depression of state of consciousness
- evidence of meningeal irritation
- retinal (subhyaloid) hemorrhages
- palsy of the iii cranial nerve, AND

Clinical history, signs, symptoms, and findings from diagnostic tests and / or autopsy are not sufficient to meet the criteria for classifying the case as a “definite” or “probable” case of one of the four specific diagnostic categories of stroke.

APPENDIX II. Instructions for Sending Duplicate Hospital Records to the CC

When a significant number of medical records have been prepared, they are put in numeric order and sent to the CSCC File Center via a secure LiquidFiles account. If CC requires hospital records for materials not sent for a particular patient's event these are also prepared and transferred in a similar fashion.

Naming Convention for Hospital Records

Stroke: Surveillance ID followed by "S"

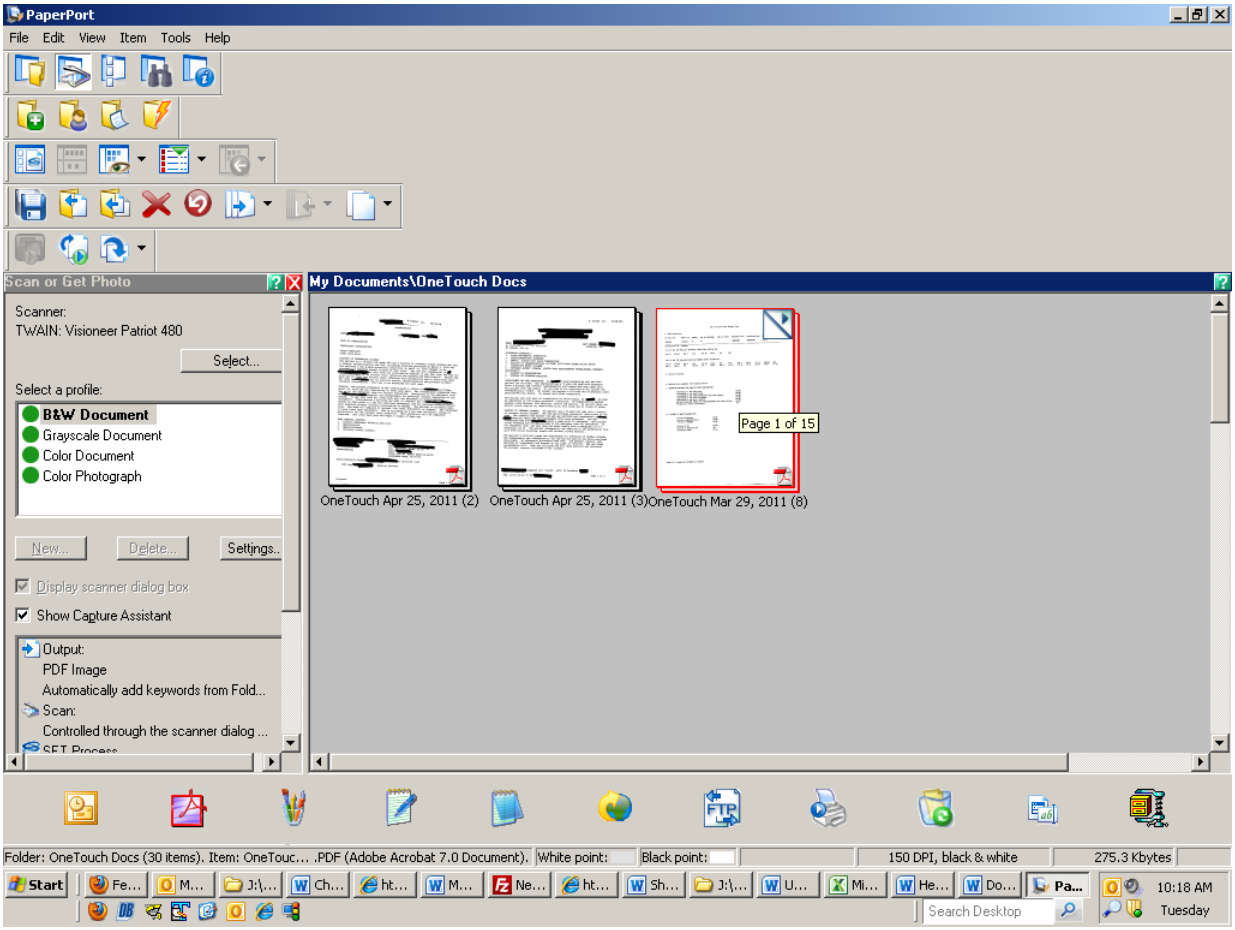
Preparing Paper Files to send to the CC

Scan all the appropriate materials for each event using your scanner set to black and white document. Include the completed "Checklist for Hospital Event Materials" as a cover page. Cut and paste the event id from the Hlist report from the DMS onto the electronic version of the checklist. If using a paper version of the checklist, write the event id in by hand. Before uploading the documents you will need to blind the documents of PHI using a redacting tool; like the one in Adobe.

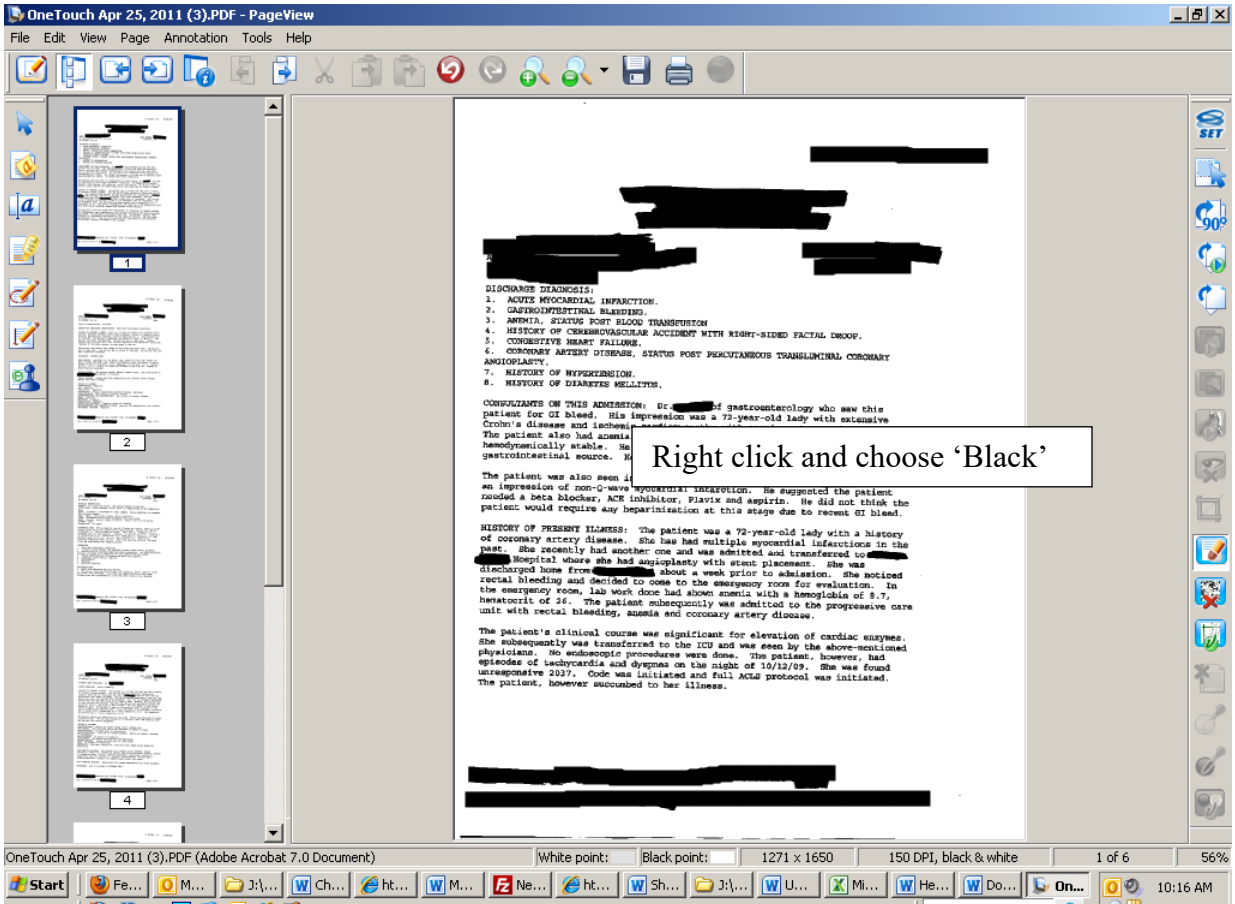
List of Items for Blinding

The following items should be blinded for all duplicate materials sent to the CC.

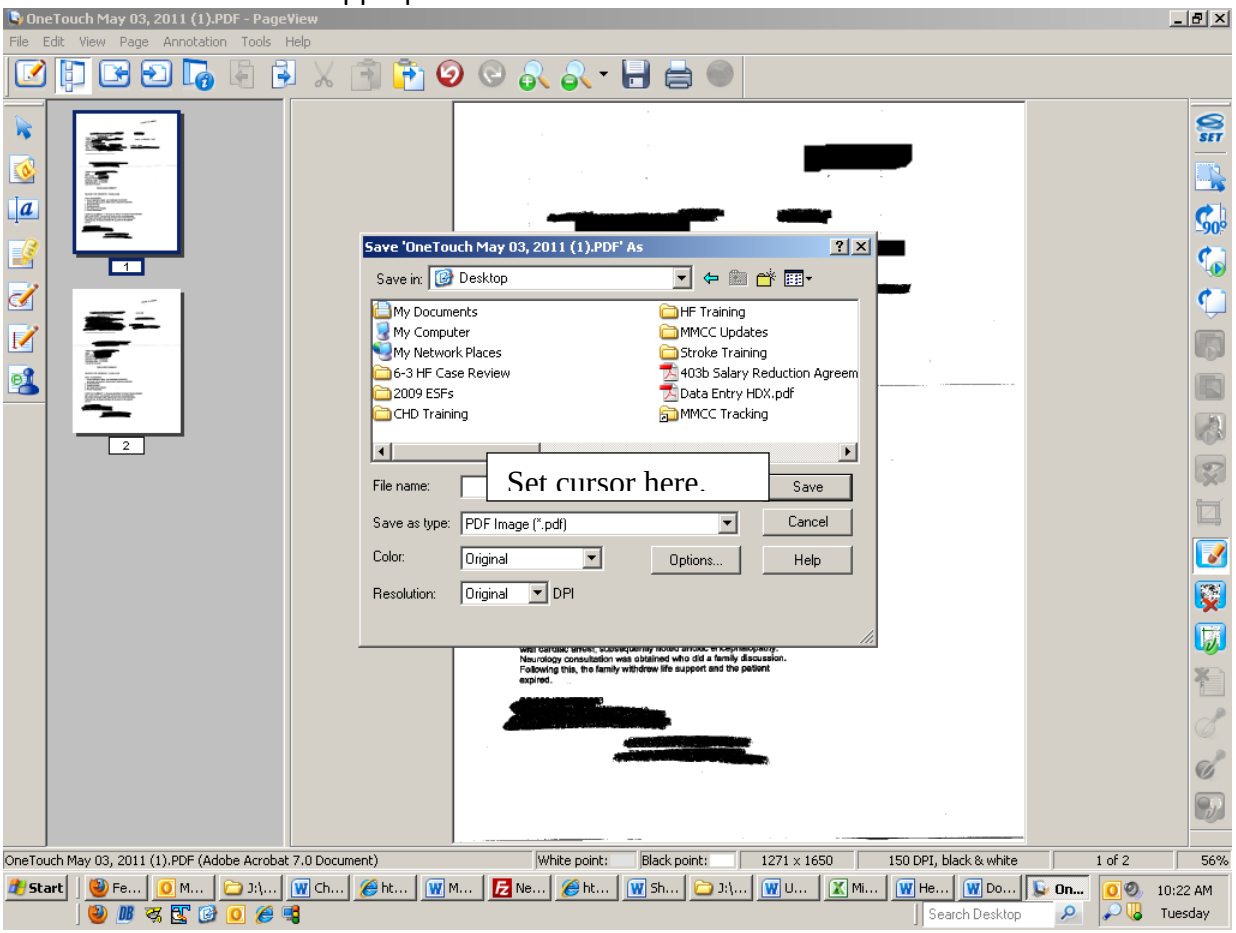
- Names of the Patient or of the Patient's Relatives, Employers, or Household Members. (Their initials need NOT be redacted. Names/Initials of hospital/medical care personnel do NOT need to be redacted.)
- Social Security number
- Date of Birth
- Street address, city county, precinct, zip code, and equivalent geocodes
- Telephone , Fax, Drivers License or plate numbers
- Email addresses
- Medical record number
- Health plan ID numbers
- Account numbers



Blind the documents using the eraser tool (set to black) found in the PaperPort software.



Save the materials as a PDF in a secure location. Choose File/Save As/Place curser in the File Name box and enter the appropriate event ID.



Preparing Electronic Files to send to the CC

The Coordinating Center recommends using Adobe Acrobat Professional Version 8 or higher to create PDFs of your electronic files.

Each field center may receive their materials in a number of different formats. Follow this link for guidance on how to convert many common file types to PDF.
http://helpx.adobe.com/en/acrobat.html

This software package also includes a redacting tool. Follow this link for instructions.
http://helpx.adobe.com/acrobat.html?content=WS5E28D332-9FF7-4569-AFAD-79AD60092D4D.html

Scan the completed “Checklist for Hospital Event Materials” as a cover page and combine with the duplicated materials into a single PDF. Add a top right header to the PDF document that contains the event id.

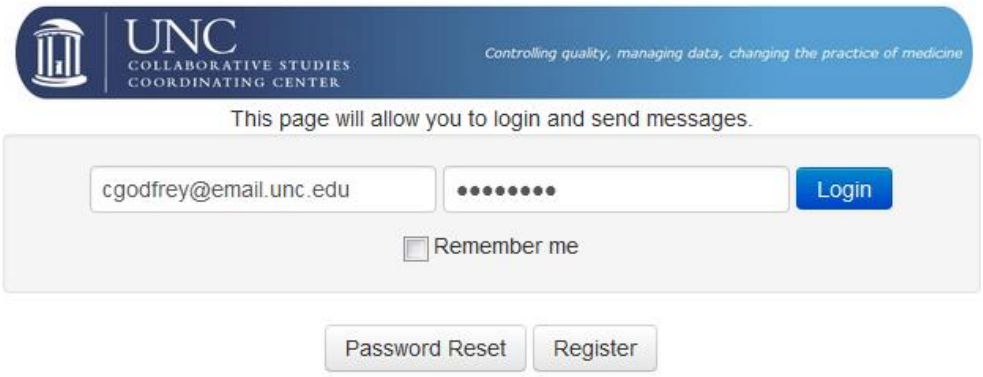
Follow this link for instructions on using adobe.
http://helpx.adobe.com/en/acrobat.html

After creating and blinding the PDF choose File/Save As and place the curser in the File Name box. Choose the appropriate folder in the Save In drop down and scan the bar code for that ID.

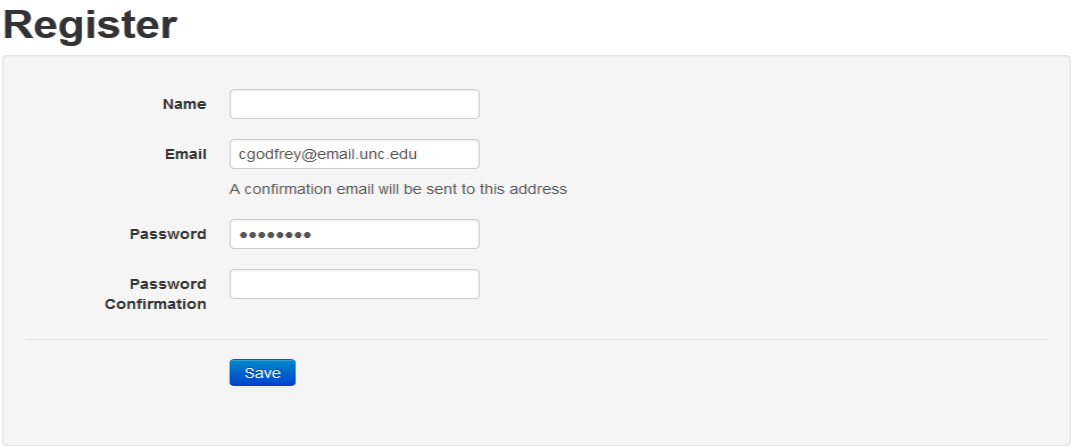
Utilizing the CSCC File Center to send documents to the CC

Creating a LiquidFiles Account

Go to the website:
https://csccex.cscc.unc.edu/

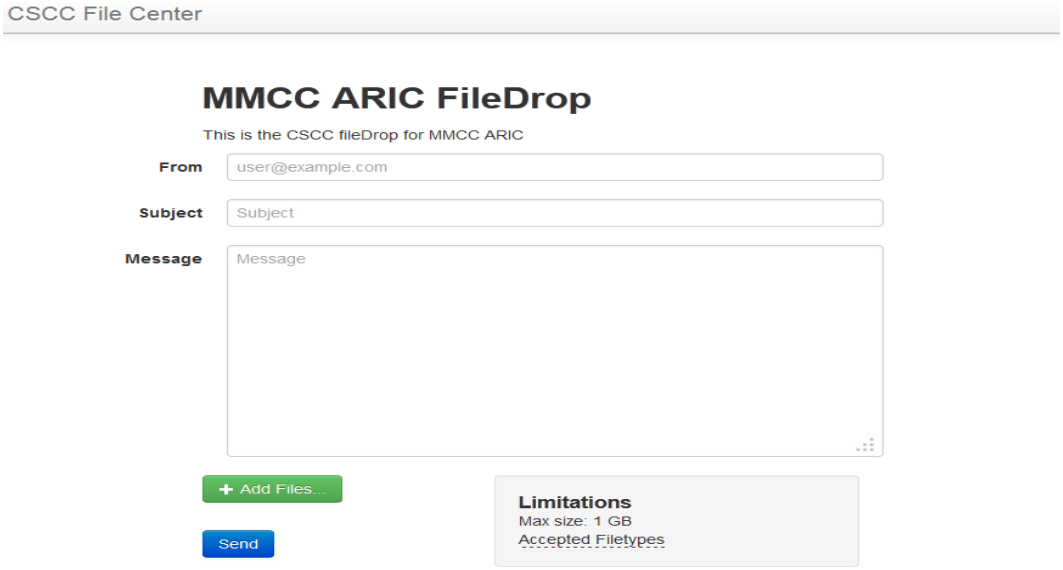


Click on Register and to create a new account. Once your account has been created you will receive a confirmation email.



Fill in name, email address and password.

Once the account has been created, hospital records in PDF format can be sent to the CC through this weblink: https://csccex.cscc.unc.edu/filedrop/MMCCARIC



Click the '+Add Files' to add files to be sent. You can review the files you are sending by looking at the attached files list before you send. When you have completed uploading all of the files click 'send'.