health care systems research network

MEDICAL RECORDS ABSTRACTION BEST PRACTICES GUIDE

A Guide to optimizing multi-site medical records abstraction studies

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1.0 INTRODUCTION

Multi-site chart abstraction studies are becoming increasingly common within the Health Care Systems Research Network (HCSRN), formerly known as the HMO Research Network (HMORN).

The Best Practice Guide is intended to provide general guidance to Investigators and Project Managers of HCSRN collaborations to use when creating project specific policies and guidelines for multi-site chart abstraction studies.

About this Guide

This guide provides a general outline and description of areas to consider when conducting a multi-site medical records abstraction project and was created to document knowledge and best practices so they can be passed on from existing projects and shared to increase efficiency, avoid duplication of effort, encourage consistency, and facilitate transparency.

Overview of Coordinating Center's Medical Records Abstraction Study Process presents a general outline of the overall process for chart review for a coordinating center or site including abstraction tool development, implementing medical records abstraction, establishing project meetings and quality assurance.

Internal Review Board (IRB) and Health Information Portability and Accountability Act (HIPPA) discusses determining if the study will entail single or multiple IRB involvement as policies, considerations and practices of Internal Review Boards (IRBs) vary among network sites. Reviews HIPAA issues and identifies issues to consider regarding IRB and HIPAA. In addition, medical record redaction is briefly discussed (procedural considerations and redaction methods are discussed in section 11.0).

Budget Considerations for Medical Records Abstraction introduces some of the complexities involved in access to medical records and provides a list of considerations to use when developing a budget for submission or spending on a multiple site medical records abstraction study.

Site Specific Access to Medical Records elaborates on the complexities of Accessing Paper charts, Electronic Medical Records (EMR), Hospital Records, Imaging and External facilities across different health systems and provides an example of a planning survey tool to identify site specific practices and collate this information for the purpose of streamlining and effective project management.

Requesting Hospital Records reviews the process that can be followed prior to requesting hospital records and suggests a process to ensure study procedures and forms are approved by an IRB, the need for adequate budget funds to cover the costs associated with requesting hospital records, sufficient time is allocated in study timeline to request, receive, abstract, and redact the copies, planning for storage and subsequent destruction of the hospital record copies, redaction procedures and a Data Use Agreement are in place if needed.

Paper-based and Web-based Systems for Chart Abstraction reviews multiple formats for data collection that have been used effectively for HCSRN projects and reviews important factors to consider when determining the format for a multiple site medical records abstraction study.

Abstractor Training reviews the importance of consistent training, identifies the types of training typically encountered; pilot, multi-site, site specific and quality assurance, and elaborates on inter-rater reliability and processes to enhance data quality.

Coordination and Communication of Information during the Abstraction Process suggests processes and considerations to enhance data quality such as regular all-site meetings and combined Question and Answer tools for the study.

Medical Records Redaction reviews common processes for redacting records, provides a table of pros and cons for each method and suggests issues to consider when determining methods to be used in a multiple site medical records abstraction study. In addition, a presentation used for training abstractors in redaction is included in Appendix A

Secure Transfer Mechanisms for Abstraction Forms and Medical Records reviews electronic and hard-copy mechanisms used across HCSRN studies and discusses the issues to consider when determining the method(s) to be used in a study.

2.0 OVERVIEW OF COORDINATING CENTER'S MEDICAL RECORDS ABSTRACTION STUDY PROCESS

Introduction

Coordinating a multiple site medical records review study requires planning and organization as well as a good working knowledge of site specific requirements and issues. The study will fall into four general categories; abstraction tool development, implementing medical records abstractions, establishing meetings and quality assurance (QA).

2.1 Overview of Process

Abstraction Tool Development

- Variable ordering and phrasing
- Pretest of the chart abstraction tool and redesign as needed
- Development of the abstraction manual including written abstraction instructions, decision-making tools, operational definitions, and a description of where data elements are to be located. This manual will be updated as new information is identified through the training process, initial data collection, or if the abstraction form is changed
- Verify the system to ensure the abstraction is accurate, reliable and consistent by the programmer
- Access data systems will be limited to authorized individuals
- Define processes so that the person who enters the data can be identified (i.e., use of a personal ID). Chart abstractors will not be able to modify other chart abstractors' records. The ability to delete records will be restricted
- Maintain documentation of the system. When systems change after abstraction has begun (i.e., a new field is added) the rationale and the change will be documented in the project files
- Provide proper workstation security such as a password-protected screen saver
- Implement standard procedures for computerized systems—system setup, maintenance, data backup, security, etc.
- Develop a plan in case of failure of electronic systems while in use

Implement Medical Records Abstraction

- Hire abstractors based on background required for type of chart abstraction specified
- Support hiring at study sites
- Provide training for all chart abstractors
- Provide ongoing supervision for all chart abstractors
- Provide ongoing quality assessment and review of charts abstracted
- Work with clinics, or medical group(s) to schedule chart abstracting, or order charts

Establish Project Meetings

- Work with PI regarding any issues that arise in chart abstraction process
- Implement regular meetings with all study sites
- Report on productivity, timeline, budget, and quality of abstractions
- Develop progress reports for investigator

Quality assurance Plan (QAP)

- Develop and outline a QAP for ongoing data quality evaluations
- Develop specific inter-rater reliability processes as well as validity checks
- Specify number of charts to be re-abstracted to allow computation of meaningful reliability statistics (for example, 5%). More complex chart abstractions require more frequent and extensive abstractions
- Define accuracy criteria (for example, minimum correlation or kappa statistic) of specific variables, as well as a plan for adjudicating inter-rater discrepancies
- Assess quality, both early in the data collection process and on an ongoing basis
- Provide reports of the results of quality checks to the research team

3.0 INTERNAL REVIEW BOARD (IRB) AND HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPPA)

3.1 Internal Review Board (IRB)

Medical record abstraction procedures and tools must be approved by an IRB. In some cases the participating sites may cede IRB review to the coordinating center site. In other cases there may be multiple IRB involvement. Policies, considerations and practices of Internal Review Boards (IRBs) vary among network sites. Medical groups outside of your organization may have their own Institutional Review Boards (IRB) that require separate IRB review and approval in order to access patient charts. For studies proposing external chart abstractions, additional time, planning, and budget will be needed to address these issues.

In order to request access to patient medical records, one of the following must be approved by the IRB and executed:

1) Signed consent form and HIPAA authorization form, or
2) Waiver of consent and authorization, or
3) Waiver of documentation of consent and waiver of authorization.

IRB Considerations

- Plan for enough time to allow for input from other sites
- Discuss specific variables to be abstracted and determine if there are any site specific differences
- Develop a streamlined abstraction form for IRB submission
- Determine the need for site specific elements regarding study materials (e.g. records request letter)
- Allow sufficient time for the IRB submission and approval process. (especially if more than one site's IRB is involved)

3.2 Health Information Portability and Accountability Act (HIPPA)

Depending on the consent scenario authorized by the IRB, there may be HIPAA issues to consider when data will be shared and/or transferred among sites. If requesting records under a waiver of consent, a data use agreement (DUA) may be needed. A DUA is needed if the study protocol involves sending the abstracted data to another site and the abstracted data includes dates.

HIPAA Considerations

- If the HCSRN contract is in place the streamlined HCSRN DUA can be used.
- Consider a Memorandum of Understanding agreement to protect data if data is not a limited dataset (check contract – in some instances the data use language in the contract will suffice)
- Release IRB approved data, not more than what has been approved
- Use a data release checklist to avoid releasing more data than what has been approved

- Ensure all study staff who encounter medical records (project managers, chart abstractors, study clinicians) have received HIPAA training. A refresher on HIPAA may be needed for each new chart review study
- Create a plan for destroying all crosswalk/linking files and other identifiers as specified in your site's IRB application. For example, this can be as simple as a calendar reminder on the PM and programmer's calendar when it's time to destroy the files or as complex as an MS Access database that sends reminders to the PM's outlook calendar

3.3 Redaction of Patient Medical Records

Pursuant to Data Use agreements, HIPPA and Study protocols, patient identifiers and possibly other information must be completely redacted (blocked out) prior to transferring patient records. Unique identifiers can differ from site to site. (see section 8.0)
The study protocol, IRB stipulations, and HIPAA requirements all factor into what information must be redacted.

The standard HIPPAA list for redaction includes: (see section 6 for further details about redaction)

- Names
- All geographical subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code
- Date of Birth (except year) and dates directly related to an individual except the Date of Death
- Telephone #s
- Fax #s
- Email addresses
- SSNs
- MRNs
- Health plan beneficiary #s
- Account #s
- Certificate/License #s
- Vehicle Identifiers and serial #s, including license plate #s
- Device identifiers and serial #s
- Web URLs
- IP address #s (Internet)
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code, unless otherwise permitted by Privacy Rule for re-identification

4.0 BUDGET CONSIDERATIONS FOR MEDICAL RECORDS ABSTRACTION

Introduction

Detailed planning is necessary for chart abstraction studies. The level of complexity is dependent on whether the chart abstractions are paper or electronic, or a combination of both, and whether the medical records are internal (patients within your health plan), or external (patients that have your insurance but are seen by other contracted medical groups). For studies that include external medical records, additional planning will be needed to address issues of patient consent and access to medical record information. Patient consent does not guarantee automatic access to patient charts, even with signed patient consent forms. A well prepared and accurate budget will ensure a successful project and being good financial stewards. The budget should be prepared before the grant is submitted.

4.1 Budget Preparation Considerations:

- Purpose of the study
- Timeline for the study
- Description of inclusion/exclusion criteria for abstracts, sampling techniques and plans for implementation
- Detailed quality assurance plan (cost for re-abstractions)
- Additional detail for the abstraction form/tool development if the research study has multi-sites, or contracted medical groups
- Number of cases to be abstracted
- Types of and variables abstracted (labs, physicians notes, health history, and prescription list)
- Training hours and number of abstractors (multi-site and internal training)
- Number of project meetings abstractors will attend
- Dates included in the abstraction
- Printing collating and redacting time
- Faxing, mailing, or FedEx costs
- Travel time to outside facilities
- Chart fees
- Storage costs and retention policies for each site
- Personnel costs for using FTP site
- Software compatibility (Win Zip/Adobe) across sites
- Review time for budget estimates

5.0 SITE SPECIFIC ACCESS TO MEDICAL RECORDS

Introduction

When coordinating a multiple site study, it's important to remember that different HCSRN sites have different relationships with the medical facilities where their patients are treated. Some sites own all of their own hospitals and have easy access to all medical records. Other sites contract with multiple hospitals. Sites may have centralized systems, non-centralized systems or a combination. The type(s) of system(s) in place for medical record access have implications for the timeliness, cost, and ease of conduction of a chart review study. When writing grants it's best to know what is accessible at study sites.

In the planning phase of the project, you will want to survey the participating sites in order to determine what records they have access to and what the procedures/costs are associated with reviewing medical records. An example questionnaire follows.

There may also be sample identification considerations dependent on the type of system in place.

5.1 Determine Access at Participating Sites

- Paper charts
  - Retention period (some sites destroy paper charts if deceased or disenrolled, organization's decision)
  - Cost
  - Centralized? If not centralized access might be iffy
  - What is the request process?
- Electronic Medical Record
  - When did the organization implement the EMR? The year implemented might not have complete data
  - What is the study period of interest – will it involve paper charts as well?
- Hospital Records
  - Organization owned? Or not?
  - What is the process for requesting records?
  - How far back are records retained?
  - Cost?
- Imaging
  - Does the study need actual images or is the PACS image in the EMR ok?
  - Retention what types of images have been retained? Destroyed?
  - Where are the actual images stored?
  - Request process?
  - Cost?
- External facilities
  - Cost
  - Procedure for request
  - IRB and HIPAA waivers/authorization

5.2 Study Example Questionnaire and Results

Electronic and Hard Copy Medical Records

To understand the availability of and the feasibility of accessing electronic and hard copy medical records at your institution, please provide the information requested below. Information should be provided for all of the following:

- Performance Site Name
- Date range: 2000 – 2010 (expand or collapse columns to capture study period of interest)
- Health Record type: Electronic (E) or hard copy (HC)
- History of research availability of health records. Please complete for each facility identified. Please reply using the following options:
    - Health record expected to be both available and readily accessible based on historical collaboration of accessing medical records
    - Health records expected to be available, but uncertain about whether accessible based on historical collaboration of accessing health records
    - Health records expected to be available, but uncertain about whether accessible based on historical collaboration of accessing medical records
    - Health records not expected to be available based on historical collaboration of accessing medical records
- Cost per chart: Electronic (E) or hard copy (HC)
- Notes on paper chart retention/destruction

5.3 Example Medical Records Survey and Results

Note: We have provided enough rows for up to 6 performance sites. If more are needed, please copy and paste the formatting to expand the table rows.

Location, Availability of Health Records,	Year										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Performance site name: **Group Health Cooperative**											
Records available HC or E?*	HC &E	HC &E	HC &E	HC &E	HC &E	E	E	E	E	E	E
Proportion HC	50	40	30	20	10						
Proportion E	50	60	70	80	90	100	100	100	100	100	100
Record availability (use code options a – d listed above)	A	A	A	A	A	A	A	A	A	A	A
Cost for HC (per chart)	$11.69	$11.69	$11.69	$11.69	$11.69	$11.69	n/a	n/a	n/a	n/a	n/a
Cost of E (per chart)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Notes: chart retention/destruction	GHC's conversion from paper to electronic charts officially started in 2003 and all charts were converted by 2005. Information from 2003 and prior was converted digitally occasionally. Thus, there is an overlap of availability of medical records by both paper and digital copy.										
Performance site name:											
Records available HC or E?**											
Proportion HC											
Proportion E											
Record availability (use code options a – d listed above)											
Cost for HC (per chart)											
Cost of E (per chart)											
Notes: chart retention/destruction											

* Respond by indicating in the cell for each year whether the medical record in that year was hard copy (HC) or electronic (E) at that facility.

Do any of the facilities listed in the table require a separate IRB approval for you to extract health records? If so, which one(s)?_____
_____
_____

Comments/additional pertinent information that we should consider:_____
_____

6.0 REQUESTING HOSPITAL RECORDS

Introduction

When the study protocol involves requesting medical records from hospitals the following processes should be in place: 1) study procedures and forms are approved by an IRB (the one exception to this is public health activities); 2) adequate budget funds are assigned to cover the costs associated with requesting hospital records (staff time, tracking system, invoice payments, FedEx charges, staff time for redaction and file transfer); 3) sufficient time is allocated in study timeline to request, receive, abstract, and redact the copies; 4) a plan in place for storage and subsequent destruction of the hospital record copies; 5) redaction procedures and a Data Use Agreement are in place if abstracted data includes dates and will be transferred to another site.

To request medical records you will need one of the following: 1) a signed consent form and authorization form, or 2) a waiver of consent and authorization, 3) a waiver of documentation of consent and waiver of authorization. Patient consent does not guarantee automatic access to patient charts, even with signed patient consent forms. Medical groups outside of your organization may have their own Institutional Review Boards (IRB) that requires separate IRB review and approval in order to access patient charts, requiring additional work on the part of the study team and potentially impact the study timeline. For studies proposing external chart abstractions, additional time, planning, and budget will be needed to address these issues. For those facilities that are hesitant to release records, a call to the facility's Compliance Officer may help.

When the sample is drawn from outside facility/hospital patients the yield is not truly a full data set, but rather a subset of patients who the study will have access to. A random selection among the subset is possible. If only a few hospitals allow you to abstract their records, you may have sample issues.

There is significant variation among the HCSRN sites. Some sites own hospitals which make it easier to abstract records, others do not. Some sites are able to send abstractors to abstract at the facility. At other sites, facilities fax or mail copies of the records to the site. The time from requesting records to their arrival can also vary significantly among different facilities.

Some hospitals will charge for copying the records while others do not.

Hospital Records Considerations

- Time intensive - consider centralizing this process to one staff person at your site
- Facilitate a timely response to requests by:
    - Call hospitals first to explain the study and request (a script for the caller is a good idea)
    - Include an introductory letter, FAQ of questions that facilities commonly ask, list of patients, and a copy of the waiver of consent in the study packet.
    - Fax the study packet to the hospital contact
    - Develop rapport with the hospital contact and follow-up frequently (best accomplished when one person who makes the requests)
    - Track requests.
- Include a fee cap for facility copy charges in the introductory letter (some sites use $25)

- Assess need for disclosure tracking for names sent without a signed consent/authorization form.
- Avoid disclosing patient information beyond the minimum necessary in any of the documents or communications with the hospital contact
- Consider providing facilities with FedEx shipping number to allow facilities to skip their invoicing process for the costs of mailing

7.0 PAPER-BASED AND WEB-BASED SYSTEMS FOR CHART ABSTRACTION

Introduction

Multiple formats for data collection have been used effectively for HCSRN projects including paper-based, web-based and computer-based chart review abstraction forms. The format used for a study depends on the scope of the project, budget, data sources (EMR or paper charts) and access to technology at a study site or coordinating center.

One of the first considerations is the "data source" for medical records at each study site. Depending on the timeframe of the study, each site may have a different mix of "data sources" i.e. paper medical records, electronic medical record (EMR) or both.

Costs, time and charges associated with accessing medical records on site at a facility or having records sent to a research office vary widely across HCSRN sites. Even if your study is using a web-based chart review form, there will be cost and coordination issues for abstractors to access the records to be reviewed for the study.

7.1 Paper-based Abstractions:

Location of medical records, access and travel requirements generally depend on two factors; timeframe of the study and relationship between the HCSRN site and the facilities where their patients receive care. Chart reviews of cases from 2008-2011 may use electronic medical records (EMRs) only. Whereas chart reviews of cases from 1995-2010 will require access to paper medical records as well as the EMR. Paper medical records may be on-site at facilities or in storage and require travel, a retrieval fee and waiting period. Some HCSRN sites own all of their facilities so access to patient records is fairly seamless. Some sites contract with all of their facilities and some sites have both scenarios. While agreements are already in place with contract facilities, they do vary regarding access to medical records.

Finally, the coordinating center will want to asses file space needed as well as costs for shipping and data entry for paper-based abstractions.

Paper-based Abstractions Considerations

- Storage space for medical records
- Printing costs
- Shipping costs

7.2 Web-based Abstractions

Introduction

Using web-based survey for chart abstraction is becoming more common. Factors to be taken into consideration are access to survey/chart review software, site specific needs for abstraction and development timeline.

Survey software may be owned by the coordinating center or need to be purchased. In addition, the coordinating center should survey the sites to determine if internet access is available in the physical location where the chart review will take place. If medical records for a

site will be sent to the research office then this should not be an issue but if abstractors need to abstract in a chart room of a facility then it may be difficult for them to access the internet or they may need laptop computers.

Several commercial software packages are designed for survey questionnaires (i.e. DatStat and RedCap).

HealthPartners became a REDCap (Research Electronic Data Capture) consortium partner in 2011. REDCap is a secure browser-based application for building and managing surveys and databases. REDCap was developed through a CTSA grant and is currently administered out of Vanderbilt University. REDCap is supported through ongoing funding from NCRR and NIH grants.

HealthPartners hosts their REDCap application on their own servers, and is maintaining internal and external servers for multiple levels of utility and security. REDCap is a data management tool that is able to collect and manage data through surveys, data forms, longitudinal project timelines and schedules, manage group project and data access, and more. HealthPartners is currently using REDCap for data capture for telephone surveys and chart abstraction.

Kaiser Permanente Northern California uses DatStat. DatStat, Inc. began operations in 1997 and provides a pure Internet based platform for multi-mode data collection. This software was used for the 2009-2012 CVRN Surveillance Study which included chart review from 15 HCSRN member sites. DatStat provided web-based access to three different medical records abstraction forms and was completed by abstractors at each of the sites.

If your organization does not currently own this type of software then the following issues should be considered before purchase.

Web-Based Software Considerations:

- Process for software review and purchase in your organization
- Development and implementation timeline
- Computer system requirements
- Costs associated with acquiring and customizing
- Licensing fees
- Study sites' technology capabilities
- End user training

7.3 Abstraction Tool Development

Introduction

Abstraction tool development includes: variable ordering and phrasing; pretest of the chart abstraction tool and redesign as needed; development of the abstraction manual, including written abstraction instructions, decision-making tools, operational definitions, and a description of where data elements are to be located. This manual will be updated as new information is identified through the training process, initial data collection, or if the abstraction form is changed.

Whether the abstraction tool is paper, MS access, or web based, it is important to define a system of data checks (and this is particularly relevant in a study where there will be no re-abstractions). Data checks are used to validate that all information collected/abstracted is accurate. Accuracy is based on a pre-determined list of qualifiers set by a protocol. Each data point has its own unique set of qualifiers.

8.0 ABSTRACTOR TRAINING

Introduction

Successful implementation of a project is greatly enhanced when all abstractors receive identical training. Consistency in training will ensure the validity of the data collected, prevent project delays, and maintain the budget. There are four types of training that should take place before project implementation; pilot, multi-site, site specific, and quality assurance. The ability to achieve the standards described below is dependent on the study budget, timeline and the type of chart review (data collection, validation, or combination of the two). When chart review is the main data collection component for a project it is most important to do as much of the described process as possible.

8.1 Types of Training

Pilot training in a multi-site project will assist the lead site in project implementation and help individual sites prepare for training and site implementation. Each site should select one abstractor to be involved in piloting. The purpose of a pilot is for each site to abstract several charts and compare notes on ease of obtaining the information, ease of the abstraction tool, and if the ranges are correct. Pilot results should be used for revisions in the abstraction tool, training, and guidelines for project implementation. Pilot training involves the following:

- Form development
- Ordering of information
- Guidelines for ranges and variables
- Alert study investigator of problems in obtaining information, length of abstraction, or site specific problems
- Address issues regarding implementation
- Address data quality

Multi-site training enhances streamlining of abstracting among sites. Abstractors are familiar with the needs of the project, understand what information should be included or excluded and the purpose of the questions. The lead site should conduct a training that involves all sites and all abstractors. Information from the pilot will be used to develop a manual. The manual should be sent to all sites one week before training for sites to become familiar with the material. Training and the manual should include the following information:

- Specify information for each data point
- How to code if the information is not in the patient's chart (best to NOT leave a data point blank, but to have a consistent code to indicate that the information is not in the chart)
- Ranges for data points on what should be included and excluded
- A walk through the abstraction form
- Who to contact if there are problems
- Establishing a quality assurance plan
- Have each abstractor at each site abstract the same chart and submit it to the lead site for verification

Site specific training ensures that all abstractors understand the project and reduces differences between abstractors. Site specific training includes:

- Understanding where to locate information

- Guidelines for ranges and information in their charts
- Consistency of abstraction
- Abstractors should abstract information of five charts together
- Select another five charts for abstractors to abstract separately for consistency. If errors occur further training must be implemented to ensure consistency.

Quality assurance training enhances consistency and validity of collected chart abstracted data. Quality assurance is part of initial training and ongoing training.

8.2 The Gold Standard

The Gold Standard approach establishes a defined set of charts that are abstracted at the beginning of the project and then re-abstracted throughout the remaining chart abstracting process. The re-abstraction process allows us to measure reliability and consistency in data collection across time for all abstractors.

8.3 Intra-Rater Reliability

Intra-rater reliability assesses consistency across time for a single abstractor. It captures drift from the Gold Standard, which is set at the beginning of the project. The monitor for intra-rater reliability will be the Chart Abstractor Lead. The chart abstractor lead will abstract the Gold Standard charts at the beginning of the project, and then will randomly re-abstract 2 Gold Standard charts per week throughout the remaining chart abstraction process. At six-week intervals, an automated data comparison will be completed against the Gold Standard charts to assess reliability and accuracy for the Abstractor Lead. A 95.0% minimum accuracy rate is expected on all key variables. A Kappa statistic will be calculated on identified key variables to assess reliability.

8.4 Data Quality

Establishing data quality includes both training abstractions and random re-abstractions to assess rater reliability. For the purpose of inter-rater reliability, abstractions will be compared against the Gold Standard described above. The Chart Abstractor Lead will set the gold standard at the beginning of the project. Random re-abstractions by the Chart Abstractor Lead will be conducted for inter-rater reliability and to detect any drift in the Gold Standard that may occur across time. Data training will be conducted for each site/abstractor to address differences in charting practice.

8.5 Data Quality Reports

To assess and monitor data quality, monthly reports will be generated starting the second month of the project. Data quality reporting will focus on performance of data collection of key items. Abstractors will receive information and feedback based on DQ reports. It is expected that all abstractors will maintain high standards for data quality across the chart abstraction process. The Project Manager and Chart Abstractor Lead will address data quality problems with additional training and supervision. Quality standards must be met for abstractors to continue with the project.

8.6 Data Quality Training Charts

Data Quality training will take place in each site. The Chart Abstractor Lead will supervise the training by having assigned abstractors complete training abstractions on 2-6 medical charts. One abstractor will be designated the primary abstractor for each chart and their data will be used as the completed abstraction for that subject.

9.0 COORDINATION AND COMMUNICATION OF INFORMATION DURING THE ABSTRACTION PROCESS

Introduction

Once the project has begun it is important to maintain quality of data collected, maintain timeline, and budget. This is accomplished through project meetings, QA abstraction, and data checks. Depending on the complexity of the data abstracted and length of the project will determine how often all abstractors in all sites meet to discuss the project.

Coordination and Communication Considerations:

- Determine regular all site meetings – frequency may vary depending on the phase of the study, (i.e weekly early in the study and monthly near the end)
- Develop a contact list to address contact with ongoing questions or difficulties
- Establish and maintain a regularly updated Questions and Answers (Q&A) Manual online or to the sites via e-mail for reference and consistency
- Encourage individual sites to have site meetings to review the question and response log, review timeline, and site difficulties
- Continue Quality Assurance (QA) throughout the project to maintain a 95% consistency between abstractors
- Maintain and report regularly on project progress and timeline

10.0 MEDICAL RECORDS REDACTION

Introduction

Multi-site chart abstraction studies will continue to have the need to have Protected Health Information (PHI) redacted when records are sent out for adjudication and other research purposes. This requires redaction of PHI in order to be HIPAA compliant and protect study participants confidentiality.

Depending on the volume of medical records to be redacted, budgetary and/or programming constraints, redaction of HIPAA identifiers can be as simple as manually using a grease pencil/china marker or with a little programming support, can be an automated process using a program such as the MITRE Identification Scrubber Toolkit (MIST). (Note: we are not endorsing the MIST we are only calling it out as an example of a redaction program.) It is recommended that when redacting PHI manually, a grease pencil offers the most opacity. PHI is still visible underneath the ink of almost all other pens.

Microsoft WORD and ADOBE software programs have also been used to redact medical records.

Redaction Considerations

Type of Redaction	Pros	Cons	Comments
Electronic Redaction (Adobe, Word, etc.)	Ease of use, accuracy, easy to complete redact PHI	Potential cost, Training on Software, lack of software license, conflicts with existing software	
Manual redaction (Black markers, correction tape, etc.)	Ease of use, minimal training, low cost	Potential to miss PHI, need to QC, potentially time consuming	It is advisable to send copies of redacted records to the coordinating center instead of originals
Photocopying	Ease of use, minimal training, low cost	Potential to miss PHI, need to QC, potentially time consuming	

Records can be redacted electronically using Adobe Acrobat 9.0, or manually using a redacting or China marker (wax based-pencil). If you are using a wax-based pencil, it is advisable to send photocopies (rather than the originals) of the redacted records to the coordinating center. The wax pencils adequately cover redacted information when photocopied but in theory, the wax could be removed if originals are sent.

Since the information in medical records is very sensitive, it is advisable to have a reviewer to review and double-check the records after they are redacted.

A presentation illustrating the redacting process using Adobe Acrobat 9.0 is available in Appendix A.

11.0 SECURE TRANSFER MECHANISMS FOR ABSTRACTION FORMS AND MEDICAL RECORDS

Introduction

Abstraction Data from research studies frequently needs to be sent to a coordinating center via secure, encrypted e-mail, FTP or secure shipping that verifies receipt. (i.e. FedEx, UPS, etc.) While some health care system-based research organizations have software tools to accomplish this, others do not have such resources. When coordinating a multi-site study, it is important to assess the capacity and requirements of each site (including the coordinating center) in order to determine the possible file transfer mechanisms.

Assessing compatibility is the most important factor in managing a multi-site study. Planning needs increase with the number of sites. Variations between encryption requirements, software compatibility (i.e. WinZip and Adobe) need to be taken into consideration. This is especially important when considering project costs. For instance, will the project pay for an upgraded/downgraded software programs for the coordinating center or the sites?

11.1 Electronic File Transfer Site (FTP)

Using an electronic File Transfer site can be a cost effective and space saving way to transfer copies of abstraction forms, medical records and other documentation between sites. For instance, KP Northwest manages a file transfer site and they often make it available for projects they participate in. This site is currently being used on a 15 site study. Transferring 5000 sets of medical records (pdf format) - uploaded by a study site then downloaded at the coordinating center is far less expensive than FedEx/UPS costs to transfer the records. In addition, if the transferred medical records are stored electronically at the coordinating center then resources for storing thousands of sets of medical records are not needed.

IT support available across the sites is another important consideration. If you are planning on using standardized software (MS Office, Adobe, WinZip, etc) of a File transfer site, it is important to survey each site to ensure that the changes needed to streamline compatibility (software upgrades, etc) will be able to be implemented.

11.2 Secure Shipping for Paper Forms

Transferring paper records via secure shipping (FedEx/UPS, etc) is the most common mechanism for transferring records. Storing paper records requires more physical space (i.e. file drawers) and shipping costs may well exceed the costs of electronic transfer.

11.3 Mixed Modes

Finally, your project may use a mix of these two mechanisms depending on capacity at the site and comfort level with technology.

Please use the survey on the following page (as applicable) to assess file transfer mechanisms as applicable to your project.

Considerations for Electronic Transfer (e-mail, secure transfer site):

Survey Questions	Coordinating Center	Site #1	Site #2	Site #3
What are the encryption/security requirements (in addition to HIPAA) at each site?				
Do all sites have compatible encryptions software (i.e. versions of WinZip and Adobe that work together?				
Password requirements at each site?				
What are the file size restrictions at each site?				
Does one of the study sites have an active file transfer site that can be used for the study?				
Is it cost effective to develop a new file transfer site for the study?				
Does each site have the necessary IT support/capacity to manage the file transfer mechanisms you are considering?				
What software packages and versions are available at each site? (MS office, Adobe, WinZip, etc.)				

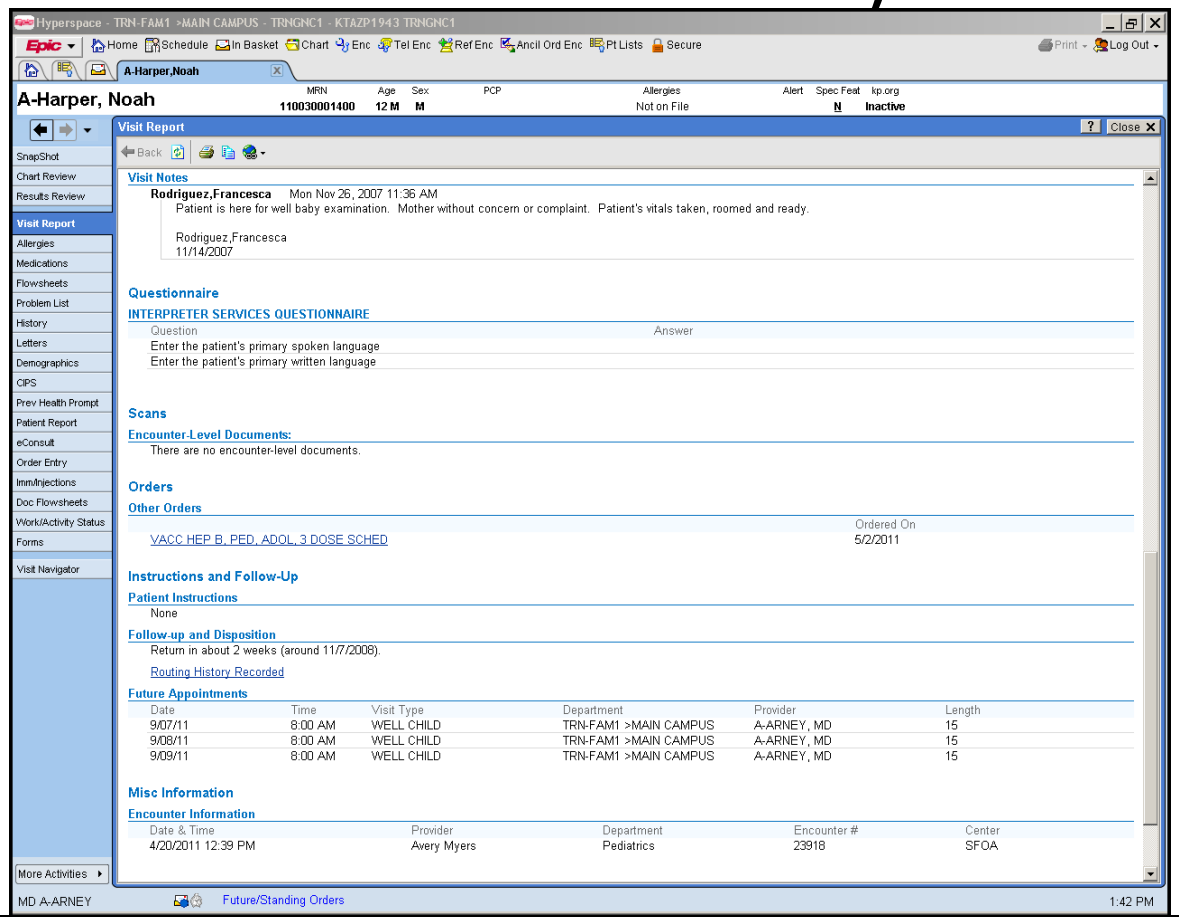
Considerations for Secure Transfer of Paper Records

Survey Questions	Coordinating Center	Site #1	Site #2	Site #3
What are the storage space requirements at the coordinating center and each site?				
Budget Consideration: estimate the cost per site of shipping for paper records.				
How often will records be shipped to the coordinating center? Weekly, Monthly?				
What is the process for documenting shipping and receipt of records?				

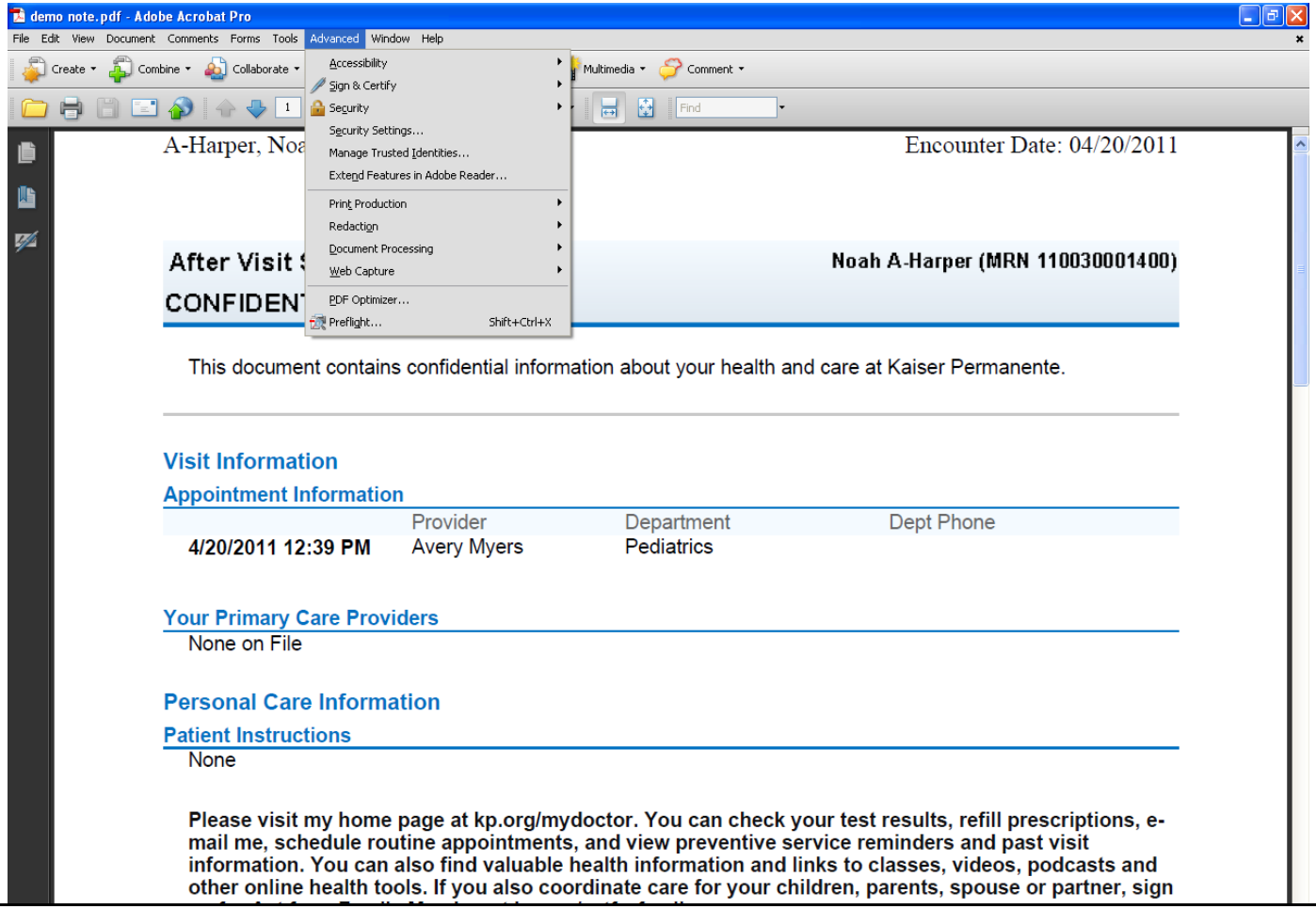
APPENDIX A: REDACTING USING ADOBE ACROBAT

The following presentation slides show test patient information for demonstration purposes.

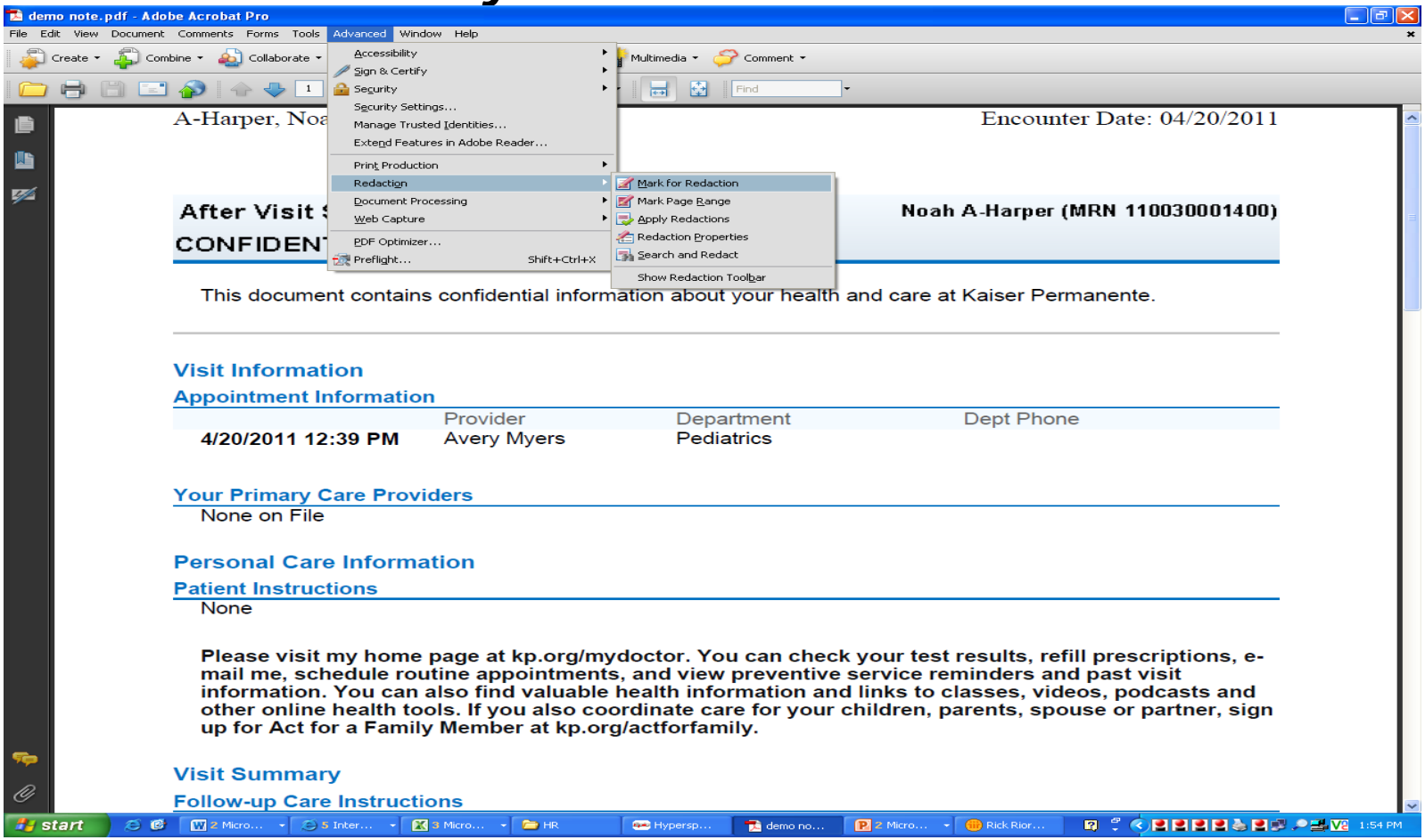
Print document with PHI to Adobe Acrobat. (Please see test patient's document below)



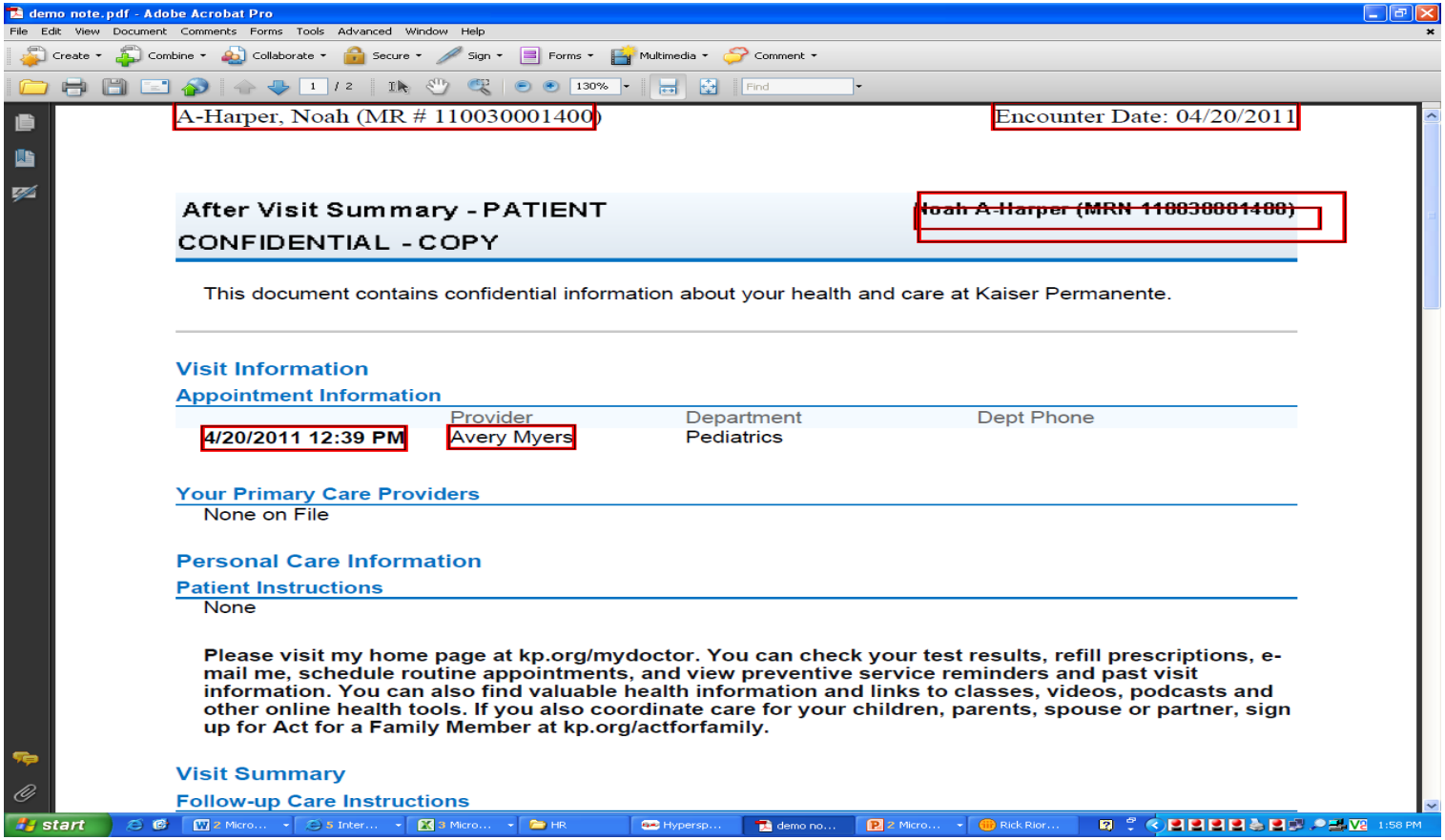
Select advanced/redaction as per the screenshot of the test patient below



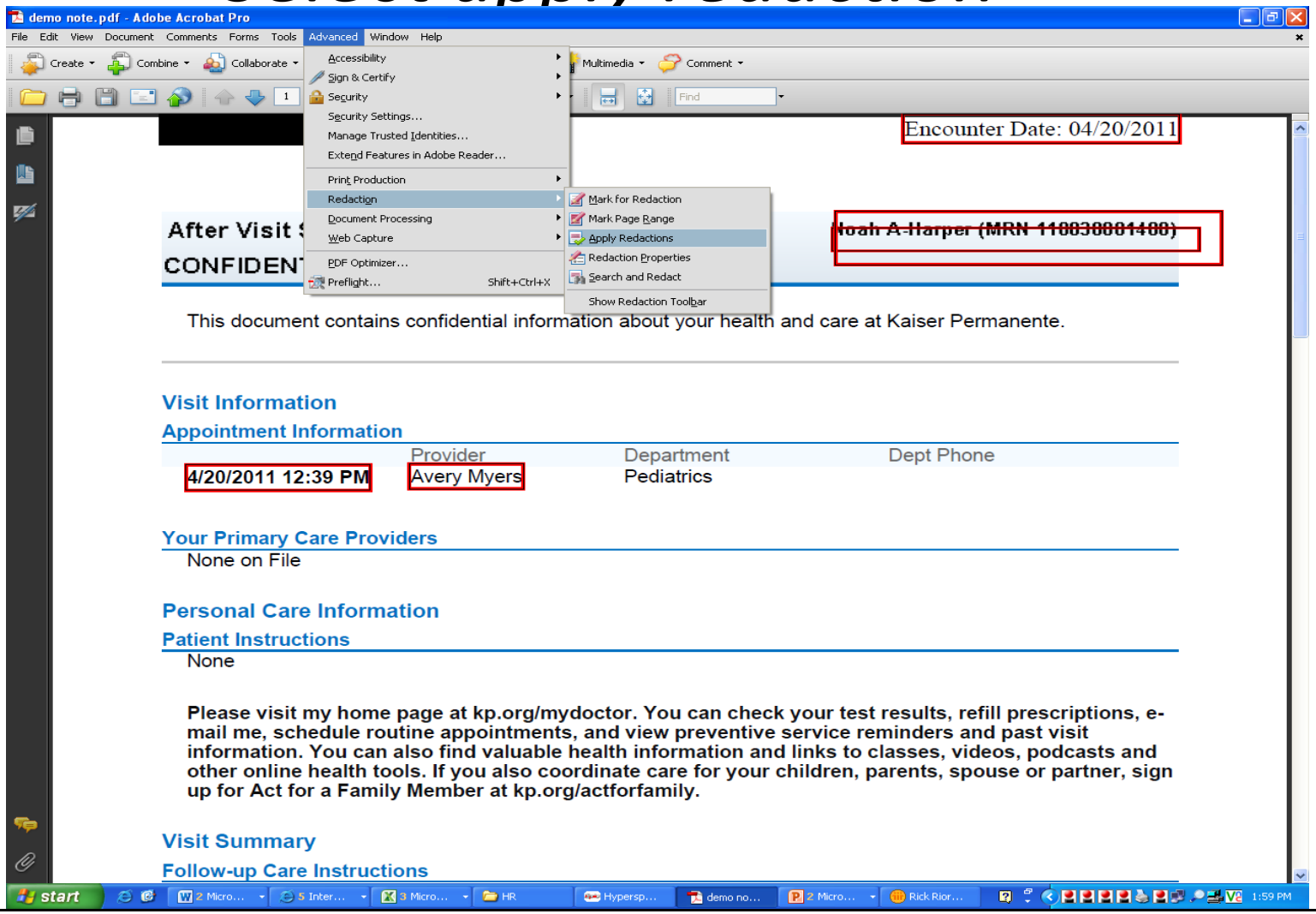
After selecting redaction, select *mark for redaction*



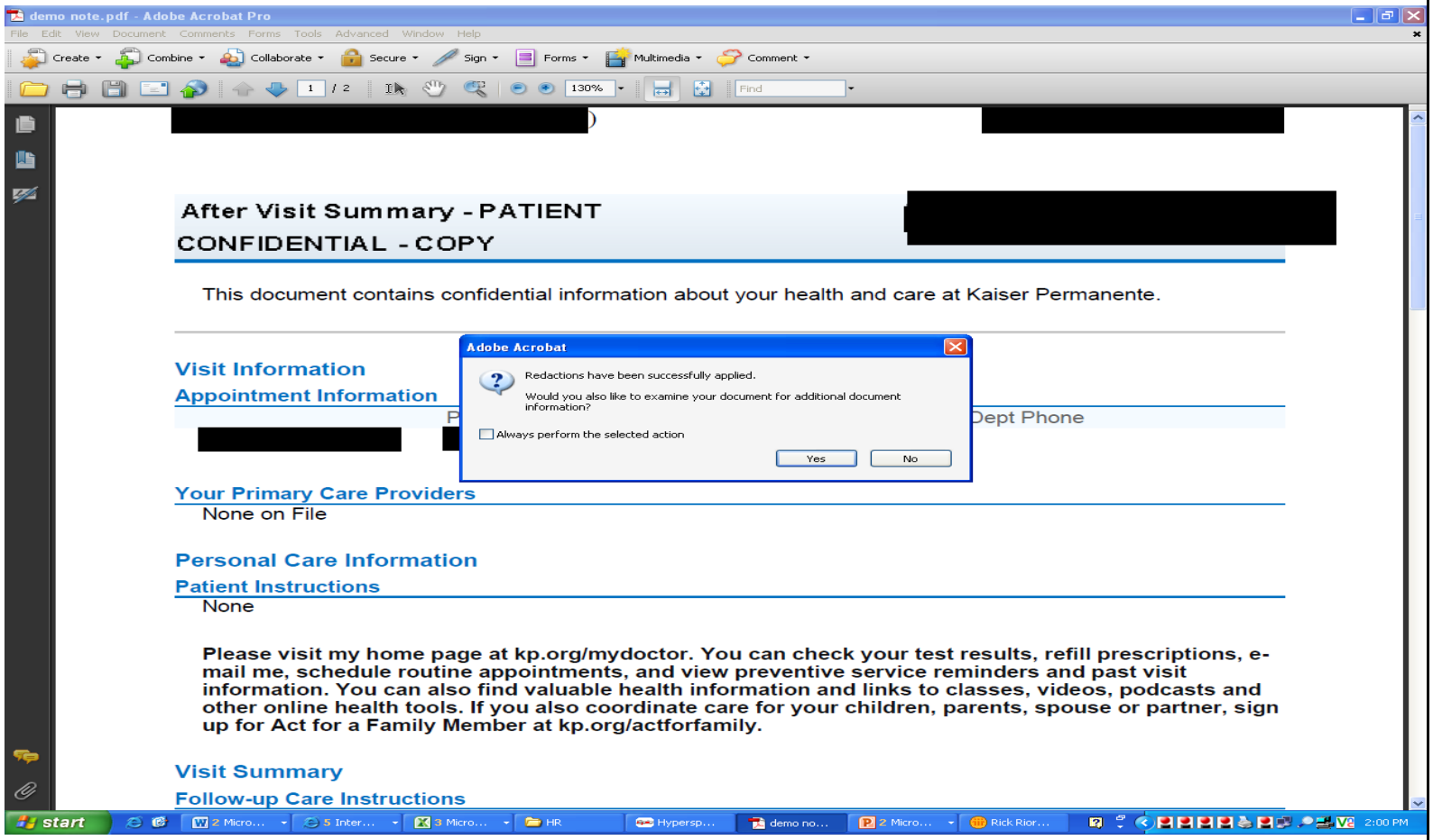
Select all sections of document with PHI



Select *apply redaction*



After applying redaction the PHI will no longer be visible



APPENDIX B: RECOMMENDED REFERENCES

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2. Thwin SS, Clough-Gorr KM, McCarty MC, Lash TL, Alford SH, Buist DS, Enger SM, Field TS, Frost F, Wei F, Silliman RA. Automated inter-rater reliability assessment and electronic data collection in a multi-center breast cancer study. BMC Med Res Methodol. 2007 Jun 18;7:23.
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5. Reisch LM, Fosse JS, Beverly K, Yu O, Barlow WE, Harris EL, Rolnick S, Barton MB, Geiger AM, Herrinton LJ, Greene SM, Fletcher SW, Elmore JG. Training, quality assurance, and assessment of medical record abstraction in a multisite study. Am J Epidemiol. 2003 Mar 15;157(6):546-51.
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