Auditing Clinical Research Billing
How Do You Know You’re Doing It Right?

Andrew Walton & Kristina Kinard | May 31, 2015

Objectives

• Background and Brief History of Research Billing
• Implementation of the Clinical Research Billing Program
• Implementation of the Clinical Research Billing Audit Plan
• Procedures to Audit Coverage Analyses and Patient Billing Claims
• Technical Tools Utilized to Provide Transparency and Help Audit
• Corrective Action to Take After Auditing Clinical Research Billing
UC Irvine Health – Current State

- Mission: Discover – Teach – Heal

- UC Irvine Health is comprised of:
  - UC Irvine Medical Center located in Orange, CA
    - 411-bed acute care hospital
    - 19,312 admissions
    - 561,021 outpatient visits
  - UC Irvine Physicians & Surgeons
  - UC Irvine School of Medicine
  - University of California, Irvine Campus

UC Irvine Health Research Centers

- Chao Family Comprehensive Cancer Center
- Beckman Laser Institute
- Institute for Clinical and Translational Science
- Susan Samueli Center for Integrative Medicine
- Sue and Bill Gross Stem Cell Research Center
- Brain Imaging Center
- Reeve-Irvine Research Center for Spinal Cord Research
- Gavin Herbert Eye Institute
- Center for Molecular & Mitochondrial Medicine and Genetics
- Center for Immunology
- Center for Virus Research
- Genetic Epidemiology Research Center
- Center for Health Policy Research
- John Tu and Thomas Yuen Center for Functional Onco-Imaging
- Alzheimer’s Disease Research Center
Corporate Compliance Office and Office of Research Oversight

- The Office of Research Oversight, formed in 1999, is part of the UC Irvine Health Corporate Compliance Office.
- The Corporate Compliance Office includes the Chief Compliance and Privacy Officer and the Research Compliance Officer.
- The Office the Research Oversight includes the Research Compliance Officer, two Clinical Research Billing Auditors and one Research Regulatory Specialist.
- Corporate Compliance Analysts assigned to Professional Fee Billing Auditing, Privacy and Hospital Compliance.

Brief History of Research Billing at UC Irvine Health

- Billing Compliance - In 2000, the Medical Center implemented a process to recognize billing services on patient claims to be recharged to a grant account fund.
- The Medical Center assigned a research nurse to provide support to researchers to help cost protocols using Medical Center services.
- Office of Research Oversight (ORO) began auditing the research recharge process in 2000. In 2007, the ORO added a full-time billing analyst position to oversee the research billing process.
- In 2010, ORO added a 2nd analyst and increased monitoring of research billing. Started the early discussions of performing a more complete billing audit, reviewing assignment of codes and modifiers to claims. ORO auditors corrected claims.
- In 2014, ORO implemented a fully operational clinical research billing audit program that included a corrective action plan to correct research billing claims.
UC Systemwide CRB Implementation Plan

The Clinical Research Billing (CRB) Implementation Plan:

• Commitment to develop Coverage Analyses (CA) for all clinical research studies that could generate charges in either the hospital or physician billing systems;

• SOPs describing process and assurance mechanisms for synchronizing the research informed consent, clinical trial agreement/budget and Coverage Analyses for new studies;

• Timeline for roll-out of Coverage Analyses for new studies and all legacy studies (those active with enrollees that receive services that could generate charges);

• A database of clinical research studies that have active enrollment or are open to enrollment (the database shall indicate whether a Coverage Analysis exists);

UC Systemwide Implementation Plan (cont.)

• Process for the health sciences campuses to implement a CTMS or database;

• Process on how research teams will update database with MRNs of enrolled subjects;

• Document-housing plan which allows central storage of study documents and the CA;

• Description of how hospital and physician billing offices and Research Compliance can access the CA, subject enrollment database, and study documents; and

• Identification of individuals in operations who are responsible and accountable for managing the coordination of information for CRB and have the authority to coordinate resolution of CRB errors.
CRB Implementation Task Force

• Departments involved included:
  • Compliance and Research Oversight – SOM & Medical Center
  • Research Support Services (RSS) – SOM
  • Center Information Systems
  • Professional Billing Group (PBG)
  • Patient Financial Services (PFS)
  • Medical Center Information Systems (IS)
  • Medical Center Registration
  • Medical Center Finance

CRB Task Force Outcomes

• Created a CRB Implementation Plan
• Agreed to, and implemented, a bill hold process
• Creation of CRB Bill Hold Claims Review Unit in Revenue Audit
• Revision to Registration Process
  • Research “R”
  • All research participants are to be registered at study for all visits
  • HL7 interface triggers bill hold
• Hiring of CTMS Manager
  • Manage implementation of CTMS
  • Train research staff on CTMS
  • Build calendars in CTMS
CRB Process – Current State

- Decentralized Budget Process
  - Each department creates their own budget

- Centralized Office for Coverage Analyses
  - Housed in Hospital Finance
  - Clinical Research Finance Analysts (2 FTEs)

- Centralized Clinical Research Billing Unit
  - Housed in Hospital Finance - Revenue Audit
  - 1 Manager, 3 Assistants (4 FTEs)

- Future State: Centralize Budget Process

Current Research Statistics

- Over 1400 open human research subject protocols

- 30% with a clinical component needing a Coverage Analysis
  - 50% High risk (lots of patients, services, mixed billing)
  - 50% Low risk (1-2 services, clinic visits)

- Approximately 50-60 new protocols per month
  - About 40% needing a Coverage Analysis

- Funding Sources
  - Industry sponsored
  - Federally sponsored
  - PI initiated (little or no funding)
Initial Risk Assessment

• Compliance performed an initial Risk Assessment of all open human research protocols in July 2013.

• In order to complete this assessment, IRB documents were read and analyzed to see if there were any studies that could potentially generate a charge*.

• Outcome
  • Out of 1123 total human subjects protocols, the initial assessment determined that 625 protocols potentially needed a Coverage Analysis (56%)

(* Please note, the Compliance Office has full access to the IRB Document Depot, Clinical Trial Management System, Award Synopsis, Electronic Medical Records, and all Billing Systems.)
Second Risk Assessment

- As part of the CRB Readiness Plan, a more in-depth risk assessment was performed by the Compliance Office on October 15, 2013 to identify all open and enrolling protocols that generate hospital or professional charges and prioritize completion of a Coverage Analysis.

- Utilizing our CTMS and talking to study staff, it was determined that some of these studies were no longer enrolling or were not generating a charge in the billing system.

Outcome
- Out of 1159 total human subjects protocols, the second assessment determined that 443 protocols needed a Coverage Analysis (38%)
- 338 out of the 443 protocols had already be reviewed by the Clinical Research Finance Office (76%)

Email to PIs/Study Staff
Risk Assessment (cont.)

• Although we had a department that had reviewed a lot of these studies, now we had to create a Coverage Analysis for each and house them in one location

• It was agreed that all coverage analyses would be located in our CTMS

• In order to build these coverage analyses into the CTMS, there were quite a few steps that needed to be taken:
  • Register the protocol
  • Upload all necessary documentation
  • Create study calendar
  • Create accurate and complete Coverage Analysis in study calendar

Risk Assessment (cont.)

• Initially, the Compliance Office helped with the creation of calendars and coverage analyses in our CTMS

• Manager hired to help oversee creation of calendars in our CTMS

• July, 2014 – 6 months after the CRB implementation
  • 1265 total human subjects protocols
  • 367 protocols in need of a Coverage Analysis (29%)

• Through these risk assessments we determined the protocols that needed a Coverage Analysis, but we wanted to prioritize the creation of each Coverage Analysis within the CTMS
Risk Assessment (cont.)

- A Risk Matrix was created for building calendars in our CTMS
- High-risk protocols had the following criteria:
  - Patient enrollment
  - High volume of clinical services
  - Mixed charges – billable to 3rd party and rechargeable to study
- Low-risk protocols were protocols with 1-2 clinical services
- January, 2015 – 1 year after CRB implementation
  - 1364 total human subjects protocols
  - 232 high-risk protocols needed a Coverage Analysis (multiple services)
  - 174 low-risk protocols (1-2 services or clinic visit only)
  - 406 total protocols needed a Coverage Analysis (30%)

Risk Assessment: ClinicalTrials.gov

- Another potential risk in clinical research billing that was mandated starting in 2014, but fully implemented in 2015, was including the ClinicalTrials.gov number on the claim to Medicare
- A review of all of the studies that potentially needed a Coverage Analysis was performed
- Only 13% of protocols were missing a ClinicalTrials.gov number
- In order to be 100% compliant with the ClinicalTrials.gov number being included on the claim, there was a lot of education and follow-up with departments and PIs
- The ClinicalTrials.gov requirement is continually tracked for all new protocols and entered into the CTMS
Identification of Study Participants

- Two fold process: Utilizing Information Services & Research Staff
- Because we had been using research plan codes as a Special Program in order to identify patients on a research protocol, we pulled a list of Special Programs from our EMR
- Initially, this list resulted in 24,968 patients
- Compliance staff eliminated 17,246 patients in non-research programs (i.e. Infectious Disease Grant and other Special Programs), resulting in 7,722 patients
- Using the list of protocols that potentially needed a Coverage Analysis, an email was sent to research staff to give the Compliance Office a list of all research subjects on each protocol

Identification of Study Participants (cont.)

- The Compliance Office created a spreadsheet and kept a master list of all research patients (RPL)
- The RPL was further identified by:
  - CTMS – Cancer Center patients only
  - Logs from research pharmacy of all patients on investigational medications
  - Radiology research requisitions of all patient-received radiology services
- As of February 2015, we had identified 1,783 patients still receiving treatment or on follow-up and needing to be on a bill hold
- Registration staff removed the research plan code/special program indicator from the rest of the patients no longer on treatment or follow-up in a clinical trial
Technical Tools

- These were the tools utilized to open communication between all CRB stakeholders (Compliance, CRB Unit, CRFAs, RSS)
  - Clinical Trial Management System
    - Created transparency in study information
    - Data management of research enterprise:
      - Study documentation
      - Patients enrolled in the study – Cancer Center only
      - Calendar of events
      - Coverage Analysis
  - Research Patient List (RPL)
    - Currently on a shared drive and updated every Monday
    - Training is in-progress for adding patients to studies in our CTMS

Initial Coverage Analysis Audits

- After we had a plan to create coverage analyses in the CTMS, 1 FTE from the Compliance Office tracked the coverage analyses completed by the Clinical Research Finance Analysts
- The Coverage Analysis was considered incomplete if:
  - The study was not registered correctly or completely in the CTMS
  - All of the necessary documentation was not present in the CTMS
  - There was no “document synchronization” (i.e. the informed consent language did not match the Coverage Analysis or the CTA, or the Coverage Analysis did not reflect the language and budget in the CTA)
  - There were no CPT codes or the CPT codes were not accurate
- Reports were sent to the CRFAs, Research Support Services, and Directors of Finance
Developed Metrics

- How many studies that needed coverage analyses were registered in our CTMS?
- How many calendars built?
- How many coverage analyses completed?
- How many new coverage analyses needed to be completed each month?
- How many new patients consented to studies that needed to be on a bill hold?

Sample Coverage Analysis Audit

<table>
<thead>
<tr>
<th>HS #</th>
<th>PI</th>
<th>Reg</th>
<th>CPT Codes</th>
<th>Doc Typ</th>
<th>Signoffs</th>
<th>Coverage Analysis</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-1122</td>
<td>MOAZAFAR</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No budget or CTA uploaded in OnCore. CPT codes are not comprehensive. No CTA uploaded in OnCore. CPT codes and no clinic visits designated in Coverage Analysis. No Signoffs in OnCore.</td>
</tr>
<tr>
<td>2014-1066</td>
<td>SU</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>No sponsor associated to registration in OnCore. No CTA uploaded in OnCore. No CPT codes and no clinic visits designated in Coverage Analysis.</td>
</tr>
<tr>
<td>2014-1065</td>
<td>SONG</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>No sponsor associated to registration in OnCore. No CTA uploaded in OnCore. CPT codes are not comprehensive for all procedures. No clinic visits reflected in Coverage Analysis.</td>
</tr>
<tr>
<td>2014-1031</td>
<td>FARID</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>No budget uploaded in OnCore. CPT codes are not comprehensive for all procedures. All CPT codes designated as no way to identify.</td>
</tr>
<tr>
<td>2014-9994</td>
<td>PIERCE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No CPT codes or clinic visits designated in Coverage Analysis. All CPT codes designated as no way to identify. No signoffs in OnCore.</td>
</tr>
<tr>
<td>2014-9992</td>
<td>SONG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No sponsor associated to registration in OnCore. No budget or CTA uploaded in OnCore. No CPT codes or clinic visits designated in Coverage Analysis. All CPT codes designated with no documentation to identify.</td>
</tr>
<tr>
<td>2014-9991</td>
<td>MULNARD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No IRB documents uploaded in OnCore. No CPT codes or clinic visits designated in Coverage Analysis. All CPT codes designated as not all items are identified in the Budget. No Signoffs in OnCore.</td>
</tr>
</tbody>
</table>
Implementation of Current CRB Audit Plan

Clinical Research Billing Audit Policy

All UC Irvine Health departments engaged in clinical research may be reviewed periodically for research billing compliance. The Office of Research Oversight (ORO) will identify specific departments, researchers and research studies to be reviewed.

The purpose of the clinical research billing audit is to provide an internal mechanism for quality assurance, quality improvement and education pursuant to research financial compliance and clinical research billing. In addition, ORO helps provide support on complying with all institutional polices and federal and state laws and regulations.

- Retrospective Audits – Legacy Protocols
- For-cause Audits
- New Protocols – 1st patient on protocol
- Coverage Analysis Audits
- Registration of Research Subjects

CRB Auditing – Recap

- Identified every patient in the EMR and hospital billing systems, both current and historic, that may have been on a research protocol. Further refined the research patient list to include only those patients currently active on a research protocol.

- Identified all research protocols (including both legacy and new research protocols) that will require a Coverage Analysis to review and audit a billing claim.

- Implemented an electronic “flag” in an effort to identify a research patient in the hospital registration system. New procedure implemented that all new patients that sign a research consent are “flagged” as a research patients.

- Implemented the electronic bill hold procedure. All patients consented to a research protocol that could generate a charge in the hospital billing system will have their billing claim data held for review.

- Established the Clinical Research Billing Unit that reviews all research claims on bill hold. Implemented procedures to assure the application of research codes and modifiers are correct on each line item. Removed services from a claim to be recharged to a grant account fund. Reviewed that the ClinicalTrials.gov number is added to each claim as applicable.
CRB Audit Staff

The Research Compliance staff includes the Research Compliance Officer, the Research Regulatory Specialist, and two Clinical Research Billing Auditors.

The CRB Billing Auditors:

- Certified Coders
- Experienced billing and research protocol auditors
- Proficient with billing claim forms and documentation
- Understands Hospital and Professional Fee billing regulations
- Proficient in all Medical Center financial systems and the CTMS
- Access to IRB documents and Sponsored Projects agreements
- Trained in Human Subjects Research - Consents, Protocols, Trial Agreements
- Knowledgeable of Medicare NCD billing regulations
- Train and provide assistance to hospital research bill hold staff

Clinical Research Billing Auditing

- ORO Billing Auditors select each protocol to audit based on risk or assignment.
- For legacy protocol audits, auditors select 5 patients from the research participant list.
- For new protocol audits, auditors select at least one patient from the research participant list.
- Auditors review available research documents, including: the protocol, patient consent document, sponsor clinical trial agreement (CTA), budget documents and study calendar.
- Auditors and ORO staff review the Coverage Analysis.
- ORO staff review that the cost language in the CTA, Coverage Analysis and Informed Consent are in agreement.
- If a Coverage Analysis is not available or is incomplete, the research auditors and ORO staff will build their own Coverage Analysis to be used for the audit.
- The auditors identify the consent date of the individual and pull all patient claim data from the start of the study to-date, from all locations using the MD Audit tool.
- The auditors audit claim data against the Coverage Analysis and research documentation.
Clinical Research Billing Audit – Outcomes & Corrective Action

- Identify refunds to 3rd party commercial payers, including Medicare
- Identify and bill 3rd party payers for qualified trials
- Identify recharges and/or refunds to sponsor grant/account funds
- Corrective action – addition/deletion of Q modifiers
- Corrective action – addition/deletion of research billing codes
- Application of ClinicalTrials.gov number to applicable claims
- Revisions and corrections to patient research consent document sent to PI and IRB
- Revisions and corrections to coverage analyses and study calendars sent to PI, clinical research staff and Coverage Analysis/Study Calendar builders

Prevention of billing errors on new patients

Clinical Research Billing Auditing (cont.)

- The ORO Billing Auditors forward the completed audit and supporting research documents to the Research Compliance Officer for review.
- The ORO staff determines if additional (or all) patients on the protocol will need corrective action, and determine how far back to audit claims.
- The ORO staff will meet to discuss any unresolved audit findings.
- Audit results are sent to the manager of the CRB unit for review.
- The CRB unit will then have the option to review the audit results with the Billing Auditors. The Billing Auditors will then provide objective evidence to support audit results.
- When the audit results are approved, all corrective actions are sent to the Hospital and Professional Fee billing and coding staff.
- All corrections to the claim need to be made within 30 days of the approved audit findings.
MD Audit Hospital Example

Audit Case Changes Listing

<table>
<thead>
<tr>
<th>Audit Case</th>
<th>MRN</th>
<th>Name</th>
<th>Statement From Date</th>
<th>Audit Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>34000000100</td>
<td>000</td>
<td>Doe, John</td>
<td>01/01/2015</td>
<td>Billing Error</td>
</tr>
<tr>
<td>34000000101</td>
<td>001</td>
<td>Smith, Jane</td>
<td>01/02/2015</td>
<td>Coding Error</td>
</tr>
<tr>
<td>34000000102</td>
<td>002</td>
<td>Johnson, Michael</td>
<td>01/03/2015</td>
<td>Documentation Error</td>
</tr>
</tbody>
</table>

Professional Fee Billing Audit Example

Study 123456: Drug Treatment

<table>
<thead>
<tr>
<th>Patient</th>
<th>Drug Name</th>
<th>Dosage</th>
<th>Route</th>
<th>Inpatient</th>
<th>Outpatient</th>
<th>Total Days</th>
<th>Days on Drug</th>
<th>Days on Placebo</th>
<th>Days on Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient A</td>
<td>Drug X</td>
<td>50 mg</td>
<td>Oral</td>
<td>30</td>
<td>20</td>
<td>50</td>
<td>28</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Patient B</td>
<td>Drug Y</td>
<td>100 mg</td>
<td>IV</td>
<td>15</td>
<td>15</td>
<td>30</td>
<td>14</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Patient C</td>
<td>Drug Z</td>
<td>25 mg</td>
<td>Oral</td>
<td>45</td>
<td>20</td>
<td>65</td>
<td>35</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

Note: This table includes data on the number of days each patient was on the drug treatment and the number of days they were on placebo.
Training and Education

- Educate and train all researchers and clinical research staff to the CTMS system in order to manage protocols and patient care.
- Provide workshops and guidance documents on preparation of a budget and Coverage Analysis.
- ORO Research Auditors to provide feedback and guidance to Medical Center Billing and Coding staff on audit results.
- Identify lack of documentation of clinical research in the medical records and train PI and research staff on providing better documentation to support billing.

Ongoing Monitoring – The Future

- Decrease the inventory of Legacy Protocols
- Review the 1st patient on all new protocols
- Move the entire research enterprise to the CTMS, and decrease manual off-line systems used to document and track research
- Document all research protocols and patients in the CTMS
- Move to patient-specific calendars/coverage analyses to the CTMS
- Continue to refine the Coverage Analysis process
- Maintain a high level of clinical research billing auditing
- Look for more electronic tools and solutions for auditing
Takeaways

• Include the Compliance Office in the implementation of Clinical Research Billing processes

• Complete access to documentation and transparency is necessary in order to audit

• Audit all Coverage Analyses

• Audit 1st patient on each new protocol

• Identify metrics to provide to leadership

• Audit to identify the barriers to implementation and provide corrective actions

Questions?

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