CTMS Support of Billing Compliance Best Practices

Research Compliance Conference
Austin TX, June 2013

Agenda

• Background
• OnCore Billing Compliance
• EMR/OnCore Integration
  — Goals
  — Integration Options
• OnCore Billing Compliance Workflow Demonstration
Background

- Founded in 2000
- 69 employees @ Headquarters: Madison, WI, USA
- 22 employees @ India office, Bangalore

OnCore eClinical

Online Collaborative Research Environment

- Clinical Research Management
- Integration
- Electronic Data Capture
- Billing Compliance
- Biospecimen Management
- Patient Registries
Billing Compliance in OnCore

1. Qualified Clinical Trial Determination Checklist
2. Protocol Event Schedule
3. Indicate Billing Designation & Rationale
4. Ability to filter and report on information
5. Attach documents to support decisions
6. Integration with EHR
Shared Protocol Calendar

- Protocol Calendar
  - Patient Billing
  - Sponsor Invoicing/Payments
  - Subject Visits
  - Coverage Analysis

Cross Functional Impact

- PI
  - Clinical Calendar (create/view)
  - Protocol Billing Grid (view)

- Research Coordinator
  - Clinical Calendar (create/view)
  - Subject Visit (add add'l procedures w/billing designations)

- Coverage Analyst
  - QCT Checklist (update)
  - Protocol Billing Grid (able to group items/services)
  - Coverage Analysis (update billing designations, Q0/Q1 modifiers, and comments)

- Research Financials Specialist
  - Clinical Calendar w/ footnotes (view)
  - Research Charge Master (view)
  - Protocol Budget incl Q0/Q1 modifiers (update/view)
  - Billing designations (view)

- Patient Billing Specialist
  - Billing Slip for a subject visit augmented with relevant Coverage Analysis details (view)
  - Coverage Analysis for a protocol with appropriate billing designations -- possibly organized differently than for Coverage Analyst (view)
Billing Compliance: New vs. Legacy Studies

Epic-OnCore Integration Goals

- Initial Effort: Define Priorities Across Teams
- Reduce Redundant Data Entry Efforts
  - Workflow in legacy system/process
  - Consolidating systems?
- Streamline Billing Compliance Efforts
**OnCore / Epic Integration for Billing Compliance**

**RPE**
- “Flagging” a patient in the EMR as participating in a research study

**Protocol Billing Grid**
- Provides an EMR with relative time points of a research study calendar including codes, billing designations and modifiers for assigned charge events & items.
- Purpose is to support billing compliance.

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**RPE – Retrieve Process for Execution**

**Overview**
- Technical profile contained within the IHE – QRPH technical framework.
- Defines how research systems exchange data with EMRs.

**Implementation Considerations**
- Unique identifiers (recommend demographics interface)
  - Protocol identifier
  - Subject identifier
- Currently Epic EMR is the only EMR to use RPE with OnCore
**RPE Operations**

OnCore & EMR - RPE (v1.0) Operations

**Overview**
- Defined by CRPC, a supplement to the RPE profile.
- Provides EMR with relative time points of a research study calendar including codes, billing designations and modifiers for assigned charge events & items.
- Purpose is to support & streamline billing compliance.

**Implementation Considerations**
- RPE integration is required
- Epic 2012 version required
- Epic Beacon oncology module considerations
- OnCore financials implementation

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**Protocol Billing Grid Integration**

**Overview**
- Defined by CRPC, a supplement to the RPE profile.
- Provides EMR with relative time points of a research study calendar including codes, billing designations and modifiers for assigned charge events & items.
- Purpose is to support & streamline billing compliance.

**Implementation Considerations**
- RPE integration is required
- Epic 2012 version required
- Epic Beacon oncology module considerations
- OnCore financials implementation
Workflow Impact of Epic-OnCore Integration

• Workflow Definition Across Teams and Systems
• Streamlining workflows: Interface does not mean no effort in Epic
• Identify and define all workflows, not just those related to the interface (e.g., Scheduling)

Key Lessons Learned: Critical Success Factors

• Shared Vision and Sense of Purpose across teams
• Strong leadership
• Efficient Decision Making Ability
• Communication – At Institution and With Forte/Epic
In Summary

• OnCore-Epic Integration:
  – Driven by goal of streamlining billing compliance
  – Current priority to improve use of integration with Beacon

• Successful Integration relies on:
  – Workflow Definition
  – Leadership, communication across teams and systems

ONCORE BILLING COMPLIANCE WORKFLOW DEMONSTRATION
OnCore Clinical Research Environment

Clinical Research Management
Integration
Electronic Data Capture
OnCore
Billing Compliance
Biospecimen Management
Patient Registries

OnCore Clinical Research Workflow

Research Administration
- Protocols
  - Basic Protocol Setup
  - Regulatory
  - Scientific Reviews
  - IRB Reviews
  - Protocol activation
  - DSMC Reviews
- Subjects
  - Pre-Screening
  - Registration
  - Consenting
  - Eligibility
  - Subject Status
  - SAEs
  - Deviations
- Financials
  - Coverage Analysis
  - Study Budgets
  - Negotiated Rates
  - Payment Milestones

Study Setup
- Calendars
  - Procedures & Evaluations
  - Treatment & FU Schedules
  - Visit Tolerances
  - Foot Notes
- eCRFs
  - Forms Design
  - Assign forms to studies

Visit Tracking & Data Capture
- Automated subject calendars
- Visit & Procedure Tracking
- Additional Visits & Procedures
- SOC vs. Research
- eCRF completion
- Query resolution

Study Data Management
- Data Monitoring
- Data Discrepancy Management
- Data Export

Revenue Management
- Automated invoice items
- Invoice generation
- Receivables tracking
- Unplanned visits & procedures
- Exceptions
Discussion

Thank You

Lessons Learned: The Implementation of an Enterprise-wide Clinical Research Management System and Integrating an Electronic Health Record

June 4, 2013

Tesheia Johnson, MBA, MHS
Associate Director for Clinical Research, Yale School of Medicine
Chief Operating Officer, Yale Center for Clinical Investigation
We are new to this game!!!

**Disclaimer**

Yale purchased EPIC in June of 2010 and went live February 2013. Yale purchased OnCore clinical research management system in March of 2011. This session is intended to share common knowledge. This session is in no way intended to imply that we have figured it all out yet.

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**EPIC - Current Status**

**Epic Timeline**

- Kickoff October 19, 2010
- Yale Medical Group first go-live October 19, 2011
- October 2012 -- 300 YMG physicians live
- February 2013 -- >800 YMG physicians live
  - YMG on Epic Revenue
  - Epic / OnCore integration
- YNHHS Hospitals
  - Greenwich April 2012
  - Yale New Haven – York Street Campus February 2013
  - Yale New Haven – Saint Raphael Campus June 2013
  - Bridgeport September 2013
- Rollout substantially complete EOY 2013
Yale clinical research profile

- Industry sponsored research presents a growth opportunity at Yale

Total submissions

Number of Submissions (Actions) Reviewed by the HIC & HSC FY 2010-2012

- FY2012: 1218
- FY2011: 1194
- FY2010: 1103

Source: Coeus data – Presentation by Jan Hewitt March 2013
New submissions

HIC New Submission Approvals FY2012
(n=1229)

- Full
- Expedited
- Not DHHS/FDA-regulated
- Exempt

625, 49%
315, 26%
112, 9%
203, 16%

Biomed IRB initial submissions by Dept: 2012

- Oncology Board
- Anesthesiology, 16
- Surgery, 124
- Medical Ed, 31
- Oncology Board, 224
- Cell Biology, 2
- Comparative Medicine, 3
- Child Studies, 41
- Dermatology, 10
- Emergency Medicine, 33
- Pathology, 27
- Orthopaedics and Rehabilitation, 19
- Ophthalmology and Visual Science, 24
- Genetics, 6
- Imaging Research, 1
- Immunobiology, 13
- Medical Ed., 31
- Pediatrics, 109
- Psych/Neuro, 250
- Medical Ed., 31
- Surgery, 124

Source: Coeus data – Presentation by Jan Hewitt March 23, 2013
Why did Yale go shopping?

• **Need a more robust solution**
  – Homegrown solution was too expensive
  – NIH (multi-center coordination/ data coordinating center grants)
  – industry research (better feasibility data)

• **Enterprise Reporting**
  – Senior leadership (YSM/YNHH), Chair, center director and dept admin level reporting

• **Regulatory Compliance**
  – Data Safety and Monitoring plan compliance
  – Clinicaltrials.gov reporting
  – IND management

• **Financial management**
  – Better invoicing and fund management
  – Enhanced reporting

120 faculty and staff participated (YSM and YNHH)

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Research Flow – Prior to Epic/OnCore
Timeline

2007
- Search and Review
  - May 2007: Formation of the Implementation/Planning Committee
  - May 2007: Request for Information (RFI) issued to 22 vendors

2008
- RFP
  - May 2008: Request for Proposal (RFP) issued to six vendors
  - February 2009: Initial CRMS site visits

2009
- In-depth Assessment
  - July 2009: Detail RFI responses analyzed
  - September 2009: Recommendation for purchase of two CRMSs

2010
- Decision
  - January 2010: Executive Committee receives recommendation

2011
- Purchase
  - February 2011: Yale Cancer Center begins using OnCore
  - July 2011: Contract negotiation

2012
- Rollout
  - January 2012: First phase of the implementation begins

2013
- Full Implementation
  - January 2013: Second phase of the implementation begins

Where are we today?
"Minimum Footprint" and Beyond

Yale University
- # of Active Users: 570
- # of Protocols: 1090
- # of Investigator Initiated: 346
- # of Industry: 445
- # of Protocols With More Than 1 Institution: 57
- # of Active Protocols: 772
- # of Subjects: 681
- # of Active Subjects: 2479
- # of Subject Forms: 860
- # of Protocol Documents: 5996

- Subjects in treatment or follow up
- Number of eCRFs completed

- All clinical department went live with EPIC go-live Feb 2013, basic science departmental implementation underway
  - Super user training
  - This phase will introduce subject calendars, case report forms, budgeting and sponsor invoicing

http://oncore.yale.edu
Where are we today?
We can get data!!!
Where are we today? We have a process!!!

New studies intake at Yale

http://medicine.yale.edu/ycci/oncore/newstudysetup/index.aspx

Where are we today? We have a process!!!

OnCore Calendar Release
Where are we today? We have a process!!!

OnCore Study Build

Protocol Approval Workflow

- Protocol Approval Workflow
- Submits and RAs for IRB submission
- Submit to IRB
- Clinically and operationally significant
- IRB approves for Open Study
- Study information sent to RAs

Clinical Operations
- Sends out study builds
- Study reviewed for billable procedures
- This is captured in the annotations in the PC Console

Budget Development
- Contracts approved by sponsor
- Contract approved by sponsor
- Study sent to Epic via the RPE Console

Calendar and Submission
- Calendar released after clinical and budgeting approval

How the interface works (in OnCore): Sending a study

Study reviewed for billable procedures.
This is captured in the annotations in the PC Console.

PC Console

- Protocol ID: 00455061
- Library: Medicine/Surgery
- PI: Jane Doe
- Sponsor: Synthes (USA)
- Protocol Target Accrual: 500
- Accrual To Date: 2
- Protocol Status: OPEN TO ACCRUAL

RPE Console

- Protocol: 00455061
- Title: Pediatric
- Status: OPEN TO ACCRUAL
- Send

Study sent to Epic via the RPE Console.
How the interface works (in OnCore): Sending a study

Confirm the correct study has been selected.

<table>
<thead>
<tr>
<th>Configuration</th>
<th>RPC Eligible Protocols</th>
<th>Referral ID</th>
<th>Protocol</th>
<th>RPC ID</th>
<th>Short Title</th>
<th>Current Study Status</th>
<th>RPC Status Date</th>
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<td>PROTOCOL-C</td>
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<td>SUCCESS</td>
<td>2012-01-01</td>
<td></td>
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<tr>
<td>Protocol 2</td>
<td>0406000352</td>
<td>PROTOCOL-C</td>
<td>OPEN TO ACCRUAL</td>
<td>SUCCESS</td>
<td>2012-01-01</td>
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</tr>
</tbody>
</table>

Verify the study went across the interface successfully.

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</table>

High Level Overview – Charge Matching

1. **Charge is Generated**
2. **What study, if any, is charge potentially related to?**
3. **Where on the patient-specific study timeline did charge occur?**
4. **System-automated pre-direction to study or patient account based on calendar definition**
5. **Review charges according to configured rules**
**Process for Subject Management**

Our overall plan: Deploy a team of YCCI staff to assist with some of the behind the scenes work to allow department research staff to continue their normal research responsibilities.

**YCCI support for ALL departments indefinitely:**
- In OnCore, send new studies, billing grids, and subjects to EPIC
- Activate new studies and publish newly released calendars/budgets in EPIC
- Set and update all study timelines in EPIC

Departments (or YCCI until they are trained/ready) will manage the following updates:
- Registering new subjects in OnCore
- Updating subject Status information in OnCore
- Checking in visits in OnCore

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### Process for Subject Management

<table>
<thead>
<tr>
<th>Category 1</th>
<th>Departments who are trained and maintain their own subject management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The need for these departments is to have an assigned YCCI support staff provide a check-in of sorts, provide support when needed, and track their department activities to ensure they are not falling behind with OnCore entries.</td>
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<tr>
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<td>Plan:</td>
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<td></td>
<td>• Reach out to these departments twice a week (Tuesdays and Fridays)</td>
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<td></td>
<td>• Ask about enrollments and subject status updates (use template email)</td>
</tr>
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<td></td>
<td>• Use Planned Visit Report in OnCore as a tool to identify and communicate recent visits not reconciled in OnCore.</td>
</tr>
<tr>
<td></td>
<td>• Communicate results (changes made) back to the Department</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category 2</th>
<th>Departments who are NOT trained but we have identified a department contact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The need for these departments is for YCCI to complete their OnCore entries until the Coordinator is trained and prepared to take over management of their subjects in OnCore. Once trained, the goal is to move them to Category I.</td>
</tr>
<tr>
<td></td>
<td>Plan:</td>
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<tr>
<td></td>
<td>• Reach out to these departments daily (at first), then back off as appropriate for the trial(s)</td>
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<tr>
<td></td>
<td>• Ask about enrollments and subject status updates and visits completed. (use template email)</td>
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<td></td>
<td>• Use Planned Visit Report as a tool to communicate expected visits.</td>
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<td></td>
<td>• Complete the enrollment and subject visit check in OnCore.</td>
</tr>
<tr>
<td></td>
<td>• Communicate results (changes made) back to the Department</td>
</tr>
</tbody>
</table>

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<tr>
<th>Category 3</th>
<th>Studies for which the research contact is NOT known at this time</th>
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<tbody>
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<td></td>
<td>• YCCI needs to quickly identify contacts and goal is to work with the departments to graduate into Category II and ultimately Category I.</td>
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<td></td>
<td>• Several attempts at contact have been made. Once contact successful, have them sign up for training, QA their clinical trial activity, and focus on moving to Category II.</td>
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<td></td>
<td>• If the department contacts are non-compliant, YCCI leadership will contact department administration for appropriate escalation</td>
</tr>
</tbody>
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What is next?
The possibilities - nationally?

OnCore sites with EPIC

CTSA sites with EPIC

What is next – My functionality wish list?

• OnCore to feed – EPIC recruitment BPA and MyChart
• Integration screening and registries functionality to support recruitment
• Integration EHR data and OnCore case report form
• MyChart as EDC for patient reported outcomes for quality of life and other research.
• NIH—Human Subjects Protection Practices of National Cancer Institute Extramural Grantees Collecting Biospecimens (New) - We will determine the extent to which informed consent documents for research that includes the collection of biospecimens comply with human subjects protection regulations. Further, we will determine the extent to which Institutional Review Boards (IRB) overseeing this type of research comply with regulations. We will also determine the extent to which principal investigators and IRBs take measures to address unique risks associated with this type of research. Biospecimens are biological materials (i.e. blood, plasma, tissue) taken from clinical trial human subjects or remaining from a clinical procedure. With research involving the collection of biospecimens, informational risks, such as a breach of privacy, are magnified because of the long-term electronic storage of the subjects’ personally identifiable information and the potential for the biospecimens to be used in research not specified at the time of collection. No current regulations directly address human subjects’ protections in research that includes the collection of human biospecimens. Regulations at 45 CFR Part 46, subpart A address human subject protections, including informed consent, for HHS-funded research. (OEI; 01-11-00520; expected issue date: FY 2013; work in progress)

• NIH—Use of Data and Safety Monitoring Boards in Clinical Trials - We will determine the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials. We will also determine how to what extent NIH is ensuring that grantees comply with the NIH policy for DSMBs in multiple clinical trials. A DSMB is made up of individuals who have pertinent expertise and who regularly review accumulated data from one or more clinical trials to ensure the safety of participants and the validity and integrity of scientific data generated. A variety of types of monitoring, including DSMBs, are used, depending on the risk, nature, size, and complexity of the clinical trial. NIH requires that all NIH-funded clinical trials establish data and safety monitoring plans. (NIH’s “Policy for Data and Safety Monitoring,” June 1998.) The proposed current minimum responsibilities that sponsoring institutes and centers must impart to DSMBs and oversee data and safety monitoring. (OEI; 12-11-00670; expected issue date: FY 2013; work in progress)

Source: OIG 2013 Work plan

Dreaming bigger than a phase on the map now:
Regulatory and metric support

Lessons so far and roadmap for the future

• Decide what you want to be when you grow up and work hard
  – What kind of things should your systems enable?
  – Dreaming in phases is easier and has rewards along the way

• Compliance is important, but not the only thing
  – Zero risk = zero research
  – What do the faculty care about?

• You can’t do everything at once
  – What is first and why?
  – Message consistently and constantly
  – Get help when you need it
  – Allocate resources to your dream
Questions?

Consulting Vendors

- (2008) Deloitte Consulting assesses current state and crafts a recommendation for a long-term draft plan
- (2009 - 2010) Kurt Salmon Associates Consulting assists with contract negotiations and develops Total Cost of Ownership (TCO) and funding models for EHR
- (2010 - 2011) Kurt Salmon Associates Consulting assists with contract negotiations and develops TCO for CRMS
- (2010-2011) Attorneys specializing in information technology contracts are engaged to develop Yale contract with CRMS vendor
- (2011 - present) Huron Consulting assists with CRMS implementation
- (2012) Meade, Roach & Annulis LLP / Aegis Compliance & Ethics Center, LLP assists with calendar build for go live
Yale-driven additional contracted functionality

- **Yale customized reports**
  - NIH, Medwatch, delegation logs, etc.
    (April and September 2012)

- **Randomization functionality**
  - automated stratified randomization through an imbedded algorithm (April 2012)

- **SAS data extracts**
  - generation of code required to export and read data in text delimited format for study analysis (April 2012)

- **Disease-centric research tools**
  - (e.g., psychiatry, etc.)
    (Delivery date: Prior to Psychiatry Implementation)

- **Epic Integration**
  - working closely with Epic and other Epic/OnCore centers to automate the exchange of protocol and subject related information
  - support clinical research and billing data exchange
  - will allow enhanced recruitment functionality and single data entry in support of billing and other functions. (Delivery date: In conjunction with Epic go live, November 2012) – Moved to Feb 2013 new Epic go live

- **Clinical data interfaces**
  - automated upload of data from clinical systems to OnCore e.g., basic demographics (EPIC interfaces), laboratory results (LabSoft). (Delivery dates: In conjunction with Phase II of Cancer Center implementation)

- **Patient access**
  - Patient access to enter data directly (i.e., quality of life questionnaires, rating scales, etc.) (Delivery date: Prior to Psychiatry Implementation)

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### Vendor Products

| CTRMS System Functionality | REL/Johns | ONCORE | Varian | Study Manager | Phase I/II | IVR | Oracle | Epic | Clinical | MINICOM
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Yale SCHOOL OF MEDICINE
OnCore vs. Epic

- Study Centric
- Clinical Research Management System
- Contains subject calendar with SOC vs R designation
- Sponsor Invoicing System
- Additional Research functionality beyond billing compliance

- Patient Centric
- Electronic Medical Record
- Patient Billing system
- Schedules patient visits
- Allows for continuity of information between research and primary care

OnCore – High Level Functionality

- Unified Registries Management
  - Allows ad-hoc development of patient registries which can be de-identified to allow for data sharing and analysis
- Clinical Research Management
  - Helps manage all regulatory, patient, and financial needs throughout the lifecycle of a clinical trial
- Bio-Specimen Management
  - Allows for data capture of collection, processing, storage and shipment information