Taming the Billing Beast: How to Better-Manage Clinical Trials Budgets

Presented By

Teri Grieb, PhD
University of Michigan Health System

Vince Jajuga
eThority, Inc.
Taming the Billing Beast:
How to Better-Manage Clinical Trials Budgets

Learning Objectives:
1. Implement best practices in clinical trials billing.
2. Build comprehensive billing calendars.
About Teri Grieb, PhD

Senior Director of Research
University of Michigan
Medical School Office of Research
&
Managing Director
Michigan Institute for Clinical and Health Research
University of Michigan Health System Overview

- Integrated Academic Health Center
  - 3 hospitals, 40 health centers, & 120 outpatient clinics
  - Medical School and its Faculty Group Practices
  - School of Nursing

- Medical School
  - $377M in research expenditures — FY2009
  - $366M in NIH awards — FFY 2009 (2.81% NIH market share for medical schools)
  - Ranked 6th (US News & World Report, 2010)
  - CTSA site (2007 cohort)
President Clinton signed an executive memorandum on June 7, 2000 directing the Secretary of Health and Human Services to “explicitly authorize (Medicare) payment for routine patient care costs. . .and costs due to medical complications associated with participation in clinical trials”.

Source: CMS Transmittal AB-00-89
Covered Routine Care

All items and services that are otherwise generally available to Medicare beneficiaries, including:

- Those provided absent a clinical trial (e.g., conventional care)
- Those required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent)
- Those required for clinically appropriate monitoring of effects of investigational item or service, or prevention of complications
- Those needed for reasonable and necessary care, for diagnosis or treatment of complications
UMHS’s Goal

Accurate billing of items and services for participants in clinical research in accordance with all applicable state and federal laws and regulations.

To be achieved with:

- mandatory billing calendars
- an automated charge capture system that adjudicates charges appropriately
- backend account reconciliation
2006 created Calendar Review & Analysis Office (CRAO)
  - Ensures items/services that research teams intend to bill to Medicare and other third party payers are consistent with federal and state laws and regulations

Required billing calendars
  - All clinical research that involves billable items and services initiated after November 1, 2006, required the creation of a billing calendar and submission to CRAO for approval
## Billing Calendar

### Clinical Research Billing Calendar Template

**Full Title:**

**Phase of Study:**

"Short" Title:

**Study Sponsor:**

Principal Investigator:

Dept/Div of PI:

Calendar Prepared by:

Calendar Revised by:

**Version Date:**

**HUM#**

**Sponsor Protocol #:**

**7000 Account:**

**Preparer's Phone #:**

**Estimated # of Subjects:**

**IND/IDE # (If applicable):**

### CLINICAL RESEARCH BILLING KEY

- **RC:** Routine Care
- **M/IC:** Monitor Complications
- **S:** Study
- **N/A:** Not Applicable

**Comments Box:**

List physical location where procedure will be performed and list any other comments that will assist with the review of your study.

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Cycle</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td><strong>Day/Week/Month</strong></td>
<td><strong>Day/Week/Month</strong></td>
</tr>
<tr>
<td><strong>Office/Inpatient Visits</strong> (Includes: History, Physical Exam, Medical Decision Making)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Laboratory (Labs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Imaging Studies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other Medical Tests</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Surgery/Procedures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medications</strong> (Separate Administration if applicable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Devices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Study Questionnaire**
- **Study specific assessments**
The Challenge…

- Decentralized structure with significant decision making and authority at department level
  - Lack of “standard” work across departments
- Two billing systems (Facility & Professional)
  - Not integrated
  - Separate management — Facility by hospital; Professional by the school
  - Not developed to handle research needs – research is a small percentage of clinical billing transactions
- Billing calendar required but not integrated into standard work stream
  - Manual processes; using email for workflow
  - Work was too late in process – creating re-work & frustration
Research teams spending significant time trying to build a budget
- Calling multiple departments for prices
- Research discounts not always applied correctly
- Not all items/costs associated with a procedure were included
- Study teams developing their own “workarounds”
- Budget shortfalls leading to charges being “written-off” by the institution

Billing calendar, budget, and compliance are all linked

Administrative and regulatory processes for clinical research are complex, lengthy, and burdensome
Who Creates the Budget?

Those who likely need the most help, get the least.
UMHS’s Goal

Accurate billing of items and services for participants in clinical research in accordance with all applicable state and federal laws and regulations (i.e., ensure we are complaint).

To be achieved with:

- mandatory billing calendars,
- an automated charge capture system that adjudicates charges appropriately,
- backend account reconciliation, AND
- the *least administrative burden* to the study team.
Solution – Part II
Additional Objectives

Identify a pricing & budgeting tool that also meets the requirements for an automated billing calendar

- Improve compliance and first-time quality
- Create value for the PI / study team
- Strive to improve clinical research through a systems approach of overall process improvement
- Make it a win-win

“Must Haves”:
- ✔ Pricing
- ✔ Billing Calendar
- ✔ Patient Enrollment

“Nice to Haves”:
- □ Milestones
- □ Invoicing
- □ Data Management

- ✔ Budget
- ✔ Usability
# High-Level Assessment Summary

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Strength</th>
<th>Weakness</th>
</tr>
</thead>
</table>
| 1      | • Clients are peers  
        • Integration experience  
        • U-M already using product  
        • Start-up costs already incurred | • Not user friendly  
        • Poor image at U-M  
        • Cumbersome  
        • Limited financial capabilities today; development required  
        • Not a total solution |
| 2      | • User friendly design  
        • Strong financials  
        • Smart charge master  
        • Base product in limited use at U-M  
        • Positive customer experience, to date | • Clients aren’t peer group  
        • Module doesn’t have broad adoption  
        • Thick-client  
        • Not a total solution |
| 3      | • Base product in use at U-M  
        • Start-up costs already incurred | • So end-user burdensome didn’t assess beyond initial demonstration |
# High-Level Assessment Summary

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Strength</th>
<th>Weakness</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>• User friendly</td>
<td>• No U-M presence</td>
</tr>
<tr>
<td></td>
<td>• Clients are peers</td>
<td>• Expensive</td>
</tr>
<tr>
<td></td>
<td>• Web-based</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Integration experience</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Comprehensive product</td>
<td></td>
</tr>
<tr>
<td>U-M Build</td>
<td>• Build off familiar Excel look and feel</td>
<td>• Requires significant enhancements</td>
</tr>
<tr>
<td></td>
<td>• Completely customizable</td>
<td>• Sacrifice functionality; immature product</td>
</tr>
<tr>
<td></td>
<td>• Less expensive (?)</td>
<td>• Competing priorities for resources</td>
</tr>
<tr>
<td></td>
<td>• Could provide interim solution while waiting for vendors to develop more complete solutions</td>
<td>• Longer time line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not a full solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Adoption challenges</td>
</tr>
</tbody>
</table>
About Vince Jajuga and eThority

- eThority was founded in 1992
- Originally served only higher education/healthcare

Vince Jajuga, VP of Business Development

Vince Jajuga brings over 14 years of experience in using technology to solve organizations’ toughest problems. He earned a Bachelor's Degree in economics and political science from the University of Connecticut.
And now, for something completely different!

The evolution of modern CPR

The Inversion Method

The Trotting Horse Method

The Fumigation Method
New CPR Guidelines for 2008

• Skip breathing  
• Begin compressions immediately

Benefits

• Higher adoptions rates (i.e. more people saving lives)  
• Higher survival rate for patients
1. Low Maintenance Architecture

2. User-Obvious Interface
Wizard-Based Budgeting

Wizards throughout the system help reduce classroom training time, which increases user adoption and retention rates.
User Obvious Design Requirements

Progressive Disclosure

Personalization

Total Revenue: 14,000,250  Total Expenses: 11,235,000  Balance: 2,765,250
## The User Interaction Cycle

<table>
<thead>
<tr>
<th>1. Interest</th>
<th>Traditional U.I.</th>
<th>“User Obvious” U.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="#" alt="User Interaction Cycle" /></td>
<td><img src="#" alt="User Interaction Cycle" /></td>
</tr>
<tr>
<td>2. Adoption</td>
<td><img src="#" alt="User Interaction Cycle" /></td>
<td><img src="#" alt="User Interaction Cycle" /></td>
</tr>
<tr>
<td>3. Retention</td>
<td><img src="#" alt="User Interaction Cycle" /></td>
<td><img src="#" alt="User Interaction Cycle" /></td>
</tr>
</tbody>
</table>
Security

Distributed Security Model

- Reduces I.T. burden of user maintenance
- Quicker deployment and revocation of rights
- Promotes collaboration
- Departmental administrator knows appropriate rights
Benefits of Implementing eThority: U-M Perspective

- Automated budget & billing calendar co-creation
- User-obvious design with easy, built-in wizards
- Strong financial capabilities – transparency of study costs, break-even analysis, milestones, invoicing, etc.
- Searchable pricing from charge master
- Subject enrollment
- PI and institutional report capabilities
- Standardizes work across departments
CDM Item Group Organization

Group related items together to increase accuracy and speed at which a CT budget is built.
### Quick & Standardized Budgeting

**Quick Analysis**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>One Time Income</td>
<td>2,000</td>
</tr>
<tr>
<td>One Time Expense</td>
<td>-3,750</td>
</tr>
<tr>
<td>Salary Burden</td>
<td>-8,383</td>
</tr>
<tr>
<td>Fixed Margin</td>
<td>-10,133</td>
</tr>
<tr>
<td>Per Subject Income</td>
<td>2,500</td>
</tr>
<tr>
<td>Per Subject Expense</td>
<td>-1,740</td>
</tr>
<tr>
<td>Per Subject Margin</td>
<td>760</td>
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<tr>
<td>Estimated Subjects</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total Estimated Subject Margin</strong></td>
<td><strong>6,080</strong></td>
</tr>
<tr>
<td><strong>Trial Margin</strong></td>
<td><strong>-4,053</strong></td>
</tr>
</tbody>
</table>

**Cost Summary**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Per Patient</td>
<td>1,392</td>
</tr>
<tr>
<td>F&amp;A Per Patient</td>
<td>240</td>
</tr>
<tr>
<td>Total Per Patient</td>
<td>1,740</td>
</tr>
<tr>
<td>Direct 1-Time/Start</td>
<td>11,383</td>
</tr>
<tr>
<td>F&amp;A 1-Time/Start</td>
<td>3,001</td>
</tr>
<tr>
<td>Total 1-Time/Start</td>
<td>14,384</td>
</tr>
<tr>
<td>Total Direct</td>
<td>22,519</td>
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<tr>
<td>Total F&amp;A</td>
<td>5,785</td>
</tr>
<tr>
<td><strong>Total for Trial</strong></td>
<td><strong>28,304</strong></td>
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</table>
## Standard of Care / Monitor for Complications

<table>
<thead>
<tr>
<th>Subject</th>
<th>Screening</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>9,890.00</td>
<td>430.00</td>
<td>885.00</td>
<td>3,170.00</td>
<td>885.00</td>
<td>3,370.00</td>
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<tr>
<td>139.00</td>
<td>215.00</td>
<td>275.00</td>
<td>175.00</td>
<td>275.00</td>
<td>275.00</td>
</tr>
<tr>
<td>10,480.00</td>
<td>646.00</td>
<td>1,160.00</td>
<td>3,346.00</td>
<td>1,160.00</td>
<td>3,645.00</td>
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</table>

**Total**

<table>
<thead>
<tr>
<th>Total</th>
<th>Screening</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>80.00</td>
<td>80.00</td>
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<td></td>
<td></td>
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<tr>
<td>1,500.00</td>
<td>250.00</td>
<td>250.00</td>
<td>250.00</td>
<td>250.00</td>
<td>250.00</td>
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<tr>
<td>600.00</td>
<td>100.00</td>
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<tr>
<td>670.00</td>
<td></td>
<td></td>
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<tr>
<td>120.00</td>
<td></td>
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<tr>
<td>450.00</td>
<td></td>
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<tr>
<td>100.00</td>
<td></td>
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<tr>
<td><strong>5,640.00</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5,040.00</td>
<td></td>
<td>2,520.00</td>
<td>2,520.00</td>
<td></td>
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</tr>
<tr>
<td>500.00</td>
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<td>100.00</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>2,520.00</strong></td>
<td></td>
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</tr>
</tbody>
</table>
Break-Even Analysis
Subject Management

Invoices to sponsors are generated automatically once milestones are met.

### Trial
- **Short Name**: Cardio Stent Study III
- **P.I.**: Daniel Hawthorne
- **Coordinator**: Dale Baker
- **Sponsor**: GlaxoSmithKline
- **Protocol Number**: UM12345
- **Project Start**: Jul 01, 2008
- **End**: Jun 30, 2009

### Subject
- **Name**: Neil Y Baker
- **Trial Subject #**: 878698
- **Gender**: Male
- **Birthdate**: 1/22/1944
- **Master ID**: 878698
- **Site**: N/A

### Visits

<table>
<thead>
<tr>
<th>Item / Group</th>
<th>Screening</th>
<th>Implant</th>
<th>Follow-up</th>
<th>Final Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Done</strong></td>
<td><strong>Date</strong></td>
<td><strong>Done</strong></td>
<td><strong>Date</strong></td>
<td><strong>Done</strong></td>
</tr>
<tr>
<td>Blood Pressure and Heart Rate</td>
<td>Aug 25, 2008</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chart Review</td>
<td>Aug 25, 2008</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Echocardiogram</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>History and Physical</strong></td>
<td></td>
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</tr>
<tr>
<td>History and Physical</td>
<td>Aug 25, 2008</td>
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<td></td>
</tr>
<tr>
<td>History and Physical</td>
<td>Aug 25, 2008</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J Hook Catheter</td>
<td>Aug 25, 2008</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Once the trial begins, accurately report on financial activity within any area of the organization by clicking on a node of the Organization Structure.
Enhancement
Additional Steps Taken

- Implemented Lean assessment of CRAO
- Instituted uniform, steeper discounts for clinical research regardless of site of service
- Executed additional policies that clarified UMHS’s business position to facilitate contracting
- Increased standardized education / training
- Integrated CRAO workflow by leveraging systems that study teams were used to (eResearch)
- Built an interim Clinical Research Pricing Tool
Interim – “Homegrown” Pricing Tool

Clinical Research Pricing

WARNING: For Demo Purposes Only - Actual Prices Have Not Been Verified

Charge Type
- Professional Fee Search (CPT)
- Hospital Fee Search (CDM)

Funding Type
- Fed
- Non-Fed

Search
New Search  Repeat Last Search  Search for Matching Professional Fee

Research Discount Price: $552.20

Price List
Add Item to Price List  Clear Price List  Copy Price List

Hospital Fee
Integrated Work Flow: eThority, the Book Ends of the Process

Billing Calendar & Budget Creation → Regulatory Review → Subject Enrollment → Subject Charges Routed in Billing System

*eResearch

Pre-submission → PRC Review (if required) → Ancillary Review* → IRB Review → Regulatory Approval

*Ancillary Review may include:
- Conflict of Interest
- Biomedical Engineering
- Institutional Biosafety
- Calendar Review and Analysis
- Investigational Drug Services
- Tissue Procurement Services
- Radioactive Drug / Radioisotope
Moving in the Right Direction:
Patient Research Complaints 2007-2010

Note: Data prior to 2007 was not regularly tracked for research.
Thank You
and
Questions