Process Mapping

Purpose, Method, Issues & (un)Expected Results

David Dilts PhD, MBA, CMA

Director of Clinical Research, Knight Cancer Institute
Professor, Healthcare Management, Division of Management
Co-director, Center for Management Research in Healthcare
Oregon Health & Science University

dilts@ohsu.edu
Outline

- Why do a process map?
- Why use a flow process map?
- What can be learned from doing a map?
- What are some of the issues that need to be faced?
- Some other fun things that can be done
- Where to start “back home”? 

The need for using data

- **Dealing with the comment:**
  - “I’ve done this job for 20 years, I don’t need more data, I know all the issues.”

- **“Lake Woebeegon” effect**
  - Are you a better-than-average investigator?
  - Are you a better-than-average administrator?
  - How confident are you?

- **Illusion of confidence**
  - Confidence is not related to accuracy
  - But it is correlated because…
  - …the worse your actual performance, the more you feel you are under rated and the more confident you are in your inaccurate opinions
Confidence versus Accuracy

![Graph showing the relationship between confidence and accuracy, with a line labeled Imposter Syndrome and a curve labeled Illusion of Confidence Zone.](Image)
Process Improvement Follows the Scientific Method

The Scientific Method
1. Observe an event.
2. Develop a model (or hypothesis) which makes a prediction.
3. Test the prediction.
4. Observe the result.
5. Revise the hypothesis.
6. Repeat as needed.

Process Improvement Method

- Define the System
- Plan Continuous Improvement
- Try Out Improvement Theory
- Assess Current Situation
- Analyze Causes
- Standardize Improvement
- Study the Results

ACT (5,6)
PLAN (1,2)
STUDY (4)
DO (3)
Fig. 1. Level 0 process flow map for activating a phase III study at ECOG. Days are the median calendar days from receipt to acceptance by the process. Concept development refers to the time the concept was developed by the principal investigator when data was available (n = 5). Brown boxes are joint efforts between ECOG and external governmental agencies. Grant development is necessary only if additional funding was requested from a pharmaceutical firm; regulatory affairs development and FDA are necessary only if ECOG is involved with IND filing process. Although initial FDA review is within 30 to 45 d, studies required multiple loops to attain final FDA approval.
Process Flows for Designing a Phase III Cooperative Group Trial
Process Flows for Opening a Phase III Cooperative Group Trial

50 ft x 5 ft in 8pt font

45 ft x 5 ft in 8pt font

37’1’ x 3’6” ft in 8pt font
Method

Part I: Process Mapping

1. Interviews & data gathering
   - *Say…..*: What participants say is done (i.e., descriptive)
   - *Should*: What policies and procedures say should be done (i.e., normative)
   - *Do……*: What study chart reviews shows was done (i.e., archival)

- Dilts DM et al. (2008) “Accrual to Clinical Trials at Selected Comprehensive Cancer Centers,” *ASCO* (Abstract #6543)
Focusing on “Why?”

- Specifically investigate what *is* done (not what *is thought* to be done) and *why* each action is done

How many “horses” are you holding?
Part I: Process Mapping

1. Interviews & data gathering
   - Say / Should / Do

2. Creation of process map
   - Building a “grid”
     - Rows ("swim lanes") – Key Players & Stakeholders
       - Start with “most” important on top row & “externals” on bottom
     - Columns – general linear flow of process (from left to right because we are Americans)
   - On a big piece of paper, begin laying out the processes by hand
     - Always flowing (as much as possible) in one direction
     - Always do this before computerizing
     - Colors help
High Level Process Map

Swim Lanes

Trial Steps

Open Trial

Set-up Steps
More Serendipity: Development vs. Operational Time by Phase*

Median number of Development and Operational Calendar Days for Clinical Trials Completed from 2000 – 2006* for Phase II and III

* Sample: All ECOG Phase II and III studies activated between 1/2000-7/2006 and closed to accrual (n=52)
Process Flows for Opening a Phase III Cooperative Group Trial
Method

Part I: Process Mapping

1. Interviews & data gathering
   - Say / Should / Do
2. Creation of process map
3. Always vet the map with those who provided data
   - This saves lots of future embarrassment
4. Have a formal presentation to all
   - With action steps for how they will improve the process
   - along the way collect:
     - timing
     - Non-value added steps
     - & outcome metrics
Method

Part I: Process Mapping

Part II: Process Timing
- Identify calendar (& work) time for total process and major steps, and potential influencers of time

Part III: Outcome Data
- Investigate actual accrual results of trials
- Being aware of serendipity
What do you get out of it?

- A great educational tool
  - Some in the process have never seen each other face-to-face
- A visceral image of how bad the process is
  - *Which is why I don’t use sub-charts*
- Count the “non-value added” activities
- Identification of the loops (back-and-forth) in the process
- Identification of participants in the process
- Discovery of throughput issues
  - i.e., where the output is being held up at
- An idea of the impact of delay on results
## Steps for Opening a Phase III Cooperative Group Trial

1. Representative Cooperative Oncology Group and Comprehensive Cancer Center

### Process Steps

<table>
<thead>
<tr>
<th></th>
<th>Cooperative Group</th>
<th>CTEP / CIRB</th>
<th>Cancer Center</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>...Working Steps</td>
<td>&gt;399</td>
<td>&gt;179</td>
<td>&gt;73</td>
<td>&gt;651</td>
</tr>
<tr>
<td>...Decision Points</td>
<td>59</td>
<td>37</td>
<td>22</td>
<td>148</td>
</tr>
<tr>
<td>Potential Loops</td>
<td>26</td>
<td>15</td>
<td>8</td>
<td>49</td>
</tr>
<tr>
<td>No. of Groups Involved</td>
<td>11</td>
<td>14</td>
<td>11</td>
<td>36</td>
</tr>
</tbody>
</table>

1. Representative Cooperative Oncology Group and Comprehensive Cancer Center
2. Process steps reported only show one loop in the process. Actual development frequently includes multiple loops.
Value-Added Statistics

Time for Opening a Phase III Cooperative Group Trial

Median: 784 to 808 days*  
Range: 435-1604 days

Median: 116 to 252 days*  
Range: 21-836 days

Total Median Time from idea to opening~920 days (2.5 years)  
Range: 456 – 2440 days  (1.25 - 6.7 yrs)

* Depending upon site, based on the Phase III trials studied
Tinkering & Looping
Looping

- Why Loop?
  - “Inspect in quality”
    - Implying an unreliable process
  - “Tweaking”
  - Scope Creep
    - When one group or organization expands the scope of its authority or power
- Implicit Theory: more reviews = better study
- Practice: more reviews = slower opening trials, with no evidence of improvement
Look for non-standardized connectors

- Each organization creates their own “standard templates”
- Little or no sharing of templates among groups
- Hence, connectors “don’t fit”
  - Example: Case Report Forms
### Participants in the Process

<table>
<thead>
<tr>
<th>Participant</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td></td>
</tr>
<tr>
<td>Principal investigators</td>
<td></td>
</tr>
<tr>
<td>Sponsor</td>
<td></td>
</tr>
<tr>
<td>Clinical trials office</td>
<td></td>
</tr>
<tr>
<td>Regulatory staff</td>
<td></td>
</tr>
<tr>
<td>Institutional review board</td>
<td></td>
</tr>
<tr>
<td>Scientific review committee</td>
<td></td>
</tr>
<tr>
<td>Contracts and grants office</td>
<td></td>
</tr>
<tr>
<td>Division chair</td>
<td></td>
</tr>
<tr>
<td>Department head</td>
<td></td>
</tr>
<tr>
<td>Core medical team</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
</tr>
<tr>
<td>Clinical research center</td>
<td></td>
</tr>
<tr>
<td>Compliance office</td>
<td></td>
</tr>
<tr>
<td>Director, medical affairs/oncology administration</td>
<td></td>
</tr>
<tr>
<td>US Food and Drug Administration</td>
<td></td>
</tr>
<tr>
<td>Finance department</td>
<td></td>
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<tr>
<td>General hospital review board</td>
<td></td>
</tr>
<tr>
<td>Human subjects radiation committee</td>
<td></td>
</tr>
<tr>
<td>Institutional biosafety committee</td>
<td></td>
</tr>
<tr>
<td>Legal department</td>
<td></td>
</tr>
<tr>
<td>Medical ethics board</td>
<td></td>
</tr>
<tr>
<td>Office of sponsored research</td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td></td>
</tr>
<tr>
<td>Radioactive drug research committee</td>
<td></td>
</tr>
<tr>
<td>Site coordinator</td>
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</table>

Who is at “Fault”?
Calendar Days of Reviews and Group response by review type* for Phase III Cooperative Group Studies (n=28 studies) activated from 2000 - 2005

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Group Response</th>
<th>Time</th>
<th>CTEP/CIRB Review</th>
<th>Time</th>
<th>Time Difference</th>
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<tbody>
<tr>
<td>Concept</td>
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<tr>
<td>CRM</td>
<td></td>
<td></td>
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<tr>
<td>CTEP</td>
<td>14</td>
<td>60.0</td>
<td>15</td>
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<td>71.5</td>
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<td>CEP</td>
<td>4</td>
<td>48.0</td>
<td>19</td>
<td>66</td>
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<tr>
<td>CTEP</td>
<td>3</td>
<td>6.0</td>
<td>1</td>
<td>6</td>
<td>17.0</td>
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<td>Industry **</td>
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<td></td>
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<td>Industry</td>
<td>14</td>
<td>32.5</td>
<td>1</td>
<td>168</td>
<td></td>
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<td>Protocol</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>CTEP</td>
<td>33</td>
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<td>5</td>
<td>69</td>
<td>32.0</td>
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<td>7.5</td>
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<td>84</td>
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<td>CIRB</td>
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<tr>
<td>CIRB</td>
<td></td>
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<td></td>
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<tr>
<td>CIRB</td>
<td>43</td>
<td>29.0</td>
<td>5</td>
<td>55</td>
<td>21.0</td>
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<tr>
<td>Re-review after CIRB</td>
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<tr>
<td>CTEP</td>
<td>19</td>
<td>12.0</td>
<td>1</td>
<td>32</td>
<td>17.0</td>
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<td>Amendment ***</td>
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<tr>
<td>CTEP</td>
<td>2</td>
<td>9.0</td>
<td>1</td>
<td>17</td>
<td>5.5</td>
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<td>2</td>
<td>34</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTEP</td>
<td>1</td>
<td>1.0</td>
<td>1</td>
<td>1</td>
<td>22.0</td>
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</tbody>
</table>

* Reviews listed are only partial list of required reviews. Other reviews including RAB, PMB, and CTSU are required but were not available at the time of data collection.

** Group response time to industry cooperation not available

*** Recorded time for amendments only include study amendments prior to study activation
Does time matter?

A bit of Serendipity

**Phase III ECOG Studies Closed to Accrual (n=15*): Ratio of Actual Accruals vs. Expected Accrual**

- **All phase III studies activated and closed to accrual between 1/2000 – 7/2006**
- **Color Code:**
  - red: studies taking greater than the median time to open
  - blue: studies taking less than the median time to open
  - gray: studies closed due to reasons other than poor accrual
Accruals Per Trial

Comprehensive Cancer Centers (CCC)

Primary endpoint: Accruals per trial

<table>
<thead>
<tr>
<th>Accrual Per Trial</th>
<th>CCC 1</th>
<th>CCC 2</th>
<th>CCC 3</th>
<th>CCC 4</th>
<th>CCC 5</th>
<th>CCC 6</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>148</td>
<td>323</td>
<td>104</td>
<td>323</td>
<td>393</td>
<td>496</td>
<td>1,787</td>
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<tr>
<td>0</td>
<td>20.9%</td>
<td>26.9%</td>
<td>26.9%</td>
<td>34.4%</td>
<td>22.1%</td>
<td>35.1%</td>
<td><strong>29.0%</strong></td>
</tr>
<tr>
<td>1 to 4</td>
<td>32.4%</td>
<td>31.0%</td>
<td>26.9%</td>
<td>31.3%</td>
<td>29.8%</td>
<td>38.1%</td>
<td>32.6%</td>
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<tr>
<td>5 or more</td>
<td>46.6%</td>
<td>42.1%</td>
<td>46.2%</td>
<td>34.4%</td>
<td>48.1%</td>
<td>26.8%</td>
<td>38.4%</td>
</tr>
</tbody>
</table>

1Excludes pediatric studies Therapeutic Studies Only

2Over 500 of nearly 1800 trials result in zero accruals
National Cancer Clinical Trials Cooperative Groups Announce Mergers

In separate announcements, several NCI-supported national cancer clinical trials cooperative groups declared their plans to merge. On March 7, the Radiation Therapy Oncology Group (RTOG) and National Surgical Adjuvant Breast and Bowel Project (NSABP) announced their plans to consolidate operations. Two days later, a merger was announced by the American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), and North Central Cancer Treatment Group (NCCTG).

Most recently, on March 18, the Eastern Cooperative Oncology Group (ECOG) and the American College of Radiology Imaging Network (ACRIN) said they will merge clinical cancer research programs.

The cooperative groups, which conduct clinical trials primarily in adult patients, are merging in response to the Institute of Medicine’s April 2010 report calling for restructuring and consolidation of NCI’s Clinical Trials Cooperative Group Program and NCI’s subsequent announcement of its plan to consolidate the program to a maximum of four adult groups (down from nine current groups) and one pediatric group.

The cooperative groups involved in the mergers indicated that they have already begun discussing the transition to consolidate their current operations. In fact, ACOSOG, CALGB, and NCCTG integrated their statistical, data management, and information technology platforms in June 2010.
Now that you have the map?

- Other fun stuff to do:
  - Hand simulations (for education)
  - Computer simulation
What happens if we double a cooperative group’s budget?

Answer: nearly nothing

...But they wouldn’t turn the money down
High Level Process Flow for Phase III Studies

Clinical Trial Idea Creation → Concept Development → CTEP Concept Review Meeting → Protocol Development → CTEP Protocol Review Committee → CIRB Activation

CTEP / CIRB Rereview

Cooperative Group Response
Simulation Results of Working Together

<table>
<thead>
<tr>
<th>Description</th>
<th>Current Simulation</th>
<th>Cooperative Group Improvement</th>
<th>CTEP Improvements</th>
<th>CTEP and Cooperative Group Improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>As-Is performance</td>
<td>Improved Selective Study Criteria</td>
<td>Improved Review Performance</td>
<td>Simultaneous Improvements</td>
</tr>
<tr>
<td>n*</td>
<td>99</td>
<td>100</td>
<td>100</td>
<td>121</td>
</tr>
<tr>
<td>mean</td>
<td>837.29</td>
<td>791.51</td>
<td>653.01</td>
<td>252.78</td>
</tr>
<tr>
<td>min</td>
<td>222</td>
<td>209.07</td>
<td>214.93</td>
<td>214.35</td>
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<tr>
<td>max</td>
<td>3857.89</td>
<td>3576.71</td>
<td>4292.98</td>
<td>311.96</td>
</tr>
<tr>
<td>st. dev/ st. err</td>
<td>760.75</td>
<td>729.3</td>
<td>670.63</td>
<td>24.14</td>
</tr>
</tbody>
</table>

* Simulation period defined over a period of 5 years (1825 Calendar Days)
* Note: Axes on the Timing Distribution Graphs are different
CRM Process Excellence Group (CPEG)
Vision

The **vision** for the Clinical Research Management Process Excellence Group (CPEG) is to identify, evaluate, modify, and improve clinical research management activities at CTSAms by using process engineering strategies, value driven systems management, and a **nationwide approach to implement process systems** that are measurably improved.
CRM Process Excellence Group (CPEG) Mission

The **mission** of CPEG is to generate measurable, transferable process systems improvements in clinical research management.

This is a **consortium-wide initiative** that must be **demonstrable with meaningful metrics**
CRM Process Excellence Group (CPEG) Subgroup Objectives

Sub-Groups

- Educational Sub-Group
  "Learners"

- Common Problem Solving Sub-Group
  "Practitioners"

- Communication Sub-Group
  "Communicators"

Objective

- Train members of the CTSA community to become facile in the use of tools and techniques of process improvement and systems thinking

- Assist institutions at academic health centers that have embarked on process improvement by sharing lessons learned and characterizing barriers to improvement, and, in accord developing and testing potential solutions

- Develop effective strategies for dissemination and understanding the science of process improvement, focusing on its role in the efficient conduct of clinical research, and its value as a discipline
Participation in CPEG – Join a Subgroup

To participate, please select one or more of the subgroups.

Please email your selections to: 
[ctsa_researchmanagement@ctsaweb.org](mailto:ctsa_researchmanagement@ctsaweb.org)

Submit selections by 10/03/2011
Remember: *Efficiency* is only one of many metrics

AMA: Nearly one in five medical claims processed inaccurately

By Bruce Japsen

Tribune staff reporter

9:00 AM CDT, June 20, 2011

Health insurance companies are inaccurately processing nearly one in five medical claims, slowing payments to doctors and adding bureaucratic headaches to patients, the American Medical Association said this morning.

In its annual report card on the health insurance industry, released during the group's annual House of Delegates meeting here, the AMA said commercial health insurance companies have an error rate of 19.3 percent, a two percentage increase from last year's report.
Where to start when you go back home

- Select a team from multiple areas
- Pick a “typical” trial to follow
  - Yes, I know there is no such thing but pick either one that

Remember: it is no one’s fault, but it is everyone’s system

- Ask “Why” a lot
  - Remember the horses
- Roughly sketch out the process
  - While documenting “discoveries”
  - Example: Pharmacy manual
- Gather data, lots & lots of data