How do we make decisions about implementation of new clinical research IT applications?

Daniel Ford, MD, MPH

Vice Dean for Clinical Investigation

Johns Hopkins School of Medicine

Current Environment

- IT infrastructure has increased dramatically in last ten years
  - Move to EHRs nearly complete in large academic centers
  - CTMS applications common but with substantial variation in how they are used
  - Clinical providers are used to working in EHR environment and expect all patient related communication to occur through this portal
  - Some research teams still minimal experience working in EHR environment
  - Health system IT programs have become large and developed own structure for setting priorities and implementing changes

Current Environment

- Clinical research is more likely to be multicenter and sponsored by commercial organizations
- Clinical research teams feeling pressured to complete studies with fewer resources
- Complexity of clinical research environment has increased

Clinical IT

- Considered major source of dissatisfaction by providers
- Probably has improved safety of health care
- Very hard to show any gains in productivity or efficiency

Decision making process

Cost-effectiveness =

$$\frac{\text{Costs(new)} - \text{Costs(old)}}{\text{Effectiveness(new)-Effectiveness(old)}}$$

Effectiveness

- Extent to which the service provided meets the objectives and/or expectation of the organization and/or customer

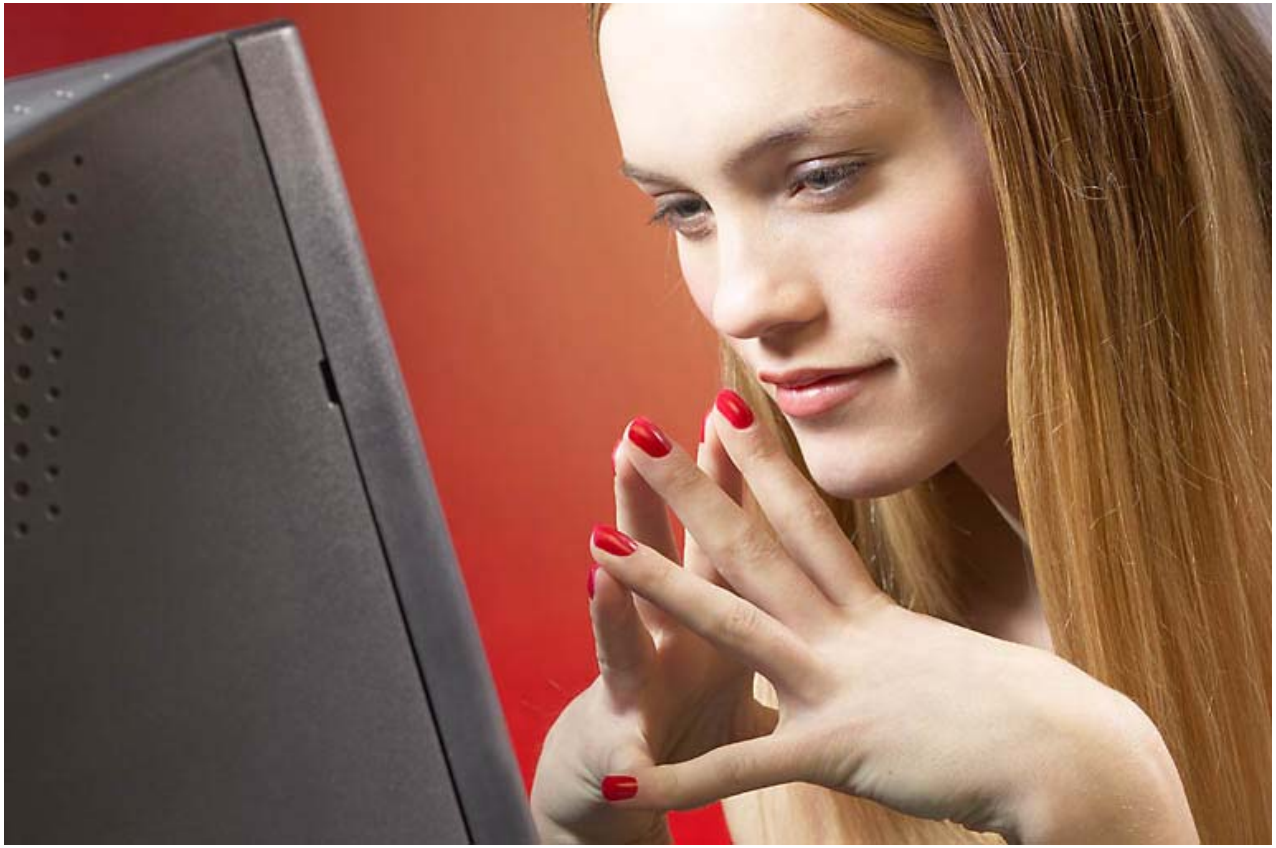
Efficiency

- Measuring inputs and outputs

- How does an organization use its resources, such as IT support and staff, to achieve organizational objectives?
  - Per unit cost – unit of research produced per resources consumed
  - Cycle time – how quick is a process performed
  - Per unit FTE – unit of research per number of FTE

Understanding our stakeholders

- Patients/research participants
- Research Team – PI, res. coord, investigational pharmacist, etc
- Clinicians
- Health system
- Regulators
- Research sponsors
- IT community



How can we make better decisions about implementing new research IT platforms?

- Specify the problem we are trying to solve
- Systematically identify stakeholders and work more closely with them
- Clarify the current process before proposing changes
- Identify the expected benefits
  - Increased patient safety – “investigational drug delivery”
  - Less time for research team – “does not have to call every provider”
  - Lower costs for research due to increased efficiency
  - More efficient recruitment – “more research participants and cost of recruitment per participant goes down”
  - Access to data in the future for secondary data analysis

How can we make better decisions about implementing new research IT platforms?

- Complete a stakeholder costs/benefits analysis
  - Make certain no one is being asked to sacrifice too much without benefits
- Specify time frames and measure outcomes
- ?Pilot new programs
- Communicate rationale and results for implementing new research IT programs to stakeholders

Current Problems

- Clinicians need immediate access to investigational drug information when caring for a patient in a research study

Summary

- Start the process now for better decision making about use of resources to support clinical research IT
- Begin to measure research productivity before others do
- Work with safety experts to incorporate research programs into their assessments