Pathologists and Prospective Specimen Collection for Research

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The Promise of the Future

Appropriate specimens from properly consented patients will provide the substrate to answer important scientific questions and provide data for future reflection and study.
The Reality of the Present

- No standardized methods of prospective collection
- Research underway but not complete to understand important collection variables
- Pathology staffing inadequate for tissue collection
- No funding for collection efforts
- No standardized data base for collection parameters
Early Efforts Failed

- At least two efforts to provide commercial infrastructure for tissue collection failed
- Pharma and Dx company initiatives are scattered and fragmented
- Local institutional and research efforts survive at the will of small group of investigators
Operational Challenges

- Patient Protection
- Sample Quality
- Clinical Data Quality
- IT/Bioinformatics
- Logistics
Patient Protection

- Legal & ethical requirements
- IRB process
- Consent process
- Permission process and monitoring
- HIPAA compliance
- De-identification of data
- Data and sample security and confidentiality
- Stewardship of samples and data
Sample Quality

- Operational standardized process
- Equipment validation and monitoring
- Process and timing validation
- Pathologic verification of sample quality
- Sample Storage and Shipping
Clinical Data Quality

- Standardized data collection format
- Standard process of data collection
- Validation of process
- Monitoring of data quality
IT/Bioinformatics

- Data capture
- Data integrity
- Data standardization
- Data transmission
- Query processes
- Query security
- Data transmission
Logistics

- Personnel recruitment, training and competency assessment
- Supplies
- Bar coding
- Shipping
- Storage
- Infrastructure
- Inventory Control
Pathologist Role

Pathologists and laboratory staff in large facilities are well trained to handle all aspects of this process

- Many team activities in laboratories
- Must adhere to patient protection issues in clinical work
- Understand constraints of data and specimen quality
- Deal daily with IT bioinformatics challenges
- Commonly deal with similar logistics
Why are Pathologists Considered Peripheral?

- Not seen as team players with researchers
- Often naturally reticent
- Inadequate staffing....No time!
- Inadequate funding....No money!
- Process is designed without their input making it seem impractical to them
Key Leverage Points

- Standardized protocols
- Standardized IT/bioinformatics
- Standardized principles
- Practical local implementation
- Funding opportunities
- Rewards for collaboration
- Peer pressure
Recommendations of NQF*

Design work so that it is easy to do it right and hard to do it wrong

*The National Forum For Health Care Quality Measurement And Reporting*
Designed Standardization

- Uniform, simple protocols based on principles that are scientifically sound
  - Consent
  - Consent tracking
  - Tissue acquisition standards
- Job aids to make process understandable
  - Videos
  - Posters
  - Kits
  - Standardized downloadable forms
Designed IT/Bioinformatics

- Easily implemented standards
- Web based deployment
- Uniform data field requirements
- Standardized bar coding and tracking software
- National standards, with flexible local deployment options
Local Flexible Deployment Options

- More than one way to follow a principle
- Must provide standard training in principles
- Allows for personal imprinting of process
- Provides opportunity for improvement and learning
Funding Options

• **CMS codes for properly obtaining specimens**
  • Professional and technical components

• **Institutional incentives**
  • RFA’s to act as local training sites
  • RFA’s for developing processes, personnel curricula, IT solutions
Rewards for Collaboration

- Requirement to have dedicated pathology resource at each site
- Pathologist involvement in study design, analysis and publication
- Enhanced status of site if team involved in process
Peer Pressure

- Recognition by NCI of sites/grants/programs which comply with standards
  - “Good housekeeping seal of approval”
- Recognition of standards by pathologists organizations like CAP
- Inspection, competency assessment and proficiency testing program with publication of results
Summary

- Research is proceeding to develop principles of sample collection to enhance quality'
- Pathologist and lab staff are key players in process
- Careful design of all elements of process are needed before deployment to enhance acceptance.
- Incentives will be needed to assure success.