Clinical Research in a Community Hospital Setting

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Presentation Topics

- Benefits and risks of nurturing a research program in a community hospital.
- What makes a community hospital unique vis-à-vis an academic environment?
- Assessing how much and what kind of clinical research is going on.
- Optimal infrastructure.
- Human research protections programs.
- Research privileges for physicians conducting research in a community hospital.
- Research patient billing issues.
- Research compliance programs to fit needs of a community hospital.
Benefits, Risks & Opportunities

### Participation in Clinical Research
#### Motivations and Benefits

- **Clinician / Scientist recruitment** – attracting high quality caregivers.
- **Participation in the advancement of science and enhancement of a clinician’s understanding, diagnosis, treatment, and prevention of disease.**
- **Clinical trials give patients access to new medications and keep doctors attuned to the latest research and therapeutics.**
- **Generate additional revenue.**
  - Attracts new patients – even patients who may not ultimately enroll may choose to continue their care at the hospital
  - Diversity revenue streams
  - Becoming a so-called “Center of Excellence”
- **Advancement of a hospital or a system’s mission.**
- **Marketing and enhancement of reputation, brand, perception – positive buzz and publicity.**
- **Opportunities for clinicians to publish findings and advance their professional profile within meaningful professional organizations.**
Participation in Clinical Research
Challenges and Risks

There has been a decline in the # of FDA-regulated investigators. 5.2% dip during period 2004-2007 and continued trends are expected.

- Costs of developing infrastructure (admin staff, IRB, labs, systems, etc).
- Patient recruitment and retention can be challenging.
- Investigators compensation models often do not allow for significant time to be invested in research pursuits.
- Financial compensation (funding) may be too low.
  - Requires hospitals and investigators to be budget savvy—to understand the full costs of conducting research and demand adequate compensation.
- Compliance expectations on organizations supporting human subjects research are considerable (e.g., operational, regulatory, market, reputational risk).
- Geography issues if a community health system is spread over wide geographic areas with several outpatient facilities; can create challenges for billing and other operations.

Complex regulations make clinical trials difficult to manage and oversee.
- Direct: OHRP, FDA, OHRP
- Tangential: HIPAA, Radiation Safety, Poison Prevention & Packaging, Medicare billing
- Conflict of Interest (“COI”): Balancing needs of patient with desire to spur enrollment in studies.
- Many physicians don’t know or fully understand the governing laws and regulations.
  - FDA, OHRP, etc.
  - Research patient billing risks
  - Potential False Claims Act violations (billing compliance)
  - Liability concerns
    - Related to concern over medical malpractice
    - Importance of indemnification in contract negotiation
    - Ethics
    - Stark/Anti-kickback
  - Financial disclosure may deter participation by physicians
    - Physician Payments Sunshine provision embedded within PPACA
- Potential concerns within the community about engaging in sensitive research (i.e., stem cells, animal research, etc.).
Clinical Research Opportunities

Many patients at university hospitals have multiple medical problems that can complicate results, or have to be recruited with the promise of payment to participate in a study.

Community hospitals, on the other hand, have a constant supply of patients who usually represent a good sampling of the general population.

To serve these patients, several resources exist:

- **Pharmaceutical Industry-Sponsored Clinical Trials**
  - Bio-tech organizations are always looking for sites to test new medications, or new indications for pre-approved medications. Many are ready made and fully funded.

- **Health services (i.e., outcomes and quality) research**
  - Hospitals performance data can be used to develop and measure the effectiveness of new interventions or procedures including a clinicians program

- **Self-funded research**

- **Foundation-funded research**

Clinical Research Opportunities

- **Academic-Community partnerships**
  - The Morehouse School of Medicine Community Physicians’ Network (CPN).

- **Federally-Sponsored Clinical Trials and Cooperative Groups**
  - The National Cancer Institute’s (NCI) Community Clinical Oncology Program (CCOP) and Minority-Based-CCOP (MB-CCOP).
  - NCI Cancer Trials Support Unit (CTSU) is a national networking program sponsored by the NCI that supports the involvement of community physicians in NCI-sponsored Phase III cancer treatment trials.
    - ACOSOG: American College of Surgeons Oncology Group
    - CALGB: Cancer and Leukemia Group B
    - ECOG: Eastern Cooperative Oncology Group
    - GOG: Gynecologic Oncology Group
    - SWOG: Southwest Oncology Group

The CCOP network allows potential investigators to participate in variety of studies, including Phase I, II, and III trials. Potential organizational participants in the CCOPs must have a proven track record of accrual to NCI-sponsored treatment and prevention and control clinical trials.
Community Hospital Research
vs.
AMC-based Research

Understanding the Differences
Academic Model vs. Community Model

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<tr>
<th>Academic Medical Centers &amp; Universities</th>
<th>Community Hospitals:</th>
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<tr>
<td>• Focus on bench, basic and animal research</td>
<td>• Greater focus on clinical research</td>
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<td>• Investigators hired and protected time granted for faculty to engage in research</td>
<td>• Open medical staff vs. Closed med staff</td>
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<td>• Research part of the mission</td>
<td>• Few community health systems have protected time for clinicians to pursue research opportunities</td>
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<td>• Pre-award and post-award administrative infrastructure in place</td>
<td>• Organizational culture does not view research as a priority</td>
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<td>• Executive-level leadership for research enterprise</td>
<td>• Limited administrative infrastructure</td>
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<td>• Sophisticated research accounting systems</td>
<td>• Leadership for research programs are at the PI or the departmental level</td>
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<td>• Prevalence of federally sponsored research</td>
<td>• Focus is on CCOPs and industry sponsored research</td>
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<td>• Publication of findings is expected</td>
<td>• Less sophisticated approach to establishing the optimal portfolio of research to match strategic objectives</td>
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Quantifying Current Research Activity

Assessment of Current State
How Much and What Kind of Clinical Research is Going on in Your Hospital?

- Many community hospitals are hosts to research without knowing it.
- Physicians may be signing Clinical Trial Agreements without hospital’s involvement with the intention of performing most services in their private practice office.
- Once services associated with a clinical trial necessitate use of hospital resources (i.e., nurses, equipment, space), the hospital must be involved.
  - Even if only Standard of Care services are involved in the trial’s tests and procedures, there are responsibilities that need to be met.
- Many organizations have developed policies that dictate the importance and requirements for clinicians to engage the hospital when/if its facilities may become necessary to execute the provisions of a clinical research protocol.
  - Research feasibility.
  - Credentialing issues.
  - Copy of IRB approval letter.
  - Identification of each research participant.
  - Contract that details payment for non-Standard of Care items and services.
  - Documentation that Medicare intermediary has provided approval, as necessary.
Assessment of Current State
How Much and What Kind of Clinical Research is Going on in Your Hospital?

• **Assessment of the current state is crucial.** The follow steps may help determine what is going on:
  1. Interview departmental administrative leads and ask for any research-related records.
  2. Interview nurses, pharmacy, and lab leads to determine if any clinician has requested research-related services or special billing procedures.
  3. Identify who has signed your institution’s Federalwide Assurance.
  4. Review COI disclosures to identify instances where a disclosure was made for the purposes of a research study.
  5. Review policy manual to check for the presence of research-related policies.
  6. Catalog all research that has been submitted to the IRB, identify PIs, notation of IRB expiration dates.
  7. Need for a signed informed consent document in the medical record.
  8. Circulate an email or make an announcement (perhaps during Grand Rounds) that requests that clinicians disclose any current research activity.
  9. Post reminders of the importance of ensuring IRB review for any research that will necessitate the use of hospital resources.

• **Additional steps:**
  10. Determine if Patient Access or Patient Accounts has been asked to develop special procedures for handling research participants.
  11. Talk to Payroll and determine if any nurses or other professional staff are having a portion of their salaries “soft” funded.
  12. Check clinicaltrials.gov and grants.gov to determine if your site has been listed as a research site for any active studies.
  13. Review internal audit and/or compliance records to determine if any recent audits or monitoring activities have focused on research activity.
  14. Contact the National Cancer Institute to determine if a CCOP application exists that involves your facility.
  15. Review the list of active accounts (or cost centers) to determine if any appear to be in place to help manage research funds.
Optimal Infrastructure and Staffing

Optimal Infrastructure for Community Hospitals
Support Services Need to Help Entice Clinicians to Engage in Research

- For employed physicians, absence of “protected time for research” implies that community hospital physicians must fulfill administrative responsibilities associated with research on their own time.
- Infrastructure needed in order to provide sufficient support so that PIs can limit the amount of time they are spending on non-clinical pursuits.
- Centralization works best for several reasons:
  - Helps better define accountability and where to go to understand expectations and policies.
  - Limits fragmented work flow.
  - Accounting and cost center management is simplified when all debits and credits to study accounts occur under the oversight of a single person or office.
  - Development of infrastructure should be inclusive of other key administrative personnel:
    - Compliance
    - General Counsel
    - Internal Audit
    - Patient Accounts
    - Patient Access
    - Medical Staff Affairs
    - Finance
    - Education
    - Information Technology
- Centralization can create significant political issues should private practice-based PIs feel that they are losing control without any perceived corresponding benefit.
Optimal Infrastructure for Community Hospitals
Support Services Need to Help Entice Clinicians to Engage in Research

- Many community hospitals establish a “pool” of clinical research coordinators who provide day-to-day study support services to PIs.
  - More formal training.
  - Common set of templates and forms.
  - Broader understanding of policies.
  - Limits multiple customized approaches to study management.
  - Gives hospital management greater control and oversight of research accounting.

- Research Advisory Council or Boards can provide useful oversight.
  - Approve and review research policies and research code of conduct.
  - Advise research leadership.
  - Provides forum for physicians and administrators to collaborate on research issues of hospital.

- Formalizing a vetting process prior to research initiation is best practice.
  - Reduces the number of studies that are opened without careful planning or forethought.
  - Requires a review of the operational and financial impact of a study prior opening.
  - Ensures that studies meet general criteria – mission, vision, adherence to strategic plan.

Importance of Human Research Protection Programs
Human Research Protection Program  
Community Hospital Need to Understand Regs and Expectations

A formal program is more common in places with larger research portfolios but best practices suggests that an HRPP is key to effective oversight of research and enforcement of standards.

**Infrastructure**
- Size of the HRPP should appropriate for the amount of human subjects research.
  - Trainings and certifications (both initial and ongoing) for IRB members, IRB staff and research staff.
  - Accessible tools and templates.

**Integration and Independence**
- Identification of an Institutional Official with enough influence within the organization and first hand understanding of the research infrastructure.
- Defined relationships between the IRB and other key research-focused committees (e.g., privacy board, departmental committees, COI committee, compliance, finance).
- Audit and monitoring functions.

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**Major Training/Certifications in Clinical Research**

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<tr>
<th>Role</th>
<th>Certification</th>
<th>Certifying body</th>
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<tr>
<td>IRB Member, Manager</td>
<td>Certified IRB Professional (CIP)</td>
<td>Council for Certification of IRB Professionals (CCIP).</td>
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<tr>
<td>Physician Investigator</td>
<td>Certified Physician Investigator (CPI)¹</td>
<td>Academy of Pharmaceutical Physicians &amp; Investigators (APPI)</td>
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<tr>
<td>Clinical Research Coordinator</td>
<td>Certified Clinical Research Coordinator (CCRC)¹,²</td>
<td>Association of Clinical Research Professionals (ACRP)</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Regulatory Affairs Certification (RAC)</td>
<td>Regulatory Affairs Professionals Society (RAPS)</td>
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¹: Independent study shows sites with both CPI and CCRC certified research staff yield fewer protocol deviations than those with only one or without. (Haeusler, J. A retrospective analysis of protocol adherence in four multicenter trials in the USA. Clinical Research and Regulatory Affairs, 2009; 26(1-2):20-23.)
Human Research Protection Program

Other Considerations

Policy and Procedures

- Validate whether or not your institutions wants to “check the box”. Impacts how much regulation an institution is beholden.
  - Attestation made to the government that they will comply with Common Rule at 45 CFR, Part 46.
  - Voluntary application of those federal standards that they will voluntarily apply those federal standards to non-PHS-funded research.

- Items to address as P&Ps are drafted.
  - Federal laws/regulations.
  - Local laws/regs/policies particularly for research with children and infectious disease.
  - Day-to-day activities related to the submission, review, and conduct of research.
  - Define at what point does the institution become “engaged” in research.

Risks of Inaction

- Failure to ensure the safety, well-being, and rights of human research participants.
- Violation of HRP Laws/Regs can result in corrective action or suspension of research and potential tort liabilities at the entire institution.
- Violation of contacts between internal and external IRBs (failure to meet obligations) may result in civil or criminal actions.

Human Research Protection Program

Conflict of Interest Issues Can be Significant in a Community Hospital

The majority of sponsored clinical research is performed in community hospitals and ordinary clinics, not academic medical centers.

- AMCs generally have far more developed conflict of interest management infrastructures than community hospitals. Why?
  - Government’s regulatory enforcement (e.g., NIH and Senator Grassley’s investigative focus).
  - Guidance and support from AAMC and AAU.
  - Publications such as the IOM report seems far more focused on AMCs and when addressing a clinical sphere - practicing physicians. Guidance is not as abundant for community hospitals.

- More likely that private practice physicians may have special agreements, or businesses on the side, developing devices, etc. This adds to the challenge and makes COI in research a very important concern for community hospitals.

- The structure to address conflicts of interest – i.e. a Standing COI Committee (common in an AMC) – is largely absent in community hospital settings.
  - In some instances, hospitals provide no (or limited) direct monitoring of PI’s financial relationships.
  - Increasingly, IRBs (internal and external) play a role in inquiring as to financial relationships.
  - Compliance offices may also function in this capacity.
Human Research Protection Program
COI Risks at Community Hospitals

• Physician-Institution relationships are another critical difference between AMC’s and community hospitals and often significantly impair the latter’s ability to manage conflicts of interest.
  – While some community hospitals employ physicians (more common in AMCs), many physicians have medical privileges but are independent and not hospital employees.
  – Consequently, many are resistant to the hospital’s inquiries into their financial affairs - making review by IRBs and Compliance Officers of physician payments more difficult.

• Incentives for community hospitals to monitor conflicts of interest:
  – Failure to be adequately compensated for research conducted on their premises (e.g., forfeiture/loss of revenue for services, items and provision of care otherwise recoverable via clinical research billing).
  – Damage to reputation from negative publicity and fallout from ‘tainted’ research or the occurrence of serious adverse events.

Collaboration with the Medical Staff
Office to Establish Research Privileges
Privileging Philosophy/Clinical Investigator Practice Area

- What’s Your Credentialing/Privileging Philosophy?
  - Research is an “Automatic Right” to be Taken Away Vs.
  - Research is an “Additional Privilege to be Earned”
- Does this translate to what you do in other privileging areas?
- Separate category for privileging a Clinical Investigator
  - Endorsed by HCPro White Paper
    - Created “Practice Area 415” for “Clinical Investigator”
  - FDA/OHRP Background Check
    - FDA Debarment/Disqualified/Assurance/Restriction Lists
    - FDA Warning Letter Search
    - FDA Clinical Investigator Inspection List
    - OHRP Determination Letters
  - Voluntary Certification (i.e. CPI) or working towards it

Working with the Medical Staff
Establishing Research Privileges

Community hospitals must ensure that individuals conducting research are trained, credentialed, and aware of contractual, legal and regulatory obligations. They must understand the hospital’s policies and procedures that apply to the conduct of research on their premises or using their resources.

Sample approach taken by some community hospitals and community health systems:
- Privileges given by tier/level for PI and also each member of the research team.
- Each tier should have implications for an individual PI’s ability to receive financial remuneration, incentives, or research-related pay.
- The “higher” the level, the more financial awards that a PI may be eligible to receive BUT they must also fulfill escalating training requirements.
  - **Tier One:** Clinicians and staff who do retrospective chart reviews, anonymous survey research and minimal risk research not conducted on human research participants.
  - **Tier Two:** PIs and research personnel who act in a sub-investigator capacity and who have contact with patients.
  - **Tier Three:** Research personnel who function as PIs on sponsored, funded or unfunded research.
  - **Tier Four:** PIs who hold their own INDs and/or who act as a “sponsor” in connection with studies.
Addressing Research Patient Billing
Risks in a Community Hospital

Research Patient Billing
Complicated Process and Lack of Ownership Create Mess for Comm. Hospitals

Medicare “double billing” has been the subject of numerous OIG/DOJ investigations and settlements. To avoid running afoul of the regs, community hospitals must work to track clinical/standard of care vs. “research only”.

Risk Areas
• Highly manual processes
• Absence of suitable IT systems
• Multiple competing interests and agendas
• Roles and responsibilities are often unclear
• Research contracts / CTAs that clearly state which patient care costs are covered
• Ineffective or insufficient training
• Insufficient effort expended early on to plan for potentially challenging billing issues
• Absence of effective vetting to ferret out research that doesn’t meet established standards – mission, financial, operational

Many community hospitals have not made sufficient investments to manage this implicitly risky process. Oversight, tools, and dedicated personnel at each step in the research patient billing process continuum are essential.
The Role of Compliance in Research

Research Compliance in a Community Hospital
Luxury or Requirement?

• The compliance function in most community hospitals is focused on revenue cycle concerns and other operational issues.
• A growing research program presents many potential compliance issues that should be addressed by management.
• Core measure reporting will become an increasingly high profile concern.
• For many, a compliance officer dedicated to research is vital to preserving organizational integrity.
  – Leadership and guidance for the various constituents and stakeholders with a role in preserving institutional integrity and compliance.
  – Need for experts who understand that health care research is fundamentally different from other operational activities of a health care organization.
  – Activities “look” the same as other key practices and processes, but the nuance and dynamics are often mistaken or incorrectly applied.
Research Compliance in a Community Hospital
Complexities that May Necessitate Compliance Oversight of Research

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<tr>
<th>Primary Risk Areas</th>
<th>Constituents with Sometimes Disparate Priorities</th>
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<tr>
<td>• Faculty start-ups</td>
<td>• Principal investigators (“PIs”)</td>
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<td>• COI / Stark / Anti-kickback</td>
<td>• Research support (research asst., CRCs, RRNs, etc.)</td>
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<tr>
<td>• Equity interests of institution</td>
<td>• Students</td>
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<tr>
<td>• International collaboration</td>
<td>• Board members</td>
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<tr>
<td>• Sub-recipient monitoring</td>
<td>• Federal agencies</td>
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<td>• Human subjects protections</td>
<td>• Commercial sponsors</td>
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<tr>
<td>• Researcher misconduct</td>
<td>• Suppliers and procurement specialists</td>
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<tr>
<td>• Cost accounting standards</td>
<td>• Foundations</td>
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<tr>
<td>• Technology transfer</td>
<td>• Donors and investors</td>
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<tr>
<td>• Clinical trials billing</td>
<td>• Human subjects</td>
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<tr>
<td>• Stem cells; scientific controversy</td>
<td>• Advocacy groups</td>
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<tr>
<td>• Fair Market Value</td>
<td>• Institutional, Departmental, and Divisional administrators</td>
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<td>• HIPAA / Privacy</td>
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<td>• Investigator Salary and Effort</td>
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Research Compliance in a Community Hospital
Additional Rationale for a Research Compliance Program

- There are multiple financial, operational compliance challenges that underscore the need for research expertise among compliance professionals.
  - Informed consent.
  - Medicare as a secondary payer.
  - Researcher misconduct and COI in research.
  - Financial research administration, grants accounting, award monitoring.
  - Credentialing of research coordinators who perform tests, do basic clinical diagnostic procedures, access secure floors or review the eHR.
  - Budgeting and contracting for services associated with clinical trials.
  - Fair Market Value for physician services rendered in connection with clinical trials.

Community hospitals that are “performance sites” for health care research need a research compliance program that can manage compliance risks, preserve regulatory integrity yet allow scientists to pursue innovative research opportunities that can lead to breakthroughs and advancements.
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