ESTABLISHING A COLLABORATIVE COMMUNITY-BASED CLINICAL RESEARCH NETWORK: CHALLENGES & LESSONS LEARNED

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DISCUSSION TOPICS COVERED TODAY…

- Community-engaged research – definition and benefits
- The evolution of a community-based research collaboration: *health IMPACTS for Florida*
- Key challenges in building community-based clinical research networks
- Lessons learned from the health IMPACTS pilot studies & success strategies
- Q & A panel discussion
COMMUNITY-BASED RESEARCH: WHAT IS IT?

- Research conducted with community partners that can span the spectrum of participation:
  - Less involvement – help recruit community participants
  - Moderate involvement – the health IMPACTS example
    - Recruit participants (e.g., physicians recruiting physicians)
    - Provide feedback on aspects of study design (e.g., focus groups)
    - Collect data and carry out other defined responsibilities for the study
  - High involvement – help define research question(s), write protocol, design & implement study, analyze & communicate results
COMMUNITY-BASED RESEARCH: WHAT IS IT?

- Community partners can be diverse:
  - **Private-practice clinicians, hospitals, school-based clinics, nonprofit health centers**
  - **Geographic locations & practice type**
    - Urban, suburban, rural
    - Pediatrics, family practice
  - **Common health-care interest**
    - Sports-related concussions
    - Risky behaviors in adolescents
COMMUNITY-BASED RESEARCH: WHY DO IT?

- Providers have unique insights into their communities’ health care needs and concerns

- “Real world” research findings can translate scientific discoveries into improved community health outcomes

- Enhance quality health care – expand access, prevent or mitigate illness through early intervention
COMMUNITY-BASED RESEARCH: WHY DO IT?

- Limited federal and philanthropic research funding is increasingly focused on community collaborations.

- Design health care interventions to overcome geographic or language barriers and recognize cultural differences.

- Include under-represented patient populations in data on public health issues and treatment strategies.
health IMPACTS for Florida:
How two gridiron rivals excelled through collaboration in community-based research
health IMPACTS: THE PARTNERSHIP

- FSU College of Medicine Clinical Research Network
  - **Statewide access** – 2,000 community-based faculty physicians, 2 million patients
  - **6 regional campuses** – ideal infrastructure to support local research
  - **Rural healthcare presence in underserved communities**

- UF Clinical and Translational Science Institute
  - **Unique programs** to support clinical and translational science research
  - **Federal partnerships** (Federally Qualified Health Centers)
  - **Research & education statewide network in life sciences** (county extension offices)
health IMPACTS: THE PILOT STUDIES

- State and federal funding
  - $600,000 joint grant to FSU and UF by State University System for collaborative community-based research to improve public health
  - Matching funds from both universities
  - NIH supplemental grant to UF CTSI

- Diverse communities involved
  - Central Florida – Orlando, Gainesville
  - Northeast Florida – Jacksonville
  - Panhandle & Big Bend – Tallahassee, Quincy, Marianna, Greenville, Havana

- Pediatric subjects & iPad-based data collection
Sports-related Concussion Surveillance and Management
- Subjects aged 9 – 18
- Facilitate ways pediatric and family medicine practices can better recognize, assess & manage mTBI in children and youth
- Assess relationship between health risk factors & injury, susceptibility and recovery for children and youth participating in organized sports activities

Adolescent Health Risk Assessment in Primary Care, Phase I and II
- Subjects aged 14 – 18
- Promote use of HRAs with teens in primary care settings through iPad technology
- Provide technology-based referral resources for teens engaged in risky behaviors
CHALLENGES IN ESTABLISHING A COLLABORATIVE COMMUNITY-BASED CLINICAL RESEARCH NETWORK

Jessica De Leon, PhD
Clinical Research Associate
INFRASTRUCTURE

- Need to build both network and research infrastructure

- Network
  - Personnel
  - Policies and procedures
  - Collaborations/partnerships
  - Funding

- Research
  - Identifying research needs/questions (bidirectional)
  - Moving ideas/questions to protocols, proposals and projects
  - Review and evaluation of projects
NETWORK BUILDING

- Promoting a culture of research across institutions and disciplines
- Building and maintaining a collaborative environment
- Forging relationships
  - New relationships and new kinds of relationships
  - Interdisciplinary networks
  - Communication, cooperation and mutual respect
  - Understanding each other’s needs and realities
DIVERSITY OF RESEARCH SETTINGS

- Implementing studies in diverse research settings
  - Variety of healthcare settings
  - Geographically distant and diverse locations
  - Diverse and vulnerable patient populations

- Adapting study procedures to fit a research site

- Implementation that fits the practice setting
  - Types of providers, research experience and capacity
  - Work flow, staff resources, information technology
  - Patient load and population
# ACADEMIA VS. HEALTHCARE PRACTICE

<table>
<thead>
<tr>
<th>Academia</th>
<th>Healthcare Practice</th>
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<tbody>
<tr>
<td>Research is one of the primary missions of academia</td>
<td>Patient care is primary mission of healthcare systems and providers</td>
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<td>Protected time to participate in research</td>
<td>Lack of protected time for research participation</td>
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<td>Academic non-clinical faculty’s research interests/methods may not be suitable for practice environment</td>
<td>Smooth implementation into practice is mandatory for community participation</td>
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<td>Professional goals include grants, conference presentations and publications</td>
<td>Academic incentives are not necessarily meaningful to clinicians</td>
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<td>Access to funding resources and expertise</td>
<td>Diminished access to funding resources and expertise</td>
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BRINGING TOGETHER KEY PERSONNEL

- Healthcare providers
- Principal investigators
- Research staff
- Office staff
- Leadership

How do we promote collaboration so all stakeholders work together?
SELECTING APPROPRIATE STUDIES

- Research is relevant and accommodates busy healthcare practice
- Linked to quality improvement (QI)
- Patient population
- Data collection not onerous or time consuming
QUALITY CONTROL

- Time-consuming to ensure accurate implementation of research protocols and procedures
  - Sites spread over a wide area
  - Network personnel not always present for real-time intervention/troubleshooting
  - Provider and staff turnover
RECRUITMENT AND RETENTION

- Provider recruitment and retention are key challenges for community-based clinical research networks.

- Maximize facilitators of recruitment and retention:
  - Address fears/realities of increased work load, disruption of practice work flow, time constraints.
  - Participation benefits provider and practice.
  - Incentives/compensation.
  - Training for providers/staff.

- Personal and professional events in providers’ lives can impact the research process.
ENGAGING PATIENTS AND THE COMMUNITY

- Community-based participatory research (CBPR)
- Recruiting trusted providers, existent community institutions
- Data collection is appropriate for target population
  - Literacy
  - Non-English speakers
  - Health literacy
  - Electronic data collection
IRBS & THE PROTECTION OF HUMAN SUBJECTS

- Studies may mandate approval from multiple IRBs
  - Academic, hospital, government, VA
- Diversity of IRB submission systems
  - In-house electronic, off site electronic (IRBNet), paper submissions
- Diversity of policies, procedures, forms, etc.
  - ICFs, human subjects training requirements
IRBS & THE PROTECTION OF HUMAN SUBJECTS

- Revision “ripple effect”
- Internal investigator may have to serve as site/intramural PI
  - Initially may not be as fully familiar with research protocol and IRB policies and procedures as off-site PI
PROVIDER AND STAFF TRAINING

- Participants will have to undergo multiple trainings
  - Human subjects, research topic, data collection methods
- Balancing advantages and disadvantages of different training techniques
- Participants differ in:
  - Educational background, training preferences, learner styles, comfort level with web-based training
INFORMATION TECHNOLOGY

- Building study-specific platforms and resources
- Facilitating understanding between desires and needs of end-users and IT personnel
- Differences in IT equipment and resources
- Differences in provider/staff knowledge and comfort level
- “Language barriers” between researchers, providers and IT personnel
FUNDING

- Funding is key for day to day operations and long-term sustainability of a research network

- Need funds for:
  - **Research** (provider and staff compensation as appropriate, incentives, equipment, supplies, dissemination of findings, IT)
  - **Network infrastructure and maintenance** (personnel, travel, training, communication)

- Community healthcare providers may not be familiar with funding processes
LESSONS LEARNED FROM PILOT STUDIES AND STRATEGIES FOR SUCCESS

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Director, Clinical Research Network
NETWORK RECRUITMENT

- Existing relationships are a great place to start
  - Established CoM teaching network
    - Clerkship directors at regional campuses
  - Physician to physician contact
  - Practice referrals
  - Professional organizations
- Website development with database for future studies
SITE RECRUITMENT

- Start with MOTIVATED providers with a true interest in research
  - Practice size may not indicate enrollment
  - Smaller sites may provide more flexibility
  - Loyalty counts!
- Analyze site work flow: does it fit?
- Ascertain who has decision-making ability
  - Lead MDs may or may not have influence
SITE RECRUITMENT

- “I’ll do it all myself” providers
  - Accurate information from one person
  - May be more disruptive to work flow

- Keep them motivated with incentives
  - Ipad
  - Framed certificate
DIVERSITY OF PRACTICES

- Hospital-based Residency Programs
  - Staff provided schedules for participating providers
  - Non-participating residents can refer eligible patients

- School-based Clinics
  - Groups of students present at once
  - Pressure to return students to class quickly
  - Required staff assistance for provider
    - Consent process
    - Intake
DIVERSITY OF PRACTICES

- Healthcare Systems (FQHCs, corporations)
  - Tiers of stakeholders/committees
  - Official agreements
    - MOUs
    - Data security, IT checklists

- Community-based Practices
  - Flexible work flow
  - Fewer levels of approval
ADAPTING STUDIES TO PRACTICE SETTINGS

- **HRA**
  - Focus Group input
  - Shortened versions of survey per practice preference

- **Concussion**
  - iPad app vs. paper assessment
    - Totals automatically = saves time
    - Variables could not be skipped accidentally

- Utilize staff
QUALITY CONTROL

- Intensive one-on-one training
- Initial patient enrollment assistance on-site
- Frequent site visits
- Trouble-shooting availability
- Continuous process improvement to facilitate consistency
  - “Cheat” sheets (study flow, ICF process)
  - Reference Binders
RETENTION

- Be flexible and motivational
- Realistic target for patient enrollment
- Medical students’ availability
  - Can be trained to assist during rotation at the practice
  - Contribute to research interests for future MDs
- CME credits
- MOC Part 4 Requirements (Pediatricians)
ENGAGING PATIENTS AND THE COMMUNITY

- Utilizing current, trusted providers
- Use of iPads to engage target study population
- Adolescent focus groups
- Concussions = Topic of concern for parents
- Staff and patient input on recruitment materials
  - Reflect diversity of the community
- Feedback of results to patients and providers
INSTITUTIONAL REVIEW BOARDS (IRBs)

- Use of multiple IRBs unavoidable
- ICF of primary IRB was used for enrollment
  - “Approved as written” from secondary IRB
  - Contact information for both IRBs
- Exploring “central IRB concept” for future studies
  - Strengthens collaborative ties and study cohesiveness
  - One set of deadlines, ICFs, and regulations
PROTECTION OF HUMAN SUBJECTS

- Primary IRB requirements take precedence
  - Multiple institution affiliation option (CITI)

- Academic faculty vs. clerkship faculty community researcher with busy practice

- Revamped FSU CoM CITI curriculum
  - Concise comprehensive curriculum for community researchers
  - Differentiation for study population
  - Study role of trainee
STUDY PROCEDURE TRAINING

- Face to Face provides most effective results
- Online training is an option
  - Tech savvy providers like its versatility
  - Traditional training may be more time efficient
- Quick reference binder helpful
- Providing lunch provides motivation
INFORMATION TECHNOLOGY

❖ Can streamline data collection
❖ IT doesn’t necessarily make things easier
❖ Dramatic variance among sites
  ▪ Operating systems; wireless access
  ▪ Test IT components at all sites individually
❖ One on one training for providers with lower IT comfort level
  ▪ Practice time with device prior to study initiation
❖ Utilize on-site MIS if available
INFORMATION TECHNOLOGY

- Do as much as you can for providers
  - Set up temporary passwords
    - Never underestimate password forgetfulness
- 4G iPads used as appropriate
  - Intermittent signals from weak routers or older buildings
  - “Hot spot” availability
- Theft risk
  - Internal vs. external
FUNDING

- Maximize funding opportunities
- Think broadly about how network research can fit into sponsors’ funding preferences
  - Increasing focus on interdisciplinary research teams and new partnerships
  - Build better integrated networks of academic centers linked to community-based healthcare providers
- Think creatively about benefits research networks can provide
  - University system grant -- fosters collaborations in health
  - NIH Supplement – improved health outcomes
CONCLUSIONS

- Establishing a community-based clinical research network is a complex undertaking
- Can potentially result in very diverse patient populations, reaching underserved areas that may not typically be involved in research
- Motivated, research-minded providers are key
- Challenges are common throughout a research network, yet each site has unique issues to address
- Research community needs to further explore collaborations among IRBs to streamline and enhance community-based clinical research process
REFERENCES


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