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:**

➤ **<u>Private-practice clinicians, hospitals, school-based clinics, nonprofit health centers</u>**

➤ **<u>Geographic locations & practice type</u>**

  ✓ Urban, suburban, rural

  ✓ Pediatrics, family practice

➤ **<u>Common health-care interest</u>**

  ✓ 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

health IMPACTS:
THE PILOT STUDIES

❑ 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

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

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

Michelle Vinson, MS RD LD/N

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

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