Building New Research Programs in GIM: Finding the Money and Opportunities, Avoiding the Pitfalls

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Overview

1. Necessary resources and financial commitments
2. Potential funding sources
3. Emerging opportunities
   - Pragmatic clinical trials & learning health systems
   - Healthcare system partnerships
Take Home Points

1. Developing de novo research programs require a significant institutional commitment & resources over an initial 4-5 year period & ongoing investment.

2. External funding is increasingly competitive → if goal is to build externally funded program, it’s critical to build around faculty with prior training in research methods & early track record of publication.

3. Clinician educators can play collaborative roles in research but unrealistic to expect them to be successful in obtaining independent funding.
4. Research is increasingly an interdisciplinary team sport \( \rightarrow \text{not feasible to recruit all of the necessary talent into GIM / partnerships with other programs (e.g., Public Health, CTSA) that can offer methodological support & mentoring are essential.} \)

5. The need of HCS for high-quality business analytics to facilitate population management & shared risk contracts represents a new opportunity for support.

6. GIM research programs can lead HCS towards their evolution towards true learning health systems in which research drives effective practice and practice informs research.
Establishing Goals / Key Questions

1. What is the primary goal of the research program?
   - *Nurturing independent investigators whose effort will be largely supported by external funding!*
   - *Providing academic outlets for faculty who are unlikely to be competitive for external funding*
   - *Supporting higher quality internal healthcare improvement projects*

2. What will be the key markers of success and what is the time frame for judging success?

3. Is institutional leadership on board with the plan and committed to providing the necessary resources?
Necessary Resources and Commitments

1. Institutional commitment to build a critical mass of investigators
   - Senior investigator within division with established track record as mentor to direct recruitment
   - Minimum of 4-5 junior investigators with significant protected time for research

2. Core resources to support investigators
   - Computer network to support data needs
   - Research personnel: study coordinators, data manager, data analyst, and part-time statistician
   - Administrative personnel: budget specialist, IRB assistance
Necessary Resources and Commitments

3. Access to methods experts & mentors in key areas → e.g., health economics, organizational behavior, informatics, epidemiology, qualitative methods
   - Schools of Public, Business, and Liberal Arts
   - CTSA Programs → Support T3 / T4 research, offer research methods consultation & internal K awards

4. Collaborations with other IM divisions or departments
   - GIM as research home for faculty interested in HSR
   - Effective strategy for leveraging recruitment funds

**Collaborations are critical → HSR is interdisciplinary / Can’t build successful research program on an island**
Financial Dynamics

1. Recruitment of junior investigators → expectations
   - Tenure track appointment in most institutions → candidates should have done 2-3 year research fellowship & should be competitive for K awards
   - ~ 3 years of protected time (70-80%) for research
   - Modest start-up package for research support staff (e.g., RA, data manager/analyst, statistician) and travel to national meetings → 50K per year
   - Investment of 450-500K / investigator over 3 years
   - Expectation that external funding would be obtained to support the effort devoted to research in 3 years
Financial Dynamics (cont.)

2. All research programs require subsidies → even highly successful, established programs!

- Hard for investigators to avoid gaps in funding
- Institutions have to cover investigator salary > NIH salary cap (~179K) → e.g., ~ 40-45K for established investigator with salary of 225K & 75% grant funded
- Most NIH K awards only provide 75K in salary for >75% effort devoted to research
- Can’t fund certain staff (e.g., secretaries) on grants
- Regulatory compliance costs have increased, making it more difficult for institutions to return indirects
Potential External Funding Sources

NIH: ~ $29B budget (~ $1B for HSR / T3-T4 research)

- Funding administered through 28 disease-specific institutes with different levels of receptivity to HSR
- Applications typically have to focus on specific conditions, less interest in delivery changes
- Critical to build relationships with program officers to understand institute priorities
- Majority of budgets for IIR awards (R01, R21, R03) → Increasingly competitive with paylines < 10%
- Increasing interest in supporting practice-based, lower cost pragmatic clinical trials
Potential External Funding Sources (cont.)

AHRQ: ~ $400M budget

- HSR methods, QI & patient safety interventions, & secondary analysis of large databases
- IIR awards, individual career development (CD) awards, HSR training programs, and centers in focused areas (drug effectiveness)
- Increasing proportion of budgets distributed via contracts → cumbersome applications
- Most of budget allocated to targeted areas → only 5-6% of budget directed to IIR with paylines typically < 10% (often <5%)
- Inconsistent support for CD awards over time
PCORI: ~ 500M budget (through 2017)

- Comparisons of the effectiveness of alternative treatment, diagnosis, & delivery strategies
- Approaches to disseminate CER data & engage patients and other stakeholders
- Improvement of CER methods
- IIR awards & clinical research data infrastructures
- Applications must demonstrate engagement of patients in study design & implementation
- Paylines typically < 10%
- Large proportion of future research via integrated research networks built around EMR data
Potential External Funding Sources (cont.)

VA: ~ 580M budget (~ $100M for HSR&D)
- *Research to improve veteran health and the access, cost, and quality of VA healthcare*
- *IIR awards, service-directed awards of care delivery innovations, CD awards, & HSR centers that provide research infrastructures*
- *Opportunities for VA funding for innovative clinical programs through program offices*
- *Increasing emphasis on conducting research in collaboration with operational partners*
- *Paylines for IIRs at 15th to 20th percentile*
Potential External Funding Sources (cont.)

Other Sources

- CMS / CMMI → Demonstration projects of delivery innovations with emphasis on saving costs
- State Medicaid Programs → demonstration projects and evaluation of mandated programs
- Disease organizations (AHA, ACS, ADA) → career development and IIR awards
- Foundations (RWJ, Hartford, Commonwealth) → grants must address foundation priority areas

Bottom Line → Establish diversified portfolio of funding to ensure long-term success!!
Emerging Opportunity:
Pragmatic Trials & Learning Health Systems

Context:

1. Increasing recognition that much of the evidence from traditional multi-site Phase 3 RCTs may not apply to patients seen in many clinical practices.

2. Costs of large RCTs ($100-150M) have escalated at a time of decreasing NIH & industry funding.

3. As a result, increasing interest in using lower cost pragmatic designs to address important questions and to create “learning health systems.”
Learning Health System
(Institute of Medicine, 2007)

A healthcare system in which ...

“science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”

Learning Health System: What’s Different?

- Tight integration between research and practice such that research findings directly inform practice and key issues faced by practitioners become the focus of future studies.

- Health system resources, such as the EMR, become an integral part of the research infrastructure.
Pragmatic Clinical Trials

- Term first used by Schwarz and Llellouch in 1967
- Described differences between trials that were pragmatic in orientation and traditional clinical trials in which interventions were delivered in a highly standardized manner by expert clinicians
- In contrast, pragmatic trials often allow flexibility to adapt interventions to individual needs of patients and to the unique capabilities of individual delivery settings
Differences Between Pragmatic and Traditional Clinical Trials

- PCTs have fewer patient selection criteria & enroll more heterogeneous populations → *findings may have greater generalizability to patients seen in practice*
- PCTs typically compare two or more currently used “standard of care” treatments, often for which there is clinical equipoise → *traditional clinical trials often compare new treatments to placebos*
- PCTs have smaller data collection infrastructures and often rely on data collected during routine practice → *less costly*
Example of a Pragmatic Trial: Nighttime Dosing of Antihypertensive Medications

**Goal:** Compare cardiovascular outcomes in patients who are randomized to take once-daily medications in the morning or to take their medications in the morning.

**Sites:** University of Iowa and Duke

**Study Sample:** 5000 patients with hypertension in General Medicine, Family Medicine, Cardiology, or Nephrology clinics identified from the EMR
Overview of Trial Design

- Informed consent obtained through an interactive website or a mailed consent letter
- Patients will be followed for 36-42 months with contacts every 6 months via an online personal health record or paper surveys
- Cardiovascular endpoints will be determined from the EMR, personal health records, written surveys, and extant data (Medicare claims, hospital discharge abstracts, & death certificates)
- Total costs: $4 million
Why is Nighttime Dosing an Ideal Topic for a Pragmatic Trial?

- HTN is common problem & major CV risk factor
- Patients eligible for intervention can be identified through EMR
- Key endpoints (adverse CV events) can be captured through EMR and other extant sources
- Nighttime dosing can be implemented in practice without the need for sophisticated infrastructure
- Intervention has high potential for sustainability if pragmatic trial confirms prior clinical trials
Developing Successful LHS Will Require New Strategies for Engaging Systems and Physicians in Practice-Based Trials

1. Study designs that can be easily embedded into practice and not interfere with work flow
2. Effective approaches to obtain input from front-line clinicians on high priority research questions
3. Integrate incentives into faculty reward systems (e.g., *PCT involvement as factor in promotion, providing RVUs for subject recruitment*)
4. Creation of institutional cultures that embed knowledge generation into practice
Emerging Opportunity: Link Research Development to HCS Analytical Needs

**Context:**

1. HCS are creating ACOs and entering into contracts with payers that have substantial risk sharing.
2. Being successful under these financial arrangements will require that HCS effectively manage risk & have analytical capacity to stratify populations by their risk for high utilization and/or poor outcomes → *skills that typically exist within GIM research programs*
3. Thus, there are new opportunities to link research strengths with HCS needs for business analytics
Linking Research Development to HCS Needs: Iowa Center for Outcomes Research (ICORE)
Linking Research Development to HCS Analytical Needs: Key Considerations

1. Most HCS purchasing costly population & utilization management tools of variable quality offered by private vendors → *must convince HCS that investing internally will yield better value.*

2. Investments by the HCS should support investigator salary and personnel plus a premium (30-50%) to support investigator’s independent research.

3. Key challenge is to work in a more timely manner than is typical for most research projects and respond promptly to HCS needs.
Questions