Building an NIH Funded Asthma Clinical Research Center: A Success Story

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1:15 to 1:40 PM, April 4, 2017
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Disclosures/Conflicts of Interest

• Funding NIH
Objectives

• Discuss One Example of a Successfully Building an NIH Funded Asthma Clinical Research Center: Success Story- and a few pearls for success
• Discuss Strategies towards Success in an Academic Career in Clinical Research
• Identify Appropriate Funding Mechanisms
• Identify Teams to Be Successful
Challenges

• My first job- FULL clinical load and to “build clinical research program on the side”
• New Place- No Connections:
• Had to find a way
PEARLS DON'T LIE ON THE SEASHORE. IF YOU WANT ONE, YOU MUST DIVE FOR IT
My EXPERIENCE- Fellowship

- Use this time to LEARN HOW TO DO CLINICAL RESEARCH
- First Project “start to finish” (IRB, Recruit, enroll, procedures, data forms, entry, analysis (with help), write the paper- GET ON PUBMED- EXPERIENCE
- This was CRITICAL for the lab I run today
- Project was primarily what my mentor had available
- Really use your fellowship to LEARN/EXPERIENCE what you will be doing- Too hard later
Early Years - Junior Faculty

- Primarily Clinical
- Needed real funding to make it Focus on the ONLY thing that is going to give you time
  (K-23, 5 Year Career Development Award)
- Sought myself foundation applications
- Sought myself a mentor in a new place different from my fellowship “knock on door”
- Protected time or classes without supportive mentoring-doomed
- Sit in on meetings- Find people, ask questions, be collaborative/team player
Types of Clinical Research/ Funding

- Drug Studies
- Foundation/Society/Association-Pilots lead to $$$
- Intramural
- NIH - K career development
- AAAAI/ ATS/Thrasher/ ALA/ OSP/Internal
- K12, Catalyst
- AHRQ- Agency for Healthcare Research and Quality
- PCORI- Patient Centered Outcomes Research Institute
- Early on MENTOR critical - K23/K-08- Career Development Award
Professional IPM & Mouse Allergen-
Funded from a $50,000 Pilot

![Graph showing the comparison of Mus m 1 levels between intervention and control groups over time](image)

Effect of an Integrated Pest Management Intervention on Asthma Symptoms Among Mouse-Sensitized Children and Adolescents With Asthma
A Randomized Clinical Trial

Elizabeth C. Matsui, MD, MHS; Matthew Perzanowski, PhD; Roger D. Peng, PhD; Robert A. Wise, MD; Susan Balcer-Whaley, MPH; Michelle Newman, BSN; Amparito Cunningham, MD, MPH; Adnan Divjan, BA; Mary E. Bollinger, DO; Shuyan Zhai, PhD; Ginger Chew, ScD; Rachel L. Miller, MD; Wanda Phipatanakul, MD, MS

JAMA 2017 On line March 6, 2017
The School Inner-City Asthma Study (SICAS)- Rationale Built from Previous Experience

- Noted a Paucity of Info in Schools
- Simple concept, but told “impossible”
- Minimal funding from my K, Collected Data on my own
- Built School/Community Relationships to convince the NIH to fund:
  - NIH/NIAID AI073964 Allergens in Inner-City Schools and Childhood Asthma (Phipatanakul)
- Primary goal: To fully evaluate school/classroom specific modifiable environmental risk factors and asthma morbidity, adjusting for home exposure
- YEARS of COMMUNITY RELATIONSHIPS- UNMET NEED
School Inner-City Asthma Study
Repeating Annual Schema - R01 AI 073964- PI Phipatanakul

350 children
38 schools

Spring
Screening & Recruitment
8-10 schools
75 Students/yr

Summer
Baseline Phenotype Survey
Spirometry
Skin testing
Blood/Nasal

Fall
Class/Home Sampling

Winter
3, 6, 9, 12 months
Follow-up Health Outcomes Linked to Sampling
Spirometry, FeNO, Nasal

Spring
Class/Home Sampling
Establishing School-Centered Asthma Programs
School Inner-City Asthma Intervention Study - IPM vs. Cont / Classroom HEPA vs Sham U01 AI 110397 PI Phipatanakul

300 children
40 schools

Spring

Screening & Recruitment
8-10 schools
75 Students/yr

Summer

Baseline Phenotype Survey Spirometry Skin testing Blood/Nasal

Fall

Class/Home Sampling

Rmz

Winter

Class Sampling X 2

2, 4, 6 months

Spring

Follow-up Health Outcomes Linked to Sampling
Spirometry, $F_{ENO}$ x 2
Nasal/Buccal x 1

Int ends
**Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) Consortium**

<table>
<thead>
<tr>
<th>Type 1 Diabetes</th>
<th>Sickle Cell Disease</th>
<th>Rheumatic Disease (JIA, SLE)</th>
<th>IBD - Crohn's/UC</th>
<th>Chronic Kidney Disease</th>
<th>Cancer (Active)</th>
<th>Cancer (Survivorship)</th>
</tr>
</thead>
</table>

**Figure 1. AAD-PEPR Accrual**

- **SICAS-2**
  - N=300
  - Inner City Schools
  - AA, Hispanic
  - English/Spanish

- **CHICAGO**
  - N=640
  - Hospital ED
  - AA, Hispanic
  - English/Spanish

- **ASIST**
  - N=200
  - Community Providers
  - AA
  - English

- **N=225**
- **N=250**
- **N=170**

**AAD-PEPR**
- N=645
- Diverse settings & asthma severity
- Race/ethnicities most affected by Asthma
- English/Spanish

NIH U19AR069526-Phipatanakul- Project Lead and Geocoding Core Lead
Creation of AsthmaNet

- NHLBI decided that the pediatric and adult asthma research networks would be combined to study asthma therapies across the ages.

- RFA was announced in 2008 requesting applications for AsthmaNet

- “Centers” applying for AsthmaNet had to apply as a combined pediatric and adult research site

- The “Boston” site was created and applied → BWH (Elliot Israel) and BCH (Wanda Phipatanakul)
Pediatric Clinical Centers/PIs:
Atlanta – Anne Fitzpatrick, PhD, APRN
Boston – Wanda Phipatanakul, MD, MS
Chicago – Jacqueline Pongracic, MD
Denver – Stanley Szefler, MD
Madison – Robert Lemanske, MD
Pittsburgh – Fernando Holguin, MD
San Francisco – Michael Cabana, MD
St. Louis – Leonard Bacharier, MD
Tucson – Fernando Martinez, MD

Data Coordinating Center:
Hershey – David Mauger, PhD

NIH FUNDING SUPPORT:
DCC  HL098115  DEN  HL098075
MAD  HL098090  CHI  HL098096
STL  HL098098  SAN  HL098107
TUC  HL098112  PIT  HL098177
BOS  HL098102  ATL  HL098103

Thanks to all of our participants and study coordinators!
Pediatric AsthmaNet/Consortium Studies

• Azithromycin to Prevent LRI (JAMA 2015)-
• Vitamin D in Asthma in Adults (JAMA 2015) Vitamin D Kids in Asthma (Celedon) - launching 2017
• Tylenol vs Motrin in Toddlers with Asthma (NEJM 2016- Sheehan/Phipatanakul)
• LTRA vs ICS daily vs ICS prn in Toddlers (JACI 2017)- 300 toddlers
• 4x ICS in Yellow Zone in Kids 2017
• Best therapies in African Americans Across the Ages- 2017
• Eosinophilic Response in Asthma-2017
Acetaminophen versus Ibuprofen in Young Children with Mild Persistent Asthma


Collaborations-Paved the way for HUGE future grants ......
Prospective Study of the Natural History of Severe Asthma

Severe Asthma Research Program

www.severeasthma.org

Phipatanakul W, AJRCCM, 2017 IN PRESS
ORBEX Primary Prevention: 1074 babies with eczema or parental asthma nationwide: 7 Centers-154 in Boston.
Preventing Asthma in high Risk Kids - PARK

U01AI126614- Principal Investigator Phipatanakul

Randomized, multicenter, DBPC Trial in allergic wheezing toddlers at high risk for developing established asthma

- Screening/Eligibility
- Run-in
- 1 month
- Randomize
- Interim Efficacy Tests
- Years 1 & 2
- Treatment – Anti-IgE or Placebo
- Observation
- Year 3 Year 4
- Primary Outcome

*Adapted Prevention of Early Asthma in Kids using ICS Guilbert TW et al. NEJM 2006;354:1985-97
Pearl: Be Passionate and Hungry

- “If you love what you do, you’ve never worked a day in your life.”
- Your words and actions need to be able to convey this passion
Take Home

• Get Experience (not just about data analysis)
• Be resourceful- Understand the system-EDUCATE
• Collaborate- Team player- Everyone is unique and can contribute to a team
• Capitalize on Opportunity- Run with IT
• Build with the infrastructure around you- but work towards solutions on successful implementation- Coordination- Harvard Catalyst, CTSU, Pharmacy, Biorepository- Hospital-Community Constantly brainstorming on improved efficiency TEAM
• Continued success and track record perpetuates itself and perpetuates funding and collaborations
• YOU CAN DO IT!
WELL WORTH IT

TRACK RECORD = CONTINUED SUCCESS

“One Cannot Fake an NIH biosketch”
Acknowledgements

- Diane Gold, MD, MPH-Environment
- Elliot Israel, MD-Clinical Trials
- Petros Koustrakis, PhD-Monitoring
- Carter Petty, MS-Stats
- Brent Coull, PhD-Stats
- Andrea Baccarelli, MD, PhD-Genetics
- Margee Louisias, MD/Merdith Dilley, MD, Marissa Hauptman, MD MPH (Public Health Services Award) T32HD0757270, K12 HS 0229860
- Lakiea Wright, MD F32 HL124919, NIAID Diversity Supplement
- Bridget Hron, MD F32 HL122080
- William Sheehan, MD K23 Al104780
- Peggy Lai, MD, MPH, K23ES023700
- Jon Gaffin, MD, MMSc K23al106945
- Perdita Permaul, MD, K 23 Al123517
- David Kantor, MD, PhD K12 HD 047349 Critical Care Scholars, K-23 HL138162
- Thai Research Scholarship from Ramathibodi Hospital (Champ Kanchongkittiphon, MD, PhD)
- Sachin Baxi, MD, K in prep
- Lisa Bartnikas, MD, K23 Al125732

- ALA/AAAI/Noonan (Phipatanakul)
- Aeorcrine/ATS/Glaxo Fellow Awards
- ACAAII/Von Clements/AAP ATS Minority Award/Bates National Medical Society
- SICAS1/2- Ann Bailey/Amparito Cunningham ACRC Staff
- Lincoln Diagnostics/Greer CTSU-NIH/Harvard Catalyst
- Community/Schools/Principals/
- R01 Al073964 (Phipatanakul)
- ARRA Al073964 Suppl (Phipatanakul)
- U01 AI 110397 (Phipatanakul)
- K24 AI 106822 (Phipatanakul)
- NIH/ NIAID/NHLBI
- EPA/PPG/CLARC
- U01AI126614(Phipatanakul)
- R01HL137192 (Phipatanakul)
- Broad Institute/ U19AR069526
- U10HL119952 (Celedon), U01 HL 1300045 (Martinez)-Phipatanakul
Preventing Asthma in high Risk Kids (CASK)
PI: Phipatanakul U01AI126614

- Elliot Israel, MD
- DCC-Penn State University- Dave Mauger, PhD

Clinical Centers
- Boston- Team- Will Sheehan, Jon Gaffin, Perdita Permaul, Sachin Baxi, etc.
- Atlanta – Anne Fitzpatrick, PhD, APRN
- Madison –Daniel Jackson, MD
- St. Louis – Leonard Bacharier, MD
- Tucson – Fernando Martinez, MD
- Cincinnati- Theresa Guilbert, MD, MS
- Seattle- Stephen Tilles, MD
- Sacramento-Bradley Chipps, MD
- Hans Oettgen, MD, PhD, Mechanistics
- NIH/NIAID, FDA, Genentech/Novartis, Alk Abello, Glaxo, Teva, Mylan, Merck, Monaghan
Questions or Comments?

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