



The Establishing Regional Practice-based Research Networks

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Disclosure Statement

In the past 12 months, I have had no relevant financial relationships with the manufacturers of any commercial product or providers of commercial services discussed in this CME activity. I do not intend to discuss an unapproved or investigative use of a commercial product or device in my presentation.



Educational Objectives

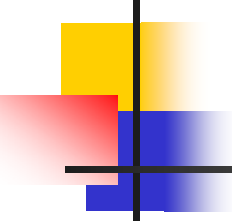
- To understand the history of practice-based research
- To be able to describe the advantages of research in office practice
- To understand the disadvantages of research done in one site



The Need for Evidence Based Medicine

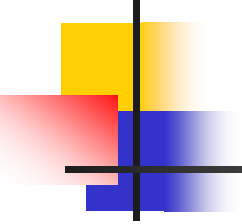
“Americans should be able to count on receiving care that meets their needs and is based on the best scientific knowledge. Yet there is strong evidence that this frequently is not the case..... Between the health care we have and the care we could have lies not just a gap, but a chasm”

Crossing the Quality Chasm
Institute of Medicine Report, 2001



“To assess it at its lowest value, this has proved to me a most interesting hobby, something to turn the face from the clod and to add interest to the daily round, which, instead of being monotonous, becomes full of delightfully exciting incidents. I have written this and a previous paper in the hope that other country doctors will realize what is peculiarly their opportunity and, I feel strongly, their bounden duty.”

William N. Pickles,
Epidemiology in country practice, 1935



*The progress of medicine will be hampered and delayed
till the general practitioner becomes an investigator*

Sir James MacKenzie
Principles of Diagnosis &
Treatment of Heart
Affections, 1916



February 18, 2008

Paul Darden MD

Dallas, Texas
Medical School
Residency

Montreal, Quebec
Fellowship

Charleston, South Carolina

Assistant Professor of Pediatrics

Continuity Clinic Director

Full time clinician

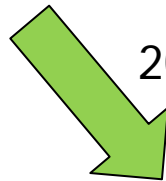
Clinic Director

Clinic Medical Director

Fellowship Director

PBRN Director

20 years



Still a clinician?

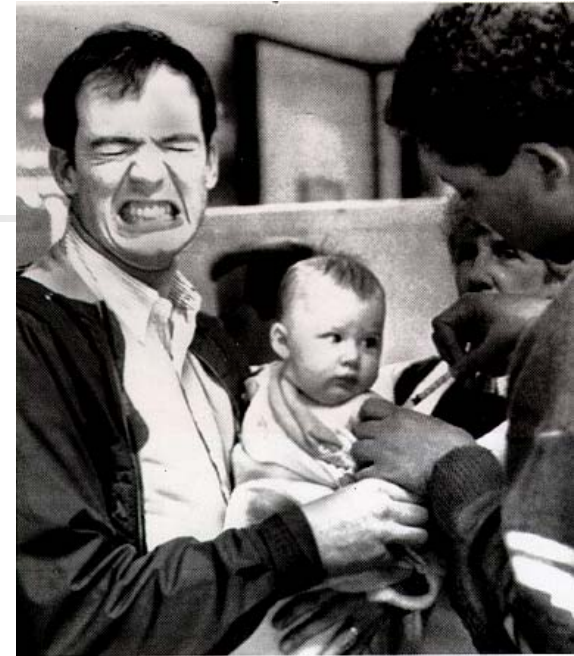
Professor of Pediatrics, Internal Medicine and of
Biostatistics, Bioinformatics and Epidemiology



OKLAHOMA!

Overview

- Introduction
- Practice-based research networks
 - History
 - Rationale
- Examples of PBRN
 - Pediatric Research in Office Settings (PROS)
 - Puget Sound Pediatric Research Network (PSPRN)
 - South Carolina Pediatric Practice Network (SCPPRN)





Acknowledgements

- Mort Wasserman – PROS/Univ of Vermont
- Jim Taylor – PSPRN/Univ of Washington
- Lisa Johnson – MUSC
- Larry Nazarian – Rochester, NY

Nazarian LF. Research in pediatric practice.

Pediatric Clinics of North America. 08 1981;28(3):585-599.

Practice-Based Research



March 24, 2008



Credentials

- AAP – Pediatric Research in Office Settings (PROS)
 - National Medical Association - NMAPedsNet
- APA – CORNET, the Continuity Clinic Research Network
 - PRIS – Pediatric Research in Inpatient Settings
- MUSC – South Carolina Pediatric Practice Research Network (SCPPRN)
- Oklahoma – please join?



In Practice-Based Research, What is a “Practice?”

- Practice is defined as any clinical setting that provides *comprehensive* primary care services (acute & chronic illness and preventive care)
- Setting can be private or public, community-based, or institutionally-based

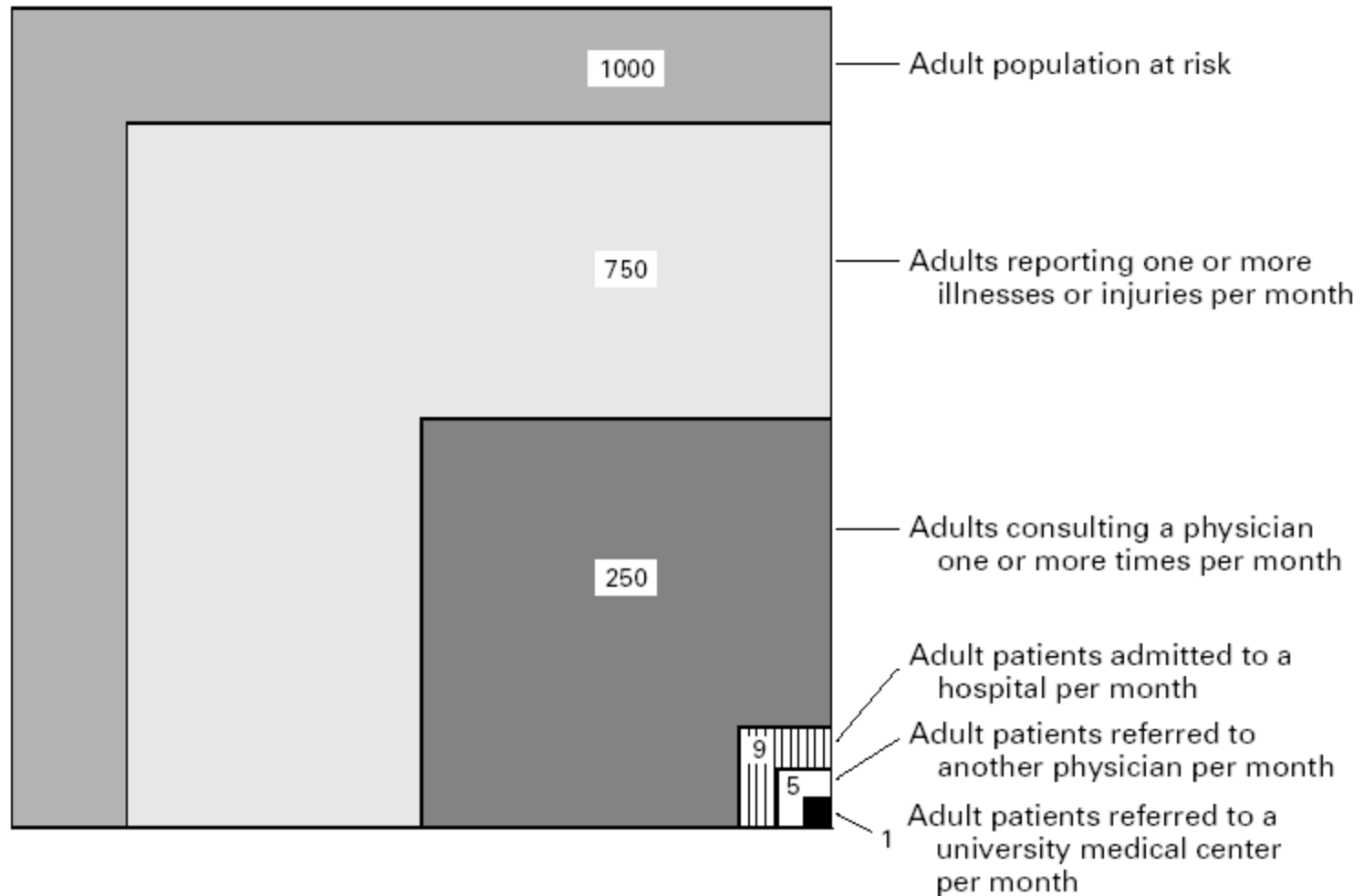
Why Do Research in Practices?



- Sutton's Law: that's where the majority of patients and problems are!
- Practices are the best place to study the *prevention* of health problems
- Practices are a good place to study problems *over time*
- Patients in practices are more *representative* of any clinical problem than those seen in hospitals
- Practices are a good place to study the problems that cause substantial morbidity, but don't result in hospitalization (e.g., psychosocial problems)

1961 The Ecology of Medical Care to Adults

White, 1961

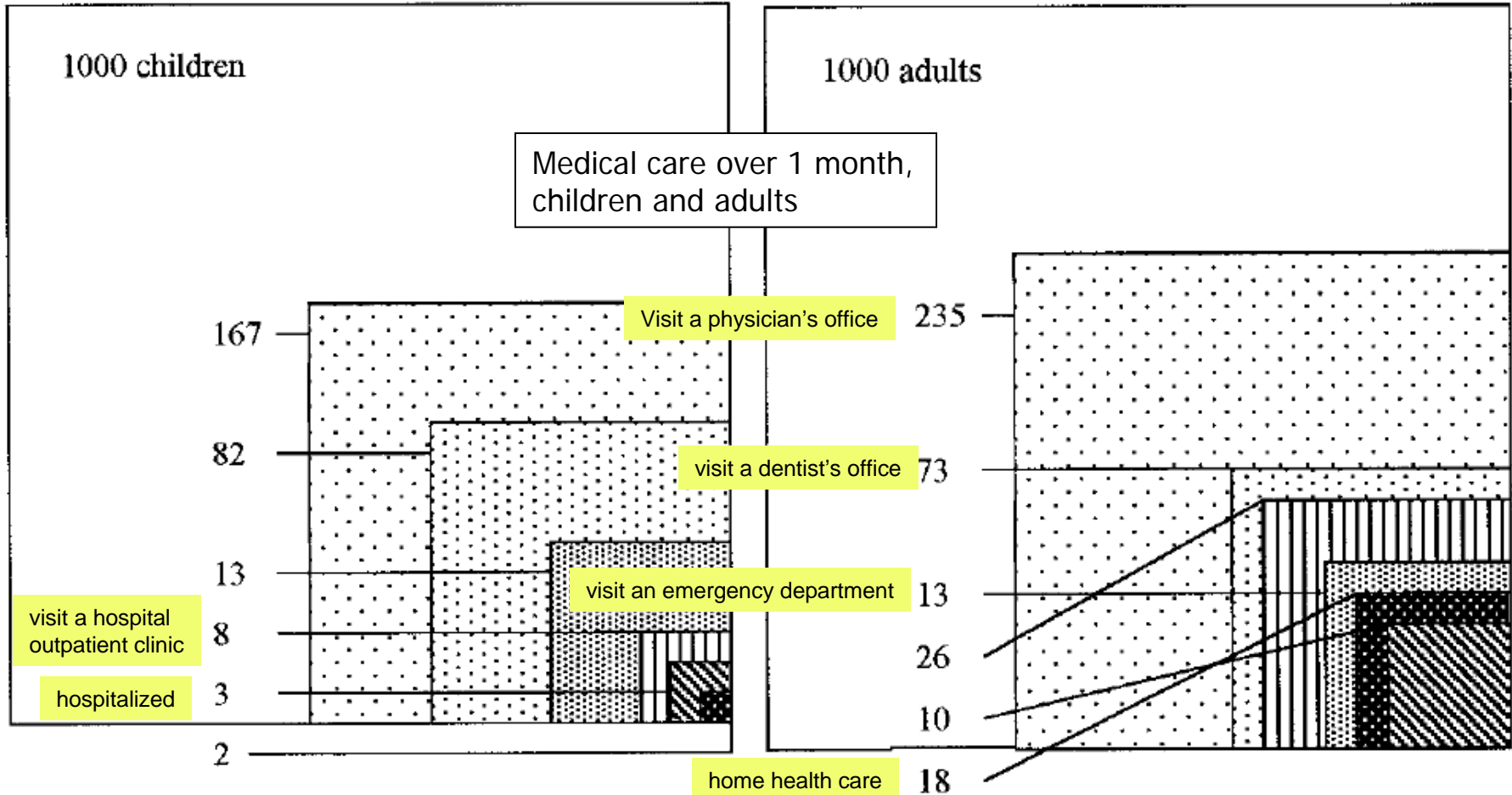


Green LA, Fryer GE, Jr., Yawn BP, Lanier D, Dovey SM. The *ecology* of medical care revisited. *N Engl J Med* 2001; 344(26):2021-2025.

White KL, Williams TF, Greenberg BG. The ecology of medical care. *N Engl J Med* 1961;265:885-92.

A. Children aged 0-17 years

B. Adults ≥ 18 years



Dovey S, Weitzman M, Fryer G, Green L, Yawn B, Lanier D et al. The **ecology** of medical care for children in the United States. *Pediatrics* 2003; 111(5 Pt 1):1024-1029.



Sampling by cluster

- About clusters
 - Examples of clusters; community, school, neighborhood, clinic
 - Those within the cluster are more similar to each other than those in other clusters
- Why sample by cluster?
 - Availability, accessibility, cost, efficiency
- We always cluster sample



Cluster Sampling Complicates Statistics

- Observations no longer
 - Independent
 - Identically distributed
- Problems for variance estimation
- Non-sophisticated methods estimates of variance are too broad



Grade inflation or sample size deflation

Design effect	ICC	Sample in cluster	"true" sample size
1.01	.001	100	91
7.45	.050	100	17
13.9	.100	100	9
72.0	.55	100	2



Once upon a time...

All medical research
was practice-based
research!!

Practitioner Researchers



- Edward Jenner -- smallpox vaccine
- James MacKenzie -- cardiac physiology
- Burtis Breese -- streptococcal infections
- T. Berry Brazelton -- child development
- William Carey -- temperament and behavior
- O.J. Roddey, Herb Clegg -- infectious diseases
- Bruce Taubman -- toilet training



Decline in Practice-Based Research

- Rise in biomedical laboratory research
- Decreased medical school emphasis on primary care (until the very end of the 20th century)
- Increased requirements for sophistication in clinical research -- beyond clinical description, using epidemiology, biostatistics, & social sciences



The conundrum of clinical research

- Researchers with training, time, salary to conduct studies have access to limited number of patients (non-representative?)
- Practitioners who see large numbers of patients, have wealth of clinical experience have no time or salary support to conduct studies



Academic Research- Practitioner Collaboration

- Availability of large number of patients
- “Real world” results
- Research infrastructure of academic center



Models of Practice-based Research

- Single study “networks”
- Industry directed networks
- Regional practice-based networks
- National/International practice-based networks



Fundamentals of Practice-Based Research

Spectrum of practice involvement

Requirements of practice

none -----> recruit, enroll
collect data

Interest in research question

low-----> high

Remuneration

none-----> high



Regional PBRN's

- Frequently oriented around academic medical center
- Types of practices
 - Primary care practices (private, other)
 - Continuity clinics
 - Underserved populations
 - Inner city
 - Rural



Regional Pediatric PBRN's

- Numbers somewhat nebulous
- Among AHRQ PBRN grantees, ~ 10/55 (18%) pediatric PBRN's



Pediatric Research In Office Settings

<http://www.aap.org/pros/>



Pediatric Research in Office Settings Network (PROS)

- Practice-based research organization within the American Academy of Pediatrics
- 1,800 practitioners, 720 practices
- Members in 50 states, Puerto Rico and Canada (2008)

PROS Organization



- Director, Full-time staff
- Steering committee of practitioners, staff, independent researchers
 - Carefully review study proposals
 - Make recommendations
- One coordinator/chapter
 - Coordinators meet twice yearly
 - Researchers propose studies
 - Coordinators approve/disapprove study, modify design and study forms



Selected PROS studies

- Prevalence of secondary sexual characteristics in young girls
 - Practitioners “passed” a test on assessing stages of sexual development before enrolling patients
 - Data collected on 17,077 girls, 9.6% were black
 - Results indicated that pubertal changes occurred in girls at earlier age than previous norms
 - Racial differences: African-American girls mature earlier

Herman-Giddens ME, Slora EJ, Wasserman RC, et al. Secondary sexual characteristics and menses in young girls seen in office practice: a study from the Pediatric Research in Office Settings network. *Pediatrics*. 04 1997;99(4):505-512.



Selected PROS Studies

- Management of febrile infants < 3 months
 - 2,755 infants enrolled, 501 practitioners
 - Rate of bacteremia/meningitis 1.9%
 - Variable care
- Current clinical guidelines
 - Would not have improved care
 - Would have resulted in more hospitalizations and laboratory testing

Pantell RH, Newman TB, Bernzweig J, et al. Management and outcomes of care of fever in early infancy. *JAMA*. 03/10/ 2004;291(10):1203-1212.



Selected PROS Studies

- Immunization status of children vaccinated by practicing pediatricians
 - Data collected on 13,520 children from 42 states
 - 79.4% of children fully immunized at 8 months of age
 - Evaluated association of patient demographic characteristics, practitioner policies and beliefs, and parental health beliefs on immunization status
- IPV not associated with lower rates
- Large variation in practice rates (21-100%)

Taylor, J. A., P. M. Darden, et al. (2001). "Impact of the change to inactivated poliovirus vaccine on the immunization status of young children in the united states: a study from Pediatric Research in Office Settings and the National Medical Association." Pediatrics **107(6): E90.**



PROS Immunization Study

- Practice/practitioner policies and beliefs associated with immunization rates
 - Fewer contraindications --- higher practice rates
 - More vaccines given at one visit--- higher
- 74% of parents indicated to significant barriers to immunization
 - Parental perception of barriers accounts for 8% of underimmunization

Taylor JA, Darden PM, Brooks DA, Hendricks JW, Baker AE, Wasserman RC. Practitioner policies and beliefs and practice immunization rates: a study from Pediatric Research in Office Settings and the National Medical Association. *Pediatrics*. 02 2002;109(2):294-300.



Is PROS Representative?

- PROS – Stratified random sample of 57 practices and 1,706 visits
- NAMCS – 33 practices and 948 visits
- Similarities
 - Gender, ethnicity, payment
 - Acute visits, diagnoses, proportion referred
- Differences
 - Race, age



Puget Sound Pediatric Research Network (PSPRN)

- Regional pediatric PBRN in Seattle
- Director: James Taylor, MD
- Formed in 1995
- Start up funds by local children's hospital
- Membership: ~50 pediatricians from 9 private practices, 1 inner-city pediatric clinic



PSPRN: Founding principles

- Based on PROS experience, visit to PPRG
- Participation in studies, attendance at meetings totally optional
- Practitioner “ownership” of studies
- Study procedures don't interfere with office flow
 - One page study forms



Example of PSPRN studies

- Prevalence of sinusitis in young children followed by practicing pediatricians
 - Parents of patients 1-5 years old completed study form while waiting for office visit
 - 1-3 week enrollment periods at offices
 - Data collected on 1307 patients
 - Collected data on 83% of those eligible



SCPPRN



South Carolina Pediatric
Practice Research Network

www.musckids.com/scpprn



SCPPRN

Founded in 2005 based on a HRSA grant.
Part-time director, half time coordinator,
steering committee with practice
representation.

SCPPRN is a practice-based research network
established by concerned primary care
physicians who see a need for outcomes-
based research that is “relevant” to their
practice.



SCPPRN – description

Description of 8 SCPPRN practices from 2007 survey	
# practitioners	38 (35 pediatricians and 5 Nurse Practitioners)
Grad Yr.	1961-2000
# and Site of office	9 offices: 5 Urban, 1 suburban, 3 rural
Visits per year	114,438 (range 10,000 to 26,000/practice)
Patient Race	Range, by practice, %
White	12-85
Black	11-83
Hispanic	1-52
Patient Insurance	Range, by practice, %
Private	1-96
Medicaid	4-95
Unfunded	2-5
Number with EMR	5 with EMR (3 with the same vendor)

Rates of Being Too Heavy for Age Appropriate Child Passenger Restraint Among SC Children

	Infants 0-11 months (n=238)		12 months – 5 years (n=479)	
	≤20 lbs. N, (%)	>20 lbs. N, (%)	≤40 lbs. N, (%)	>40 lbs. N, (%)
Entire Sample	199 (83.6)	39 (16.4)	383 (80.0)	96 (20.0)
By Race/Ethnicity*				
White	87 (83)	18 (17)	156 (80)	39 (20)
Black	78 (83.9)	15 (16)	170 (81)	40 (19)
Hispanic	32 (84)	6 (15.8)	52 (79)	14 (21)
By Gender				
Male	99 (79)	27 (21) †	216 (79)	56 (21)
Female	100 (89)	12 (11)	167 (81)	40(19)



Immunization Project

- Results 349 patients
 - Race/ethnicity - 21% Hispanic, 38% white, 38% black and 3% other
 - Immunization rates – mean 76%, range by practice 70% to 92%
- Practice immunization routines



Office practices – with variation: Immunization rates

Office Practices – 7 participating	UTD-yes	UTD-no
Assessment (2/2)		
Immunization rates in the practice are assessed at least annually	78.3	84.9
Providers get feedback about their immunization rates compared to other providers/practices*	75.5	84.7
Records (2/6)		
Immunization records from previous providers are routinely available at the time of the first visit for patients transferring into the practice	79.6	83.6
Providers are prompted about immunizations due at sick or acute visits	82.5	80.2

P<.05



Number of procedures and UTD

# office practices	14	15	16	17	18
UTD	89	84	81	...	76

Trend P=.08



Conclusions

- The practice a child attends is the strongest predictor of being up to date at 8 months of age
- In this group of practices Hispanic ethnicity was associated with being up to date
- Office practices, as measured, do not predict being up to date beyond practice
- Where there was variation, recommended office practices were usually associated with a lower immunization rate



Question

- What are the characteristics of an office that are associated with more complete immunization of children?
- How should those characteristics be measured?



Selected SCPPRN Publications

- Lemon HM, Darden PM. Measuring Practice Immunization Rates Quickly and Accurately in the Era of HIPAA: Validation of the Quick Count Method in Practice Settings. *Journal of the South Carolina Medical Association*, (August) 2008:104(6);194-197.
- *Hocevar S⁴, Kennedy SA⁴*, Darden PM, Reigart JR. Headache in Children. *Journal of the South Carolina Medical Association*, (August) 2008:104(6);191-193.
- Basco WT, Hletko PJ, West L, Darden PM, for the South Carolina Pediatric Practice Research Network (SCPPRN). Determining the Proportion of Children Too Heavy for Age Appropriate Car Seats in a Practice-based Research Network. *Clinical Pediatrics*

Selected SCPPRN Presentations



- *Kennedy SA⁴, Gustafson KK, Reigart JR, **Maria BL**, Darden PM.* Prevalence of Headache (SCPPRN). Presented, Pediatric Academic Societies Meeting. Toronto, Canada, May 2007.
- *Lemon HM, Darden PM.* Measuring Practice Immunization Rates Quickly, Accurately and Confidentially (SCPPRN). Presented, Pediatric Academic Societies Meeting. Toronto, Canada, May 2007.
- *Reigart JR, Hocevar SN⁴, *Kennedy SA⁴, **Maria BL**, Darden PM.* Prevalence of Diagnosis of Headache in SCPPRN and the National Ambulatory Medical Care Survey (NAMCS) ; a Cause for Concern and Opportunity for Intervention. Presented, AHRQ Annual Practice-based Research Network (PBRN) Research Meeting, Bethesda, MD, May, 2007.*

SCPPRN

Presentations or ...

- *McElligott JT⁴*, Darden PM. Patient-Held Vaccination Records; Do They Improve Vaccination Coverage Rates? Southern Societies Meeting, New Orleans, LA, February 2008. Submitted, Pediatric Academic Societies Meeting. Honolulu, Hawaii, May 2008.
- *Mennito S⁴*, Darden PM. The Impact of Practice Policies on Pediatric Immunization Rates. Southern Societies Meeting, New Orleans, LA, February 2008.
- *Kennedy SA⁴*, Darden PM. Vitamin D Levels and Infection in Children: Data from 2003-2004 NHANES. Submitted, Pediatric Academic Societies Meeting. Honolulu, Hawaii, May 2008. (**Bruce Hollis** and **Carol Wagner**)



Lessons Learned:

1. Network participants generate ideas
 1. Paul Hletko – car seat proposal, dental varnish
 2. Abe Moskow – developmental screening
 3. Francis Rushton – psychosocial screening
2. Subspecialists generate ideas
 1. Bernie Maria – Headache/Migraine
 2. Carol Wagner and Bruce Hollis – Vitamin D and infection
3. Trainees are invaluable
 1. Fellows – Shannon Kennedy, Susan Hocevar, Jimmy McElligott, Sarah Mennito
 2. Residents –?



APA and Research Networks

- APA – Academic Pediatric Association
 - CORNET – **C**Ontinuity **R**esearch **NET**work (CORNET)
 - Janet Serwint
 - http://www.ambpeds.org/Site/research/research_cornet.htm
 - PRIS - **P**ediatric **R**esearch in **I**npatient **S**ettings (PRIS) Network
 - Chris Landrigan
 - http://www.ambpeds.org/Site/research/research_PRIS.htm

PBRN – Challenges

- Support
 - Infrastructure
 - Study specific
- Human subjects





Oklahoma

- Oklahoma Physician Resource/Research Network (OKPRN) – Jim Mold
- Laura McGuinn
- J. W. Hendricks – Chapter President, Oklahoma AAP



“The Cow Pock – or – the Wonderful Effects of the New Inoculation!”

J. Gillray, 1802