Patient Recruitment: Challenges, Trends and Best Practices

April 28, 2010

Multi-Grantee Open Forum #3

AHRQ National Resource Center for Health IT

Agenda

- Welcome and Overview of AHRQ Technical Assistance
  - Barbara Lund, AHRQ NRC TA Lead, Massachusetts eHealth Collaborative
  - Vera Rosenthal, AHRQ NRC, Junior Service Fellow
- Format for Today's Session
- Grantee and Presenter Introductions
- Presentations
- Response from Grantee Discussants
- Group Discussion

Overview of AHRQ Technical Assistance

- Goal: To support grantees in the meaningful progress and on-time completion of Health IT-funded grant projects
- Technical Assistance (TA) services include
  - One-on-one grantee technical assistance
  - Multi-grantee open forum technical assistance
- Multi-grantee open forums
  - Webinars focused on topics of interest for groups of grantees
  - Format includes presentations by subject matter experts, peers and peer-to-peer discussion
  - We welcome your ideas for future webinars

Key Resources

- AHRQ National Resource Center for Health IT
  - www.healthit.ahrq.gov
- AHRQ Points of Contact
  - Vera Rosenthal, vera.rosenthal@ahrq.hhs.gov
- AHRQ NRC TA Team
  - Erin Grant, Booz Allen Hamilton, grant_erin@bah.com
  - Barbara Lund, Massachusetts eHealth Collaborative, *NRC-TechAssist@AHRQ.hhs.gov*
  - Jessica Kriss, Booz Allen Hamilton, kriss_jessica@bah.com
- AHRQ NRC Project Monitoring and Reporting Team: John Snow Inc.

Format for Today's Session

- Brief introduction of each grantee on the call
- Questions and discussion
  - We encourage interaction among presenters and attendees during the call; time for questions after each presentation and at end of call
  - Questions may also be submitted at any time via 'Chat' feature on Webinar console
- During the presentations, you may wish to mute your line (*6 to mute, *7 to un-mute)
- Do not put call 'on hold'
- Discussion summary will be distributed to attendees
- Formal, brief evaluation is requested from each attendee – sent directly from ReadyTalk at conclusion of Webinar

Grantee Introductions

- Name, Organization, Project PI
- Very brief description of your AHRQ Project
- Note any Patient Recruitment issues for discussion

Today's Presentation

Patient Recruitment:
Challenges, Trends and Best Practices

Presenters and Discussants

- **Presenters**
  - ***Margaret Rukstalis, MD,*** **Geisinger Health System Center, University of Pennsylvania School of Medicine**
  - ***Jonathan Wald, MD, MPH,*** **Partners HealthCare System**

- **Discussants**
  - ***Alfred Bove, MD, PhD,*** **Temple University**
  - ***Silke von Esenwein, PhD,*** **Emory University**

Patient Recruitment: Setting the Stage

Recruitment Components	Challenges
Recruitment Strategies	• General resistance to participating in research studies • Recruitment materials should be designed to meet the needs and literacy levels of the target participants – may be costly • 'Active' recruitment methods more effective but more costly
Identifying and targeting participants	• Recruiting specialty populations • Recruiting in urban settings • Language barriers
Obtaining consent	• Communicating complicated information during the consent process • Slower pace of recruitment than expected • IRB approval process can be cumbersome

Patient Recruitment: Setting the Stage

Recruitment Components	Challenges
Using technology	• Training on the project's health IT application may take longer than expected
Recruiting 2.0	• Efficacy of using online recruiting (e.g. Google ads, Craig's list, etc.) • Privacy & security issues related to using social media for recruitment
Retaining participants	• Ongoing engagement during study • Offering adequate and appropriate incentives • Supporting partner organizations during study

Patient Recruitment

Margaret Rukstalis, MD

Geisinger Health System Center

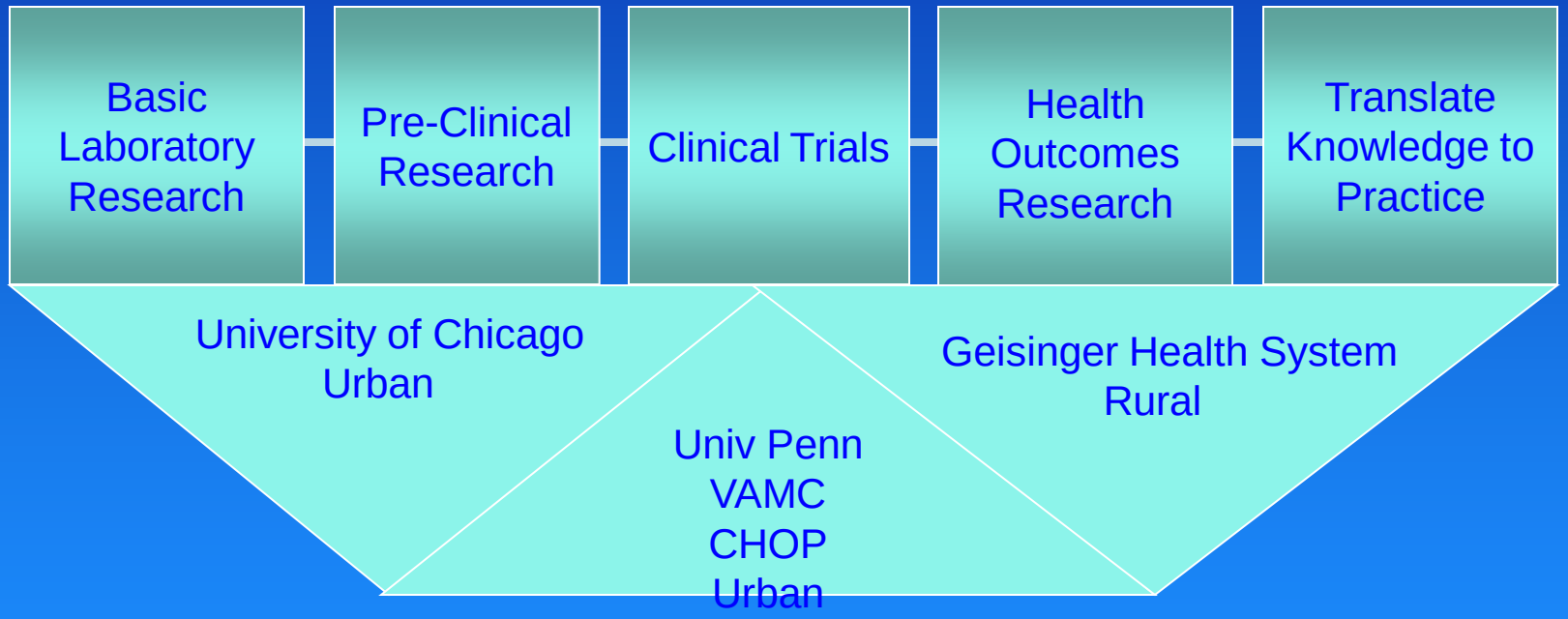
University of Pennsylvania School of Medicine

Recruitment: Art & Science

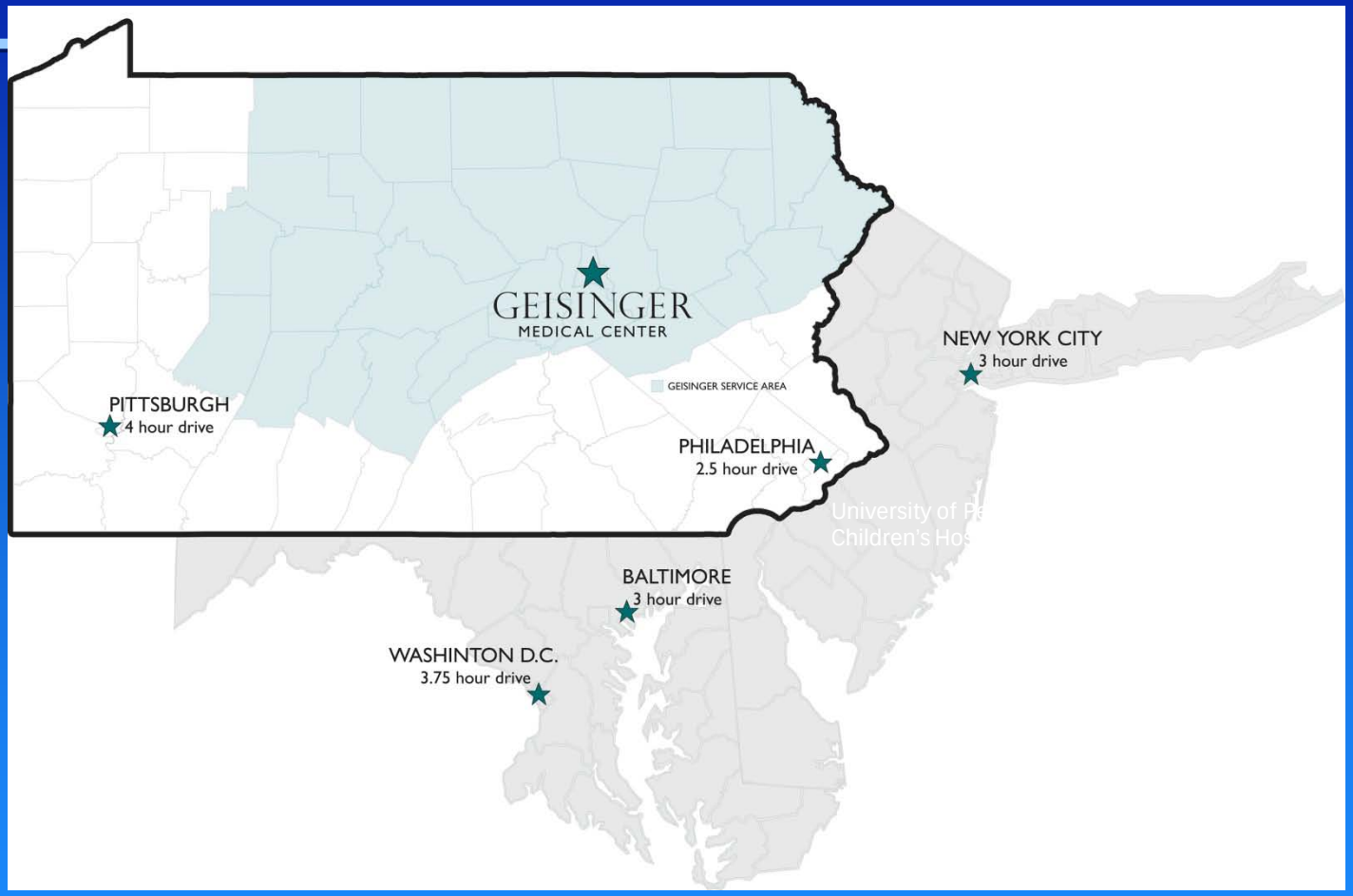
- Set Up
- Methods
- Identify Participants
- Lessons Learned

Recruitment

Translational



- Synergy with clinical enterprise
- Patient population and EHR

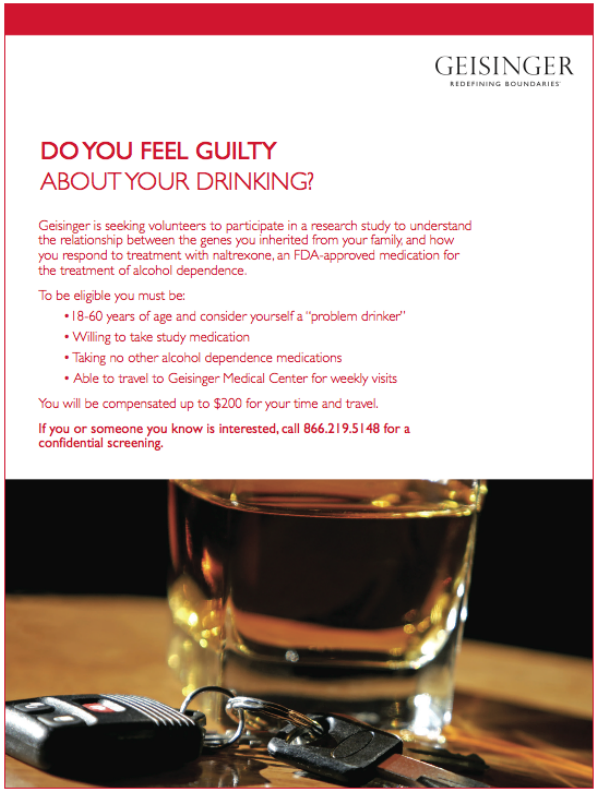

GEISINGER
MEDICAL CENTER
GEISINGER SERVICE AREA
PITTSBURGH
4 hour drive
PHILADELPHIA
2.5 hour drive
NEW YORK CITY
3 hour drive
BALTIMORE
3 hour drive
WASHINTON D.C.
3.75 hour drive

Set Up

- Budget (costs) & IRB approval
  - Content
  - Location/Venue
- Decision maker approval
  - Via letter signed
  - Ads may require approval stamp
  - Handouts sent home to parents need principal and superintendent approval

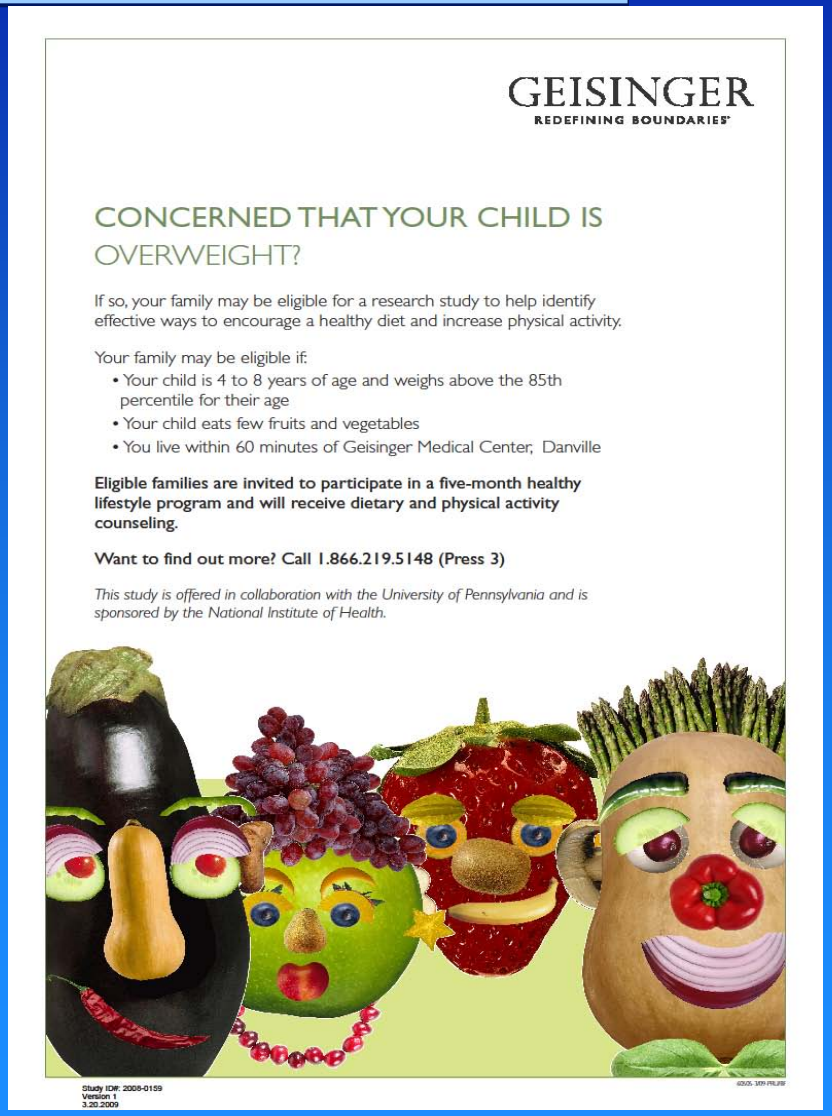
Example: IRB and PR approved this poster, but hospital administrator did not like the photo

  - Photo had to be removed to post



Set Up

- Involve Public Relations
- Use FREE options often
  - Website Ads
  - Press Releases
  - Talks
- Monitor dose, response:
  - Strategy frequency
  - Source of referral
  - # calls, # consents



GEISINGER
REDEFINING BOUNDARIES®

CONCERNED THAT YOUR CHILD IS OVERWEIGHT?

If so, your family may be eligible for a research study to help identify effective ways to encourage a healthy diet and increase physical activity.

Your family may be eligible if:

- Your child is 4 to 8 years of age and weighs above the 85th percentile for their age
- Your child eats few fruits and vegetables
- You live within 60 minutes of Geisinger Medical Center, Danville

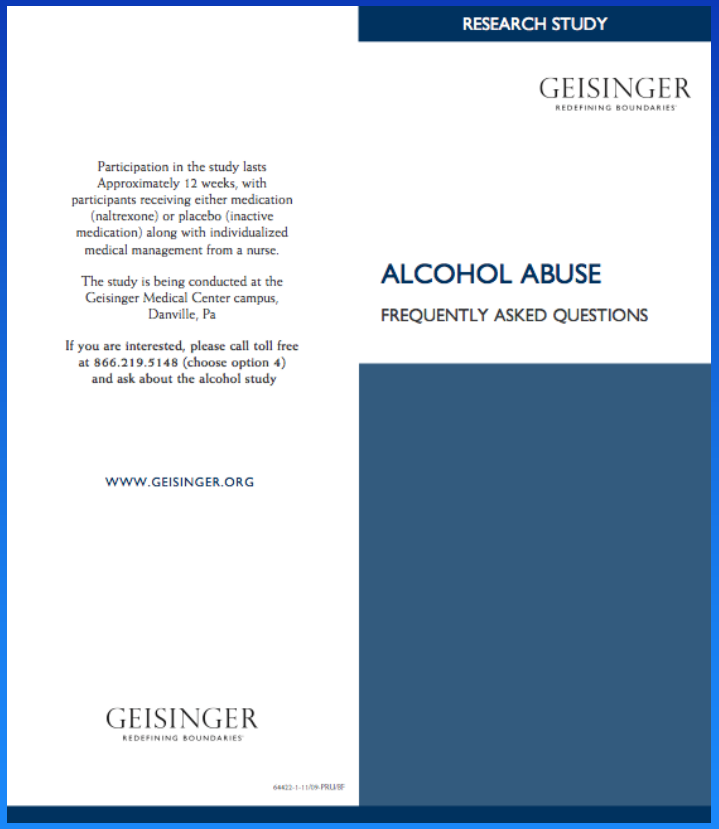
Eligible families are invited to participate in a five-month healthy lifestyle program and will receive dietary and physical activity counseling.

Want to find out more? Call 1.866.219.5148 (Press 3)

This study is offered in collaboration with the University of Pennsylvania and is sponsored by the National Institute of Health.

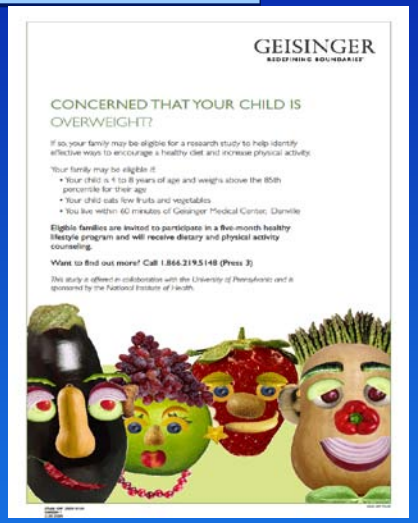
Traditional Methods

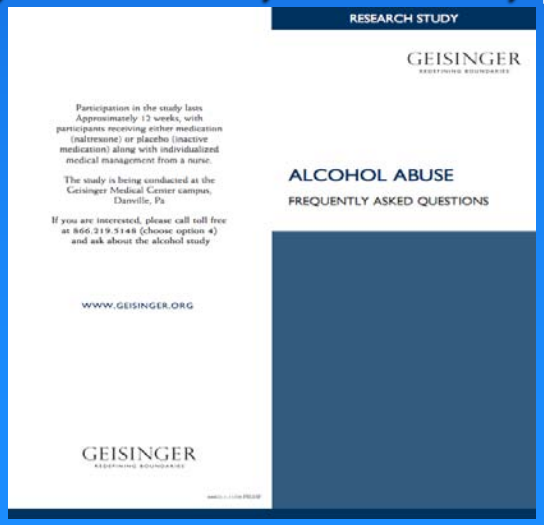
- Press releases
- Posters, brochures
- Mailings (mass, registry)
- Ads (TV, radio, newspaper)



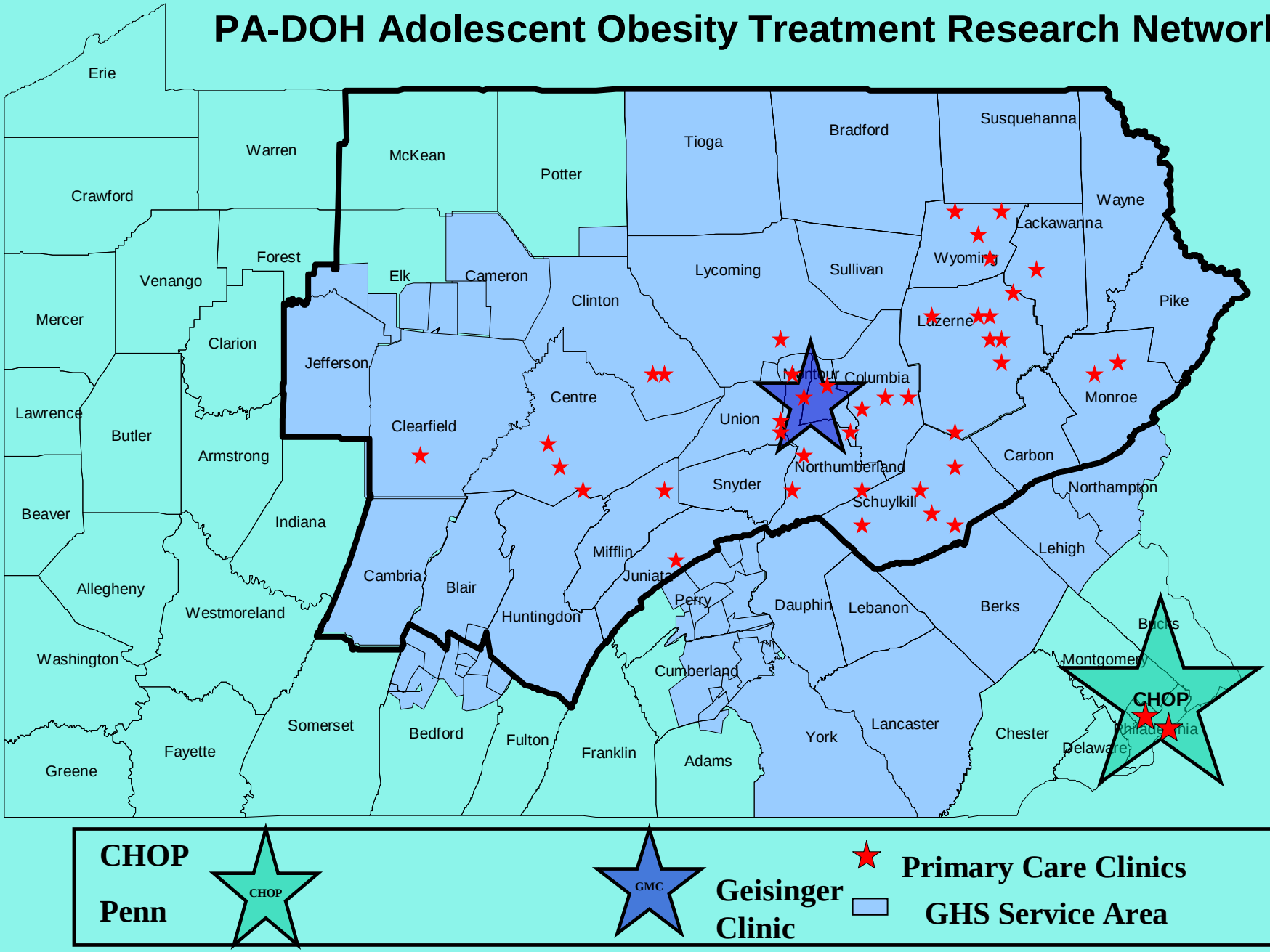
Traditional Methods

- Community communications:
  - Bulletins
  - School newsletters, handouts
- Word of mouth:
  CME, booths, clinics, provider education



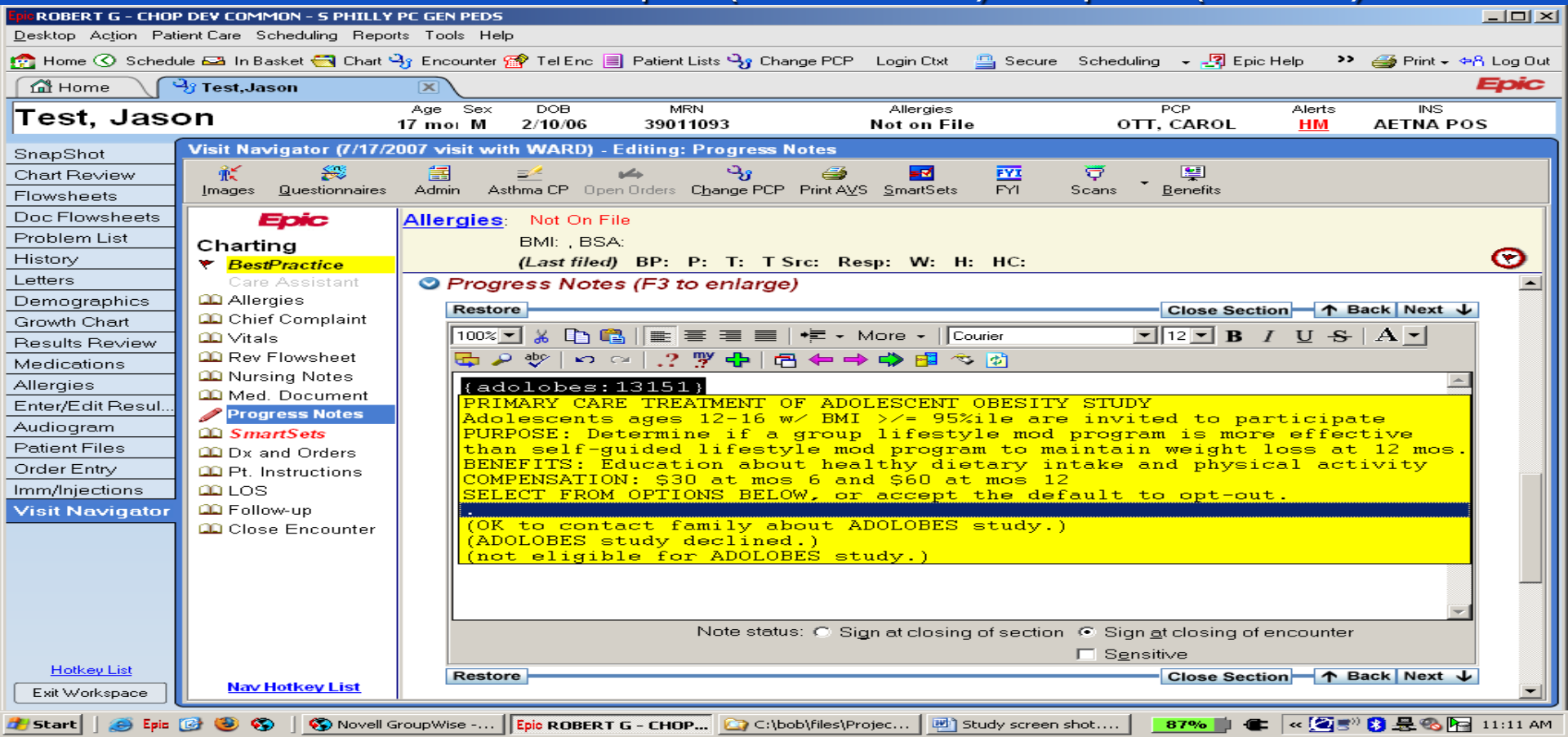


PA-DOH Adolescent Obesity Treatment Research Network



IT Methods: Disease Registries

- Electronic Medical Records/Disease Registries
  - Search for Inclusion, Exclusion criteria
  - Letters to eligible participants: low cost, high yield
- Electronic Provider alerts: opt in (OK to contact) vs. opt out (declined)



IT Methods: Web Tools

- Health System/Employee/Community web sites:
  - Ads
  - Pod Casts
- NIH Clinical Trials.gov
- Email: patient portal electronic invitations (eVites)
  - MyGeisinger.org
    - eVite
    - Interventions
  - Patient Gateway
    - Online consents
    - Assessments
    - Interventions

Subject: A New Diabetes Day Research Study

Your Geisinger doctors invite you to participate in “A New Diabetes Day” research study to improve healthy eating & physical activity for Type II Diabetics.

Click here to learn more or call: 1-800-New-Diab

Identify Participant Sources

- Disease specific registry letters
  - Call if interested (opt in)
  - Call if not interested (opt out)
- Health Care Organizations: in person
  - Routine office visits
  - Inpatients
- Existing patients/groups: in person
  - Informally, ask questions about how to best reach
  - Ask for in person referrals to study
  - Attend formal groups
  - Create focus groups to collect strategies for recruitment

Monitor Source of Referrals

	Letter from EHR	Employee Website Ad	PCP Referral	Other
Calls (N=92)	55	17	1	19
Eligible After Phone Screen (N=51)	45	5	1	0
Consents (n=38)	33	4	1	0

Top 3 Challenges in Recruitment

- Budget:
  - Use Public Relations
  - Free Public Announcements, talks
  - Web tools
- No calls: need to locate target
  - Country western/sports radio ads for alcoholics
  - Try posters with tabs in private spaces
  - Opt out letters: we call you phone screen team
- Time:
  - Monitor recruitment efforts
  - Try more than 1 strategy at a time
  - Consider outside help (call center, recruiters)

Lessons Learned

- Maximize free/low cost recruitment
- Use health literacy lessons in ads/letters
  - 5th grade reading level
  - Short sentences or bullets
  - Action verbs
- Tailor media ads to audience
  - Sports & country radio stations for alcoholics
  - Grocery stores, day cares for mothers
- Track dose/response per recruitment strategies

Questions?

Patient Recruitment

Jonathan Wald, MD, MPH

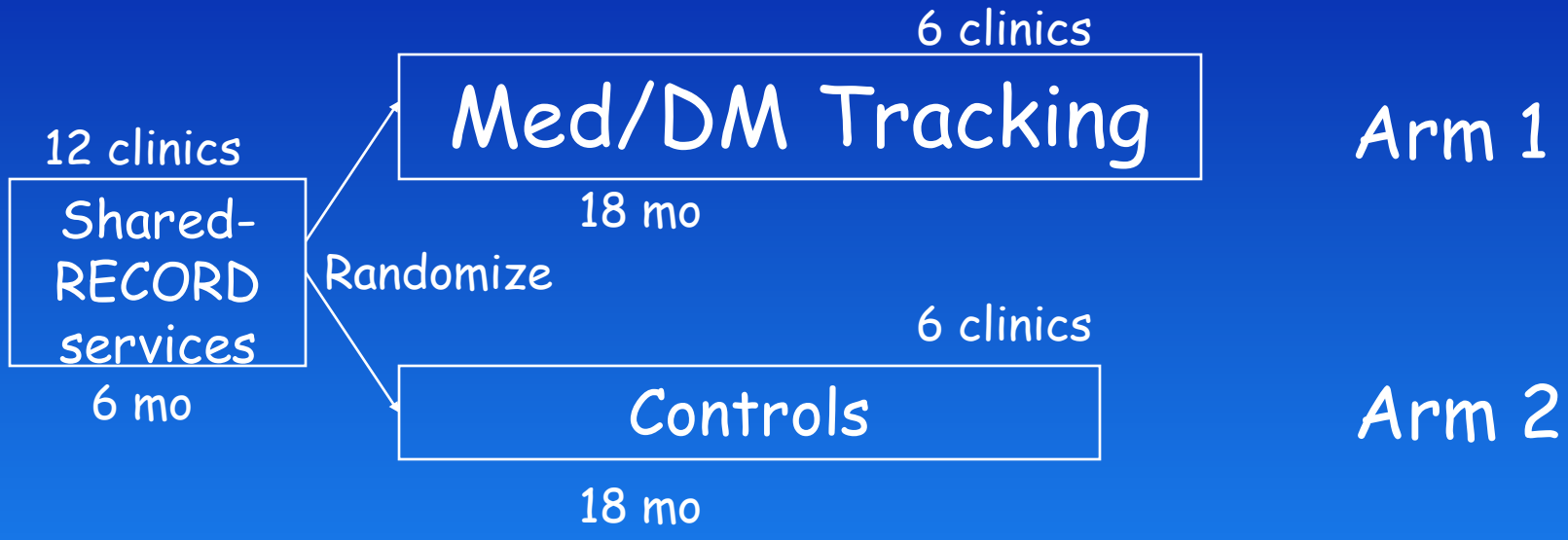
Partners HealthCare System

Prepare for Care

Study description

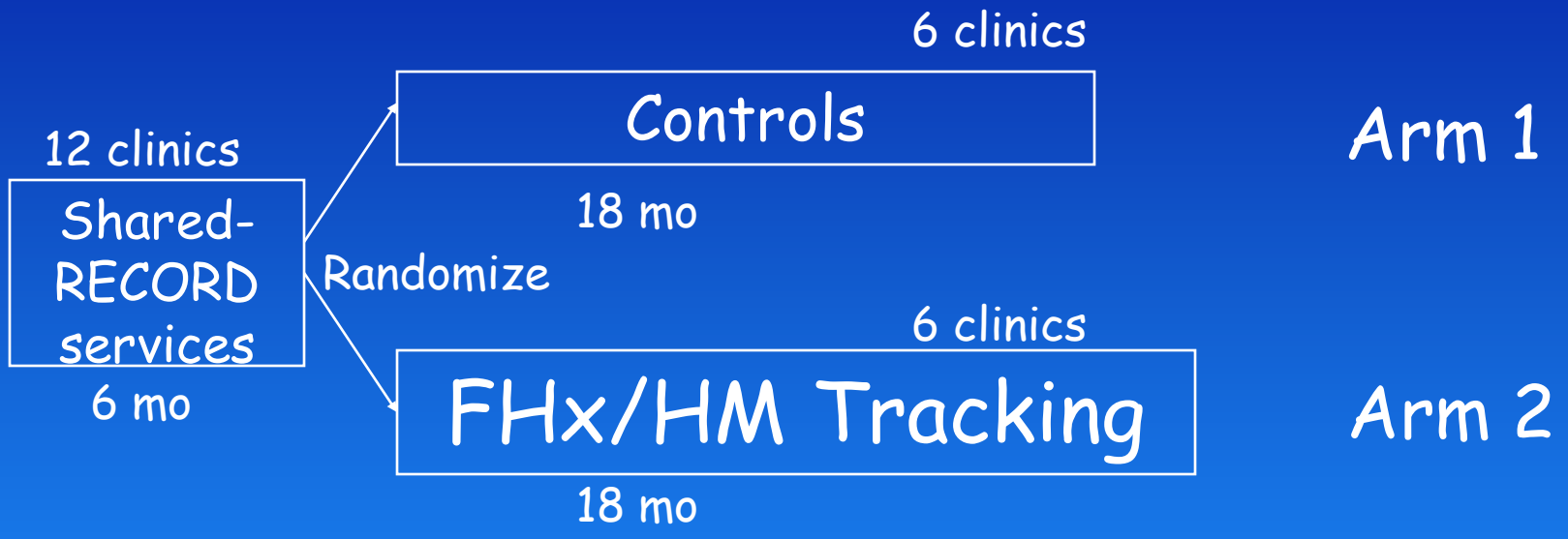
- RCT using an EHR-connected PHR, 2005-2007
- Flow
  - Patients sign up for PHR > Study invitation > Online consent > Qualifying appointment > Invited to use pre-visit eJournal > Submit the eJournal before a visit
  - Providers open/review the eJournal, complete the visit, and document visit-based care
- Study methods/metrics
  - Chart review – for clinical outcomes
  - Pre- and Post-surveys – for user experience
  - Usage data – for many process measures

Prepare for Care



- Multiple parallel trials
- Unit of analysis varied
  - Visit-based, patient-based, practice-based

Prepare for Care



- Multiple parallel trials
- Unit of analysis varied
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Study Outcomes

- Study patients who use eJournal/physician's EMR to share health information and communicate will have improved:
  - **Clinical Outcomes** [PRIMARY]:
    - ↓ADE rate (1.1), faster amelioration of side effects (1.2))
    - ↑outcomes for diabetics: HbA1C and BP (2.1)
    - ↑Adherence to guidelines in HCM (2.2) and DM (2.3)
    - ↑Detection of risk factors from family history (3.1)
  - **EMR Documentation** [SECONDARY]:
    - ↑correctness/completeness of medications and alternative therapies (1.3)
    - ↑HCM and diabetes screening documentation (2.4)
    - ↑Family History documentation (3.2)
  - **Knowledge** [SECONDARY]:
    - ↑patient knowledge of their medications (1.4)
  - **Satisfaction and Use** [SECONDARY]:
    - ↑patient and physician satisfaction with care (4.1, 4.2)

Power Estimate

- Example
  - If 50% of patients are “at goal” for HbA1c at baseline, how much of a change can we detect with 2000 pts per Arm?

Table 3. Sampe Size Requirement, Per Arm, For 90% Power

Increase in the endpoint rate in the active arm:	Endpoint Rate in the Control Arm: 10%	15%	20%	25%	30%	35%	40%	50%
+ 3%	2929	3937	4806	5534	6127	6571	6880	7076
+ 4%	1721	2281	2761	3163	3487	3731	3896	3991
+ 5%	1148	1501	1804	2057	2258	2410	2510	2561
+ 7%	632	808	956	1080	1178	1250	1296	1312
+ 10%	343	425	494	551	595	626	646	646
+ 15%	175	209	236	259	276	287	293	287

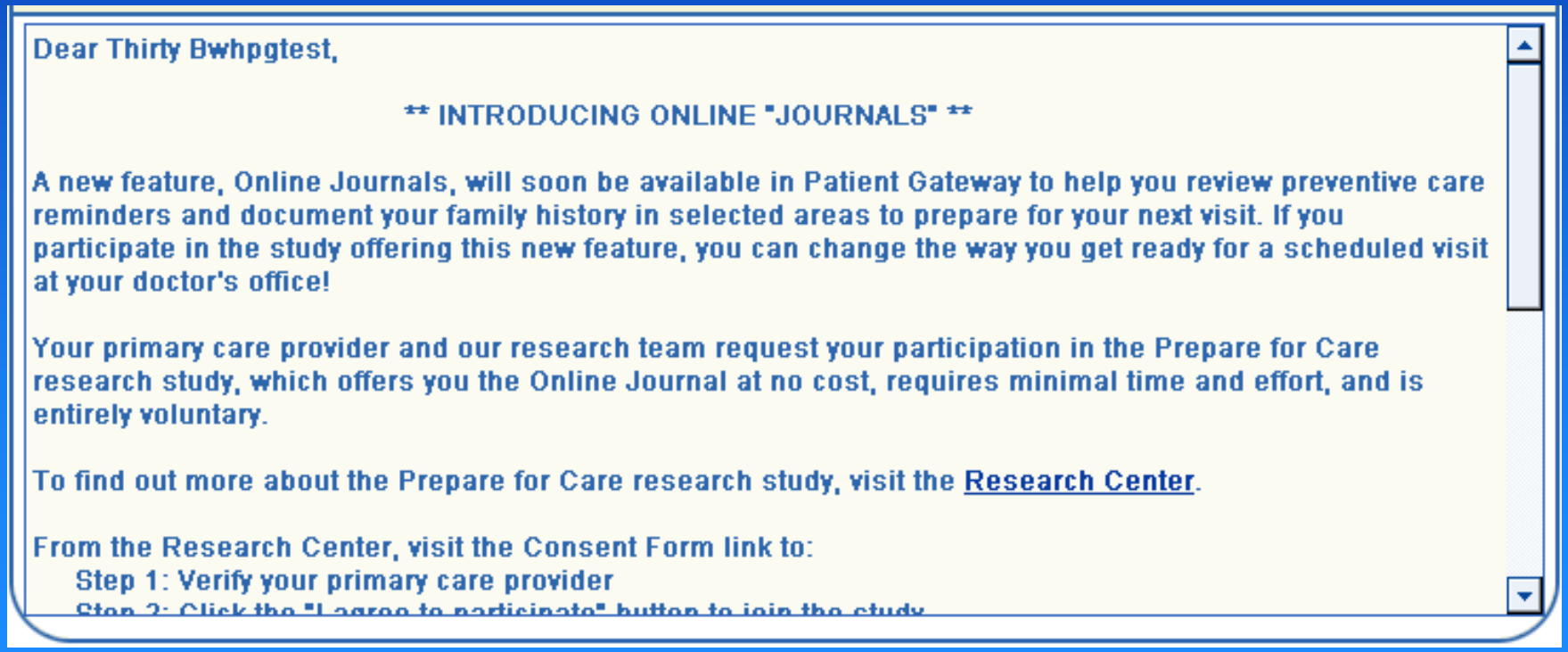
Given the anticipated number of patients who will participate in this trial (see prior description), the table indicates that we will have adequate power to detect intervention effects which improve reporting/recording rates by as little as 3 to 5%.

Recruitment

- Initial goal
  - 5400 consented patients
  - To get there…. 20,000 Patient Gateway (PG) users?
  - Would mean 384/week * 52 weeks
- Reality
  - ~190/week signups
  - Took 2 years
  - (We needed the development time anyway…)
- Methods
  - PG marketing: Practice-dependent
    - Phone, waiting room, postcards, physicians
  - Study marketing
    - Online only – via PG message
    - Online consent – IRB approved

Study Invitation

- Arm 2 patient invite to the study



Dear Thirty Bwhpgtest,

** INTRODUCING ONLINE "JOURNALS" **

A new feature, Online Journals, will soon be available in Patient Gateway to help you review preventive care reminders and document your family history in selected areas to prepare for your next visit. If you participate in the study offering this new feature, you can change the way you get ready for a scheduled visit at your doctor's office!

Your primary care provider and our research team request your participation in the Prepare for Care research study, which offers you the Online Journal at no cost, requires minimal time and effort, and is entirely voluntary.

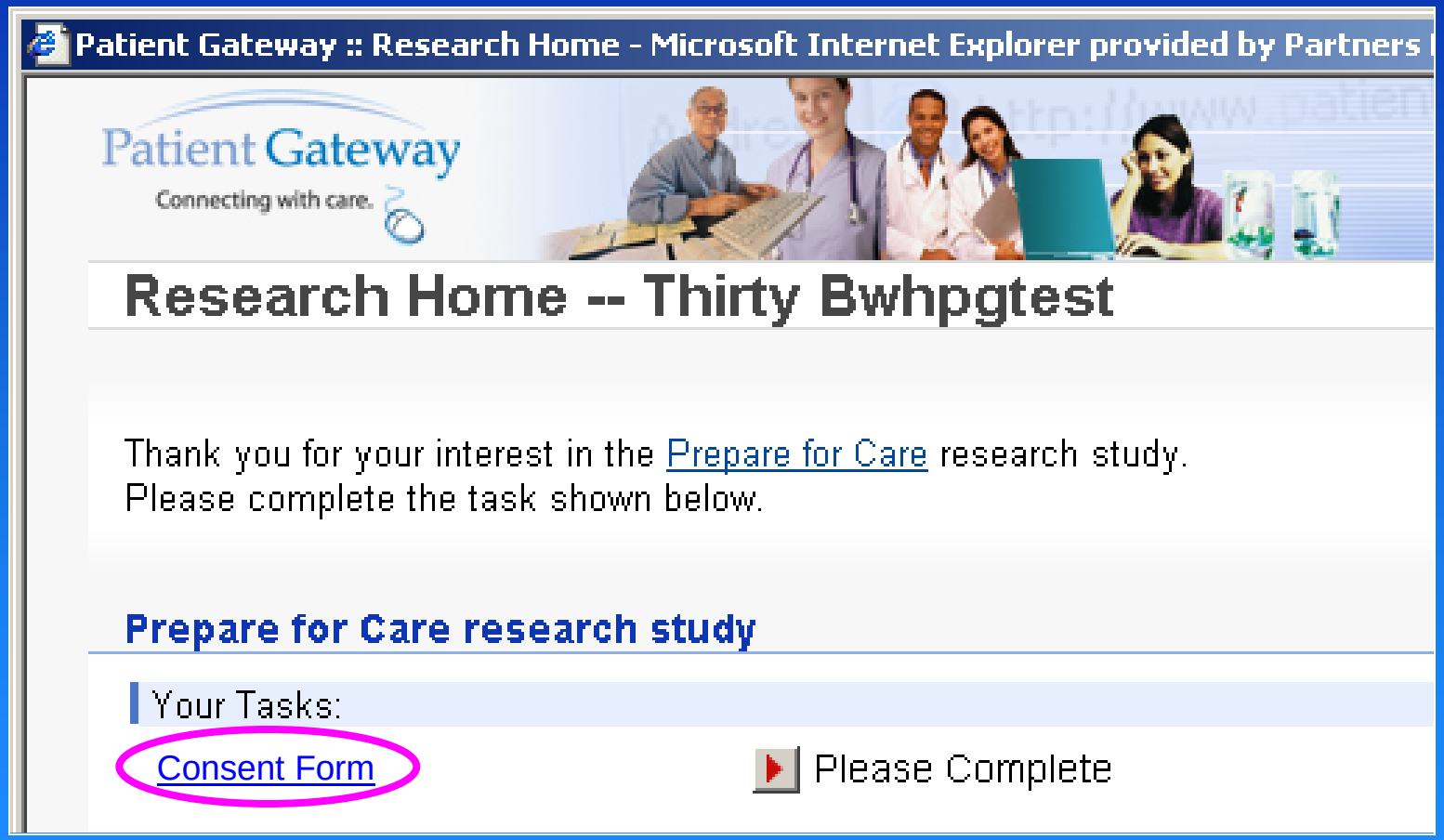
To find out more about the Prepare for Care research study, visit the Research Center.

From the Research Center, visit the Consent Form link to:

Step 1: Verify your primary care provider

Step 2: Click the "I agree to participate" button to join the study

Research Portal



Patient Gateway :: Research Home :: Consent - Microsoft Internet Explorer provided by Partners HealthCare System

PATIENT GATEWAY :: RESEARCH CENTER

CONSENT FORM

Please review the study information below and click a button telling us if you would like to participate, or not.

This research study has been reviewed and approved by the Partners Institutional Review Board.
IRB Protocol Number: 2002-P-001491/3. Approved 3/30/2005. Expires 6/21/2006.

Protocol Title: Shared Online Health Records for Patient Safety and Care
Principal Investigator: Blackford Middleton, MD, MPH, MSc
Site-Principal Investigator(s)/Institution: Dr. Blackford Middleton (BWH), Dr. Richard Grant (MGH)
Description of Subject Population: Patients seeking care at one of the MGH/BWH/PCHI study sites.

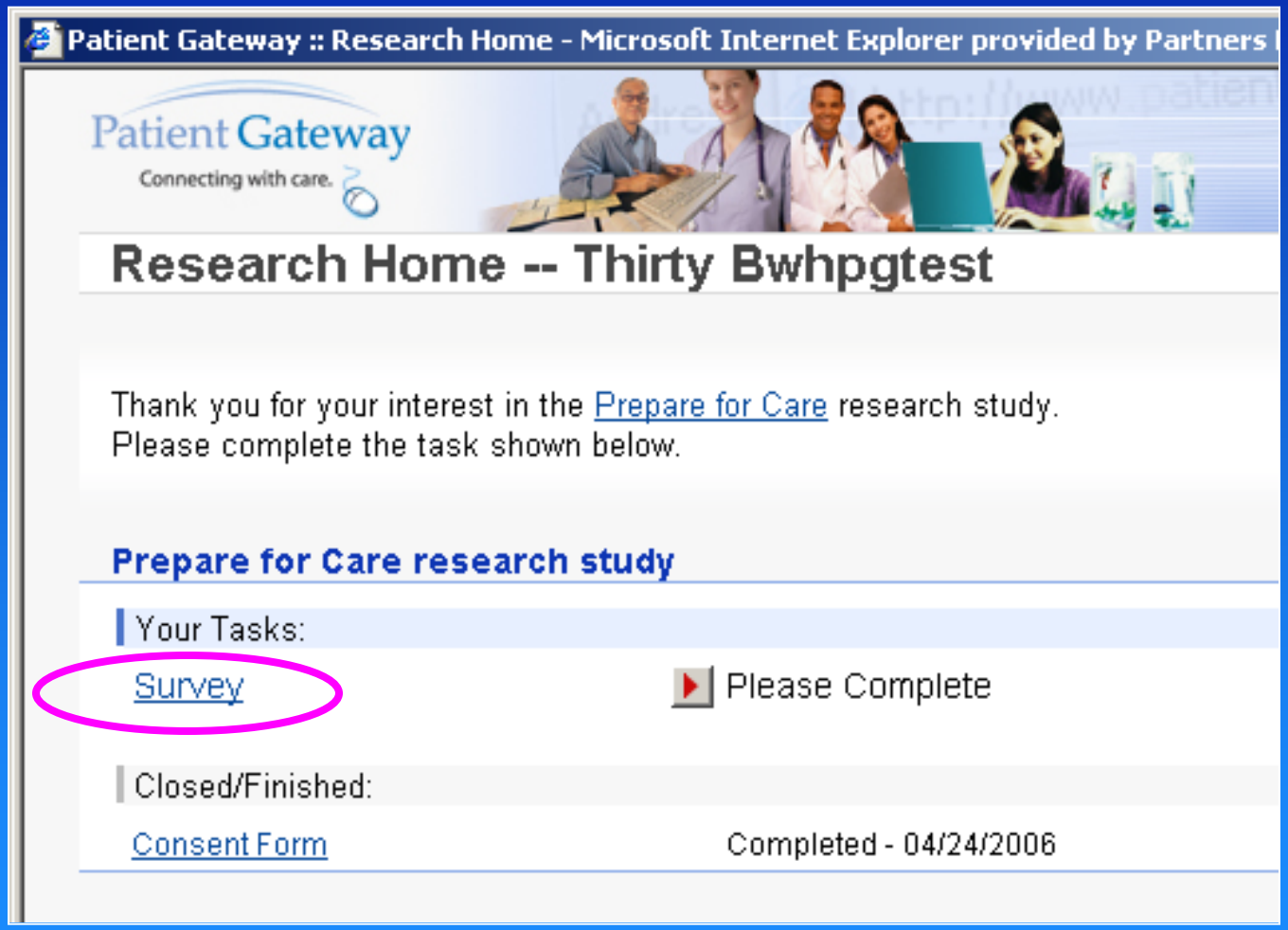
PURPOSE

We would like permission to enroll you as a participant in a research study concerning the quality of care patients receive with the use of new online tools. If you participate, you will be asked to use Patient Gateway to review personal health information such as your medications, screening tests to help you stay healthy, your family medical history, and if applicable, diabetes information. You were chosen to participate in this study because you have been enrolled in Patient Gateway. This study is important because many believe that patients and doctors can improve the quality of care and the way they work together using online tools like Patient Gateway, but few large studies have been done to show the benefits. This study is expected to have over five thousand participants and will be conducted over three years.

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts and potential benefits that I may experience have been explained to me. Alternatives to my participation in this research study also have been discussed. All my questions have been answered. I have read this consent form and understand that the Research Team is available to answer any questions I may have in the future. Clicking "I agree to participate" below indicates my willingness to participate in this study and my authorization to use and share with others my "protected health information" as described in the preceding paragraphs.

I agree to participate | I do not agree to participate | Print

Survey Link


Patient Gateway :: Research Home - Microsoft Internet Explorer provided by Partners
Patient Gateway
Connecting with care.
Research Home -- Thirty Bwhpgtest
Thank you for your interest in the Prepare for Care research study.
Please complete the task shown below.
Prepare for Care research study
Your Tasks:
Survey
Please Complete
Closed/Finished:
Consent Form
Completed - 04/24/2006

Patient Gateway :: Research Home :: Survey - Microsoft Internet Explorer provided by Partners HealthCare System

Patient Gateway
Connecting with care.

Back | Print | Close

Prepare for Care -- Survey

Research Home > Survey

Instructions

The survey takes approximately 15-20 minutes to complete.

If you would like to keep a record of your answers, please print your survey by using the "Print Survey" link at the top or bottom of the page. Please print before clicking the "Submit" button. Once you click "Submit", you will not be able to return to the survey to view or change your answers. If you close the survey without clicking "Submit" your answers will not be saved. For your privacy, Patient Gateway has a timeout feature that will end your session after 60 minutes of inactivity. Please be advised that if your session times out before you have submitted your survey, your data will be lost.

Please answer as many questions as you can, and click the "Submit" button. You do not need to answer all questions. Answer the questions by clicking on the box or circle that best fits your answer choice. You may have a family member or friend help you fill out this survey.

All information that would let someone identify you or your family will be kept private. You may choose to answer this survey or not. If you choose not to submit the survey, then you will not have access to the new Online Journal feature of the Prepare for Care study.

If you want to know more about this survey, please contact the Research Team at 781-416-9216 or by sending a message to the Research Desk through Patient Gateway.

In appreciation for your help with this study, please allow us to make a donation to the charity of your choice from the list below (check one):

- ○ The American Diabetes Association
- ○ The American Cancer Society
- ○ The American Heart Association

Alert on Home Page

Journal Link

Patient Eligibility

- Patient of a participating practice
- Signed up for Patient Gateway (PG)
  - Received invitation via PG
- Completed online consent form

- Completed pre-survey
- Each eligible visit - invited to view / submit eJournal
- Study closure: Invited to complete post-survey

Physician Participation

- Member of participating practice
- During the trial - did not leave a practice
- Post trial (for some analyses)
  - Had a patient who submitted an eJournal

Actual

- PG enrolled (invited) ~20,000
- Consented 20% (4000)
- Invited to start an eJournal 10% (2000)
- Opened the eJournal 7.5% (1500)
- Submitted the eJournal 6.8% (1360)

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- Providers receiving an eJournal 31%*
  - *Out of 272 providers in study practices

Lessons Learned

- Pre-intervention
  - Power calculations
  - Detailed walk-through of recruitment/consent process – anticipate drop-off
  - Start recruiting early – anticipate extending the trial
- During – maintain engagement
  - Engage, engage, engage
    - Patients, admin staff, physicians
  - Update recruitment estimates based on experience
  - Revise power calculations (if needed)
  - Lengthen the trial if needed (and possible)
- After
  - Hope to avoid changes in eligibility / disqualifications

Lessons Learned

- Whole practice vs. selected physicians
- Technology-oriented patients vs. not
- Small incentives may help
- Consider intensity of exposure (dose-response)
- Very useful to consult a statistician

Questions?

Recruiting for IT studies

Alfred A. Bove, MD, PhD
Temple University School of Medicine
Philadelphia, Pa

Challenges

- Digital Divide
- Medical Divide
- Medical Status
- Communication and Advertising
- Financial Reward

Digital Divide

- Underserved Communities
  - PCs in the home
    - About 50%
  - Community Centers
  - Libraries
  - Churches
    - Purchase PC for a church
    - Set up an ISP for study duration
  - Telephone – Internet connection
    - 30-40% using cell phone communications

New Message	BP	Pulse	Weight	BMI
	125/85	82	273	42.8
	130/80	85	273	42.8
	127/79	84	274	43.0
	122/77	92	274	43.0
	128/80	81	274	43.0
	118/85	89	225	30.6
	124/81	74	225	30.6
	125/82	76	224	30.4
	138/87	85	234	41.5
	132/73	72	190	28.9
	132/82	69	232	37.5
	127/78	65	150	23.5
	127/81	81	141	25.0

Medical Divide

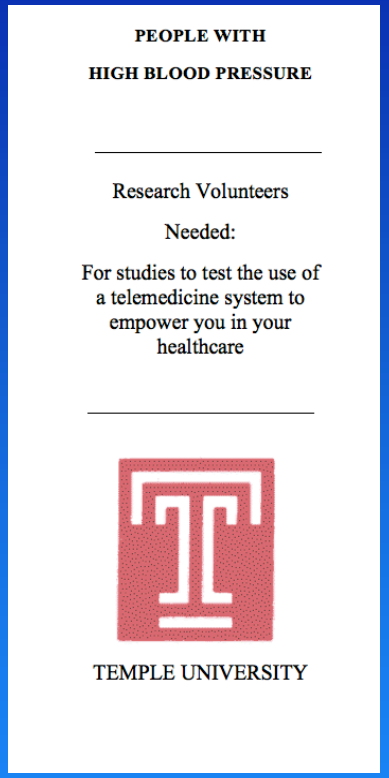
- Need for Health Education
  - Heart Failure
  - Hypertension
  - Type II diabetes
  - Hyperlipidemia
- Goals
  - Improved long term outcome
  - Self care
  - Patient empowerment

Health Status

- Overt CVD (heart failure)
  - Symptomatic
  - Chronic
  - Needs frequent surveillance
  - Patient must participate in care
- Occult CVD (hypertension)
  - Asymptomatic
  - Needs occasional surveillance

Communication/Advertising

- Local newspapers
  - Ads need IRB approval
- Radio
  - Ads need IRB approval
- Health Center bulletin boards
  - Patient ads - need IRB approval
  - Provider ads - do not need IRB approval



Communication/Advertising

- Clinics
  - Buy-in by clinic providers
  - Research staff chart review for eligibility
  - EHR review for eligibility
  - Personal provider recommends participation
- Health Fairs
  - Participation by Research staff

Financial Reward

- Needs IRB approval
- Not a payment for risk
- Not an enticement
- Cover usual expenses
  - Travel
  - Meals
  - Telephone calls
  - Incidental costs

Recruiting for an IT Study in Safety-net Mental Health Center

Silke von Esenwein, PhD

Benjamin Druss, MD (PI)

Emory University
Rollins School of Public Health

My Health Record Study

- Randomized trial of PHR vs. Usual Care for patients with serious mental illnesses with one or more chronic medical condition (n=150)
- Main Outcomes: Patient activation, quality of medical care, coordination of care.
  - Other outcomes: Health service use including ER use; recovery; medication adherence; quality of care
  - Setting: Inter-City public sector

Main Recruitment Strategies

- Participants from completed studies
- Focus groups
- Clinician referral
- Waiting room/flyers
- Word of mouth

Strategies

- Know your audience
  - Focus groups
- Good recruitment materials
- Language
  - Reading level
  - Avoid legalese and science talk

  (e.g., “Project” rather than “Study”)

Strategies

- Importance of participant benefit
  - Direct benefit
  - Helping other
- Good recruiters

Retention Strategies

- Small incentives for interviews
  - Increasing amounts
- Incentives for updating contact information
- Regular contact
  (e.g., reminder cards, birthday cards)
  - Address correction request
- Determine barriers

Increasing Clinician Buy-in

- “Lunch and Learns”
- Promotional materials
- Providing feedback on referrals

Questions?

Group Discussion

- We welcome your questions and comments
- Be sure to un-mute your line before you speak (press *7)

Final Comments

- Discussion Summary
  - Will be distributed to all Webinar participants
- Evaluation Form
  - Will be sent to each participant directly from ReadyTalk at conclusion of Webinar
  - We value your input
  - Thank you for joining us today!

Some Useful Resources

- "Registries for Evaluating Patient Outcomes: A User's Guide", Chapter 7. Patient and Provider Recruitment and Management," Prepared for AHRQ by Outcome Sciences, Inc, 2007
  - http://library.ahima.org/xpedio/groups/public/documents/government/bok1_037334.pdf
- "A Feasibility Study for the Computerized Recruitment of Subjects for Research Studies", Gerard Jenkins, MS and Dominik Aronsky, MD, PhD, 2005
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1560824/?tool=pubmed
- "Development of an Electronic Health Record-based Clinical Trial Alert System to Enhance Recruitment at the Point of Care", Peter J. Embi, MD, MS, Anil Jain, MD, Jeffrey Clark, BS, Martin Harris, MD, MBA, 2005
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1560758/?tool=pubmed
- "Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials", Prepared for AHRQ by Johns Hopkins University Evidence-based Practice Center, 2005
  - http://www.ahrq.gov/downloads/pub/evidence/pdf/recruitcantrials/recruit.pdf

Panelist Bios

Margaret Rukstalis, MD

Margaret Rukstalis is a board certified addiction psychiatrist, Clinician Investigator for the Geisinger Health System Center for Health Research and Rural Advocacy. She is also Adjunct Assistant Professor of Psychiatry at the University of Pennsylvania School of Medicine and serves on the executive committee as a Co-Investigator in the Penn Transdisciplinary Tobacco Research Center.

After she graduated from Dartmouth Medical School, Margaret did her residency training at Harvard Medical School (Internship) and the University of Chicago Department of Psychiatry. She did fellowships in clinical pharmacology at the University of Chicago and addiction psychiatry at the University of Pennsylvania.

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Jonathan Wald, MD, MPH

Jonathan Wald is Associate Director of the Clinical Informatics Research and Development (CIRD) group at Partners HealthCare System. The CIRD group provides leadership and expertise in advanced clinical systems development and deployment, including strategy, requirements and design, medical practice, and evaluation. He received his MD from Brown University (1988), a MPH degree at the Harvard School for Public Health (1994), and a BA from Dartmouth College (1983).

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Discussant Bios

Alfred A. Bove, MD, PhD, FACC

Dr. Bove is the immediate past president of the American College of Cardiology. He received his bachelor's degree in Electrical Engineering from Drexel University in 1962, and received the MD and PhD (Physiology) degrees from Temple University Medical School.

Dr. Bove practices Clinical Cardiology with particular expertise in heart failure and heart transplantation, Undersea Medicine and Sports Medicine.

His current research involves Internet based medical information systems for management of chronic heart disease in underserved urban and rural communities.
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Silke von Esenwein, PhD

Dr. von Esenwein received her PhD in Neuroscience and Animal Behavior from Emory University in 2005. She is currently overseeing several federally-funded grants in the research group of Benjamin Druss MD, MPH at the Rollins School of Public Health at Emory University. These projects are developing and testing new evidence-based strategies to integrate services and improve health in persons with serious mental illnesses.
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