



Community Engagement for a Population-Based Biobank: the Marshfield Clinic Personalized Medicine Research Project Experience

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Personalized Medicine Research Project

- Ultimate Goal:
 - Translate genetic data into specific knowledge about disease that is clinically relevant and will enhance patient care
- Short term Goal:
 - Establish database to allow research in genetic epidemiology, pharmacogenetics, population genetics





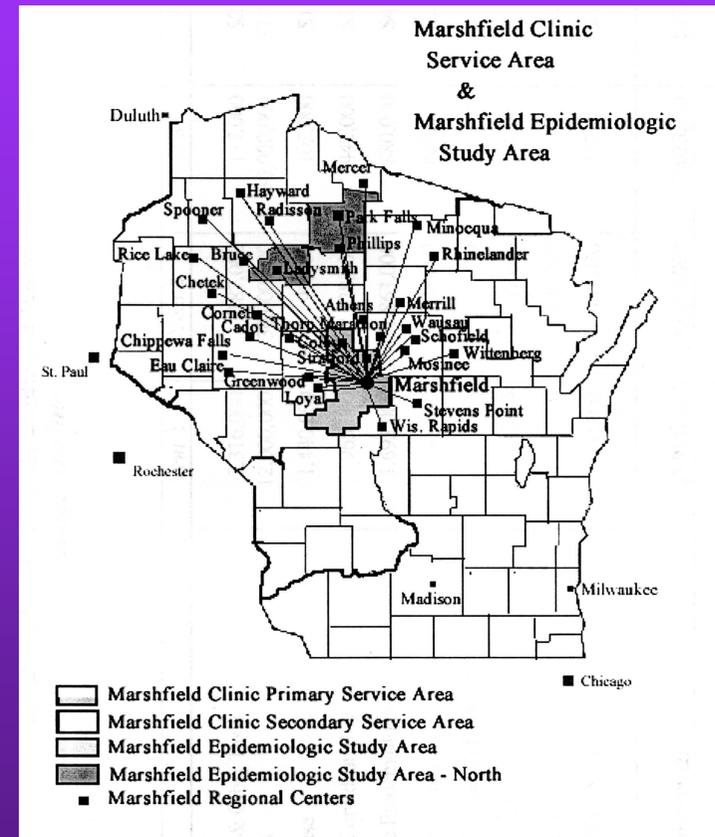
Personalized Medicine Research Project

- Phase I: Consultation and initial enrollment, completed April 2004
- Phase II: Creating the infrastructure for a national resource and expanding the database
- Phase III: Genetic discovery projects, physician and community education and consultation



Unique Aspects of Marshfield (Rural town of 19,000)

- Marshfield Epidemiologic Study Area (MESA)
- 75% have 20+ years of medical history, average 30 years
- MC system of care
- Extensive Electronic Medical Record (CMR) for two decades
- Security Health Plan to capture diagnoses outside Marshfield Clinic (55% overall)



Consultation Activities

- Ethics and Security Advisory Board
- Scientific Advisory Board
- Community Advisory Group

- Focus group discussions
- Talks to community groups
- Video in patient waiting areas
- Print and radio interviews
- Newsletters



Planning Focus Groups, 2001-2002

- Purpose: consider project, review materials
- Conducted off-site by outside agency
- Separate focus groups for employees
- Over arching themes:
 - Trust in the Marshfield Clinic
 - Opposition to human cloning
 - Concern about insurance discrimination
 - Confidentiality of data, particularly clinical data (Marshfield Clinic employees especially concerned)
 - Some would never participate regardless
- Recommendations: data security, simple materials



Security Provisions

- Encryption
- Security (physical and non-physical)
 - No one with access to identifiable medical information will have access to genetic data
- Marshfield Clinic Policy
- Wisconsin laws
 - 1991: health care, employment
- Certificate of Confidentiality obtained
 - Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals





Focus Groups With “Not Interested” Residents, 2003

- Conducted by a market research firm in 2003
- 4 groups: Spencer, Pittsville, Marshfield, Clinic staff
- Age- and gender-balanced
- Wide range of occupations
- Received \$75 for participation



2003 Focus Group Results

- 2 primary concerns:
 - Time to learn/enroll
 - Confidentiality (especially for employees)
- Perception: little or no benefit for time
- No or little awareness of PMRP
- Suggestions: more concise information, more money
- Response: new recruitment materials



Newspaper insert



RESEARCH HAS LONG BEEN THE BASIS FOR IMPROVING MEDICINE AND HEALTH CARE

- In as little as 30 minutes, you can contribute to medical research.
- You will be compensated \$20 for your time.
- Over 14,000 central Wisconsin residents have already enrolled.

WHAT IF, IN THE FUTURE, YOUR DOCTOR COULD:

- prevent or detect which illnesses you or your family have or are likely to get and design a personalized health care plan to diagnose and treat early
- diagnose diseases accurately and use medications and other treatments that would work best for each individual
- treat appropriately, avoiding medications that would cause you to have bad side effects

If you are 18 or over and living in one of these 19 ZIP codes, you are eligible.

54405	54420	54437	54454	54484
54410	54421	54441	54466	54488
54412	54425	54446	54771	54489
54415	54438	54449	54479	

If you would like to learn more about Marshfield Clinic's Personalized Medicine Research Project, what it is and is not, and how to participate, ask your health care provider or call **715-389-7733** or toll free at **1-888-334-2232** to talk with one of our research coordinators. Appointments are not necessary. Walk-ins are welcome.



"When I found out about the personalized medicine program, I saw the project as a good thing for the future. If participating benefits someone down the line, we should be doing these things. It goes hand in hand with what we do here at the Pittsville Fire Department. We help people. There is some personal satisfaction in helping people."

Bo Gled Jerry Meier

Bo Gled and Jim Chevrolet, Bob Wolf
Bo Gled and Jerry Meier, Jerry Meier, Paul Hessel

MARSHFIELD CLINIC.
Where the future of medicine lives



Community Advisory Group

- 20 members
- Initially 18-month appointments that were extended
- Selected to represent various demographics
- Compensation: travel, stipend
- Meet 2-5 times per year
- Provide advice on all aspects of the project
- Have added additional members
 - Patient advocate, members with genetic conditions in their family, young person, lawyer



Past CAG Discussions

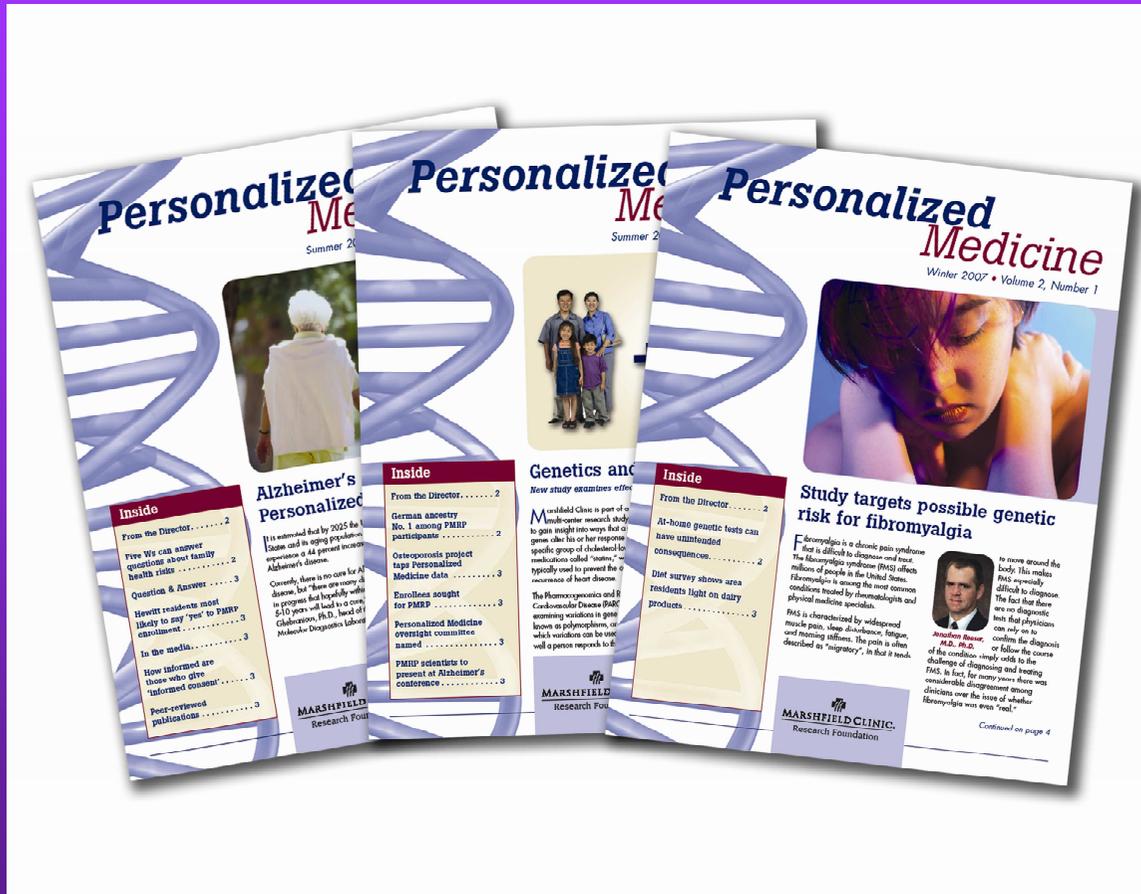
- RFI on proposed policy for sharing of data from GWAS
 - Supported the idea of sharing data
 - Concerned about using entire EMR
 - Certificate of Confidentiality needs to be honored
- Collaborations with industry
 - Very mixed reactions
 - Communication is key (purpose, who stands to gain, who directs research)
- Newsletter topics – FMS, internet genetic testing



CAG Discussions About dbGAP

- Some hesitation due to distrust of the government
 - e.g. VA laptop theft and breach of confidentiality
- NHGRI program officer spoke to the CAG
- CAG attended PRIMR webinar
- CAG reviewed consent form that allows for data and sample sharing
- Advised a newsletter article about dbGAP, wait for responses
 - One woman asked that her data not to go to dbGAP
 - Validated recommendation not to re consent





Personalized Medicine

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Alzheimer's Personalized

Marshfield Clinic is part of a multi-center research study to gain insight into ways that a gene other than the APOE4 gene affects Alzheimer's disease. Currently, there is no cure for Alzheimer's disease, but "there are many clinical trials in progress that hold promise for new treatments," says Dr. David M. Holtzman, M.D., head of Marshfield's Department of Neurology.



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Study targets possible genetic risk for fibromyalgia

Fibromyalgia is a chronic pain syndrome that is difficult to diagnose and affects millions of people in the United States. The fact that there are no diagnostic tests that physicians can rely on to confirm the diagnosis of the condition adds to the challenge of diagnosing and treating considerable disagreement among clinicians over the issue of whether fibromyalgia was even "real."



to move around the body. This makes it difficult to diagnose. The fact that there are no diagnostic tests that physicians can rely on to confirm the diagnosis of the condition adds to the challenge of diagnosing and treating considerable disagreement among clinicians over the issue of whether fibromyalgia was even "real."

Continued on page 4



Future CAG Discussions

- Revise consent form
 - Describe dbGAP
 - Address access to stored pathology samples
 - Not legally part of consent form
 - Apply for waiver of consent?
 - Focus groups/surveys or interviews?
 - Allow access to remainder of clinical samples
 - Opt-out?
- Term limits
- Consider inclusion of children



Ethical, Legal & Social Issues (ELSI) Research Project

- Survey of 1593 PMRP subjects (10%)
- Males and younger subjects significantly more likely to answer incorrectly
- 34% felt \$20 greatly influenced decision to participate
- 46% unaware or unsure about access to medical records
- 61% unsure or thought that they would learn what conditions they will develop
- Response: further education at time of consent and in newsletter



Study Logistics

- Recruitment commenced September 2002
- MESA residents aged 18+ contacted by letter and phone
- Saturday and evening times, regional centers
- Spanish interpreter
- 30 minute appts
- Written informed consent and questionnaire
- Blood draw for DNA extraction, plasma and serum
- \$20 reimbursement for expenses (10% return)
- Dietary intake and physical activity questionnaires (\$10)
- Nearly 20,000 enrolled





Opt-out on Consent form

- 159/18,823 (0.8%) participants asked to not be contacted for future studies
- 67% agreed to complete dietary and physical activity questionnaires when asked



Process to Access Samples

- Feasibility request for phenotype
- Scientific merit review
 - External peer-reviewed funding mechanism OR Marshfield Clinic Research Committee
- IRB review/approval for all studies
- Oversight Committee to release samples
 - CAG did not want membership on the committee
- Material Transfer Agreement
- Funding is required for phenotyping and identification and retrieval of samples
- Data deposit within 6 months after completing analyses



Further Information

- www.mfldclin.edu/pmrp



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National Human Genome Research Institute

