



VIRGO News

A Newsletter of the Variation In Recovery: Role of Gender on Outcomes

Volume I, Issue II

May 2009

VIRGO Team Members —Jo Cecille Demarest and Monique Plinck

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Jo Cecille Demarest joined the VIRGO project in the summer of 2008



building on her extensive experience in project management and coordination while working on several large multi-site studies and community-based research projects focused on disease prevention, nutrition, respiratory health, diabetes, epidemiology, and environmental health. For six years prior to joining the VIRGO team, Jo Cecille managed APRNet, a regional practice-based research network. During that time, she was also Project Director of *A Lifestyle Change Program to Prevent Type 2 Diabetes* at the Yale School of Nursing.

Jo Cecille enjoys nature and wildlife, art and history, and has been frequently spotted doting over the mammoth donkeys residing in Guilford, Connecticut. Jo Cecille's greatest love however is her son, David, who shares her love of nature. After receiving a degree in environmental science, David began his own company focusing on sustainable mushroom cultivation and using fungi for bioremediation and improving water quality. He lives in a self-built straw bale house in upper Vermont. Jo Cecille's volunteer activities have included serving as an EMT for the local ambulance service and as a religious instructor for incarcerated youth.

Monique Plinck brings 17 years of experience in the health industry to VIRGO; with training in regulatory filings, project coordination, business system analyses and customer service. Always available to answer a question or direct a call, she has worked with every site as the team's site agreement liaison and supports the project's toll free line and e-mail address.

Monique was previously owned by 2 Great Danes and a Rottweiler, but now lives with 4 dogs, 2 cats and a 90 gallon salt water aquarium. Dur-



ing her personal time, Monique can also be found showing her award winning dogs in agility competitions all over the Northeast as well as across the United States. Her youngest dog, a Papillion named Tiki, has qualified to compete at the United States Dog Agility International competition in Scottsdale, Arizona this November. Stay tuned as Monique and Tiki hope to represent the US in future International competitions.





**Note from Judith Lichtman, PhD, MPH
VIRGO Study Co-Principal Investigator**

We are very pleased with the ongoing progress of the VIRGO Study and wish to thank everyone

for scientific presentations and publications. We are pleased with the richness and quality of the data that has been collected so far and look forward sharing some initial findings with you as they become available over the coming months of the project.

for their contributions in making this research project possible. One of the greatest challenges of studying a relatively rare population is ensuring that the study is successfully implemented across multiple research settings. We appreciate the dedication you have shown during the start up phase and initial patient enrollment phases of the study.

We appreciate the thoughtful questions many of you have asked about the selection of the questions for the VIRGO baseline and follow-up interviews. Our team spent many months identifying research questions that could substantively improve our understanding of the presentation, care and outcomes of young patients with AMI. We thought it would be enjoyable to share our experience developing the VIRGO interviews with you through a series of informal conference calls. Each session will be led by one of our investigators familiar with the selected research topic.

With approximately 10% of the VIRGO baseline interviews completed, we have started our initial data processing and review of the collected data. This is the first step in developing the final VIRGO database that will be used

Brown Bag Lunch Series

You are invited to attend a series of brown bag lunches via conference call which will explore some of the research questions and preliminary findings. Each conference call will be capped with a modest audience of about 20 sites per call, so be sure to register early for the research topics listed below:

Date	Topic	Presenter
5/20/2009 1-2pm EST	Early Clinical Insights	Harlan Krumholz, MD, SM
6/1/2009 1-2pm EST	Rationale for the Sexuality Measures	Stacy Lindau, MD, MA
6/17/2009 1-2pm EST	Symptom Presentation	Judith Lichtman, PhD, MPH
7/1/2009 1-2pm EST	Influence of Depression	Judith Lichtman PhD, MPH
7/15/2009 1-2pm EST	Minorities in Studies	Erica Spatz, MD

To complement the brown bag lunch series, a listserv has been created to facilitate dialogue around the topics of discussion and areas of interest. To subscribe to the VIRGO listserv, please visit:

http://mailman.yale.edu/mailman/listinfo/virgo_discussion.

Variation In Recovery: Role of Gender on Outcomes of Young AMI Patients

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Enrollment Update

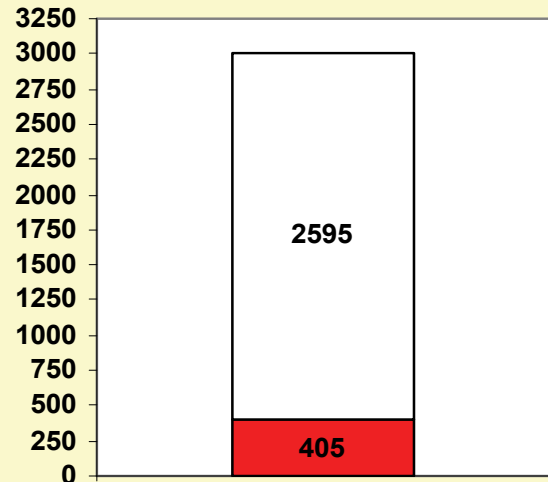
As of May 5th, we have **405** participants enrolled in VIRGO! **63** sites have enrolled at least 1 participant and an additional **17** sites are actively screening and awaiting their first eligible participant. **30** sites are still working their way through the IRB and site agreement process.

Leading the way with 27 enrolled participants is site #102 **Sentara Hospital**, followed closely by site #080 **Spectrum Health** with 24 and site #110 **Baylor Research Institute** with 20 enrolled participants.

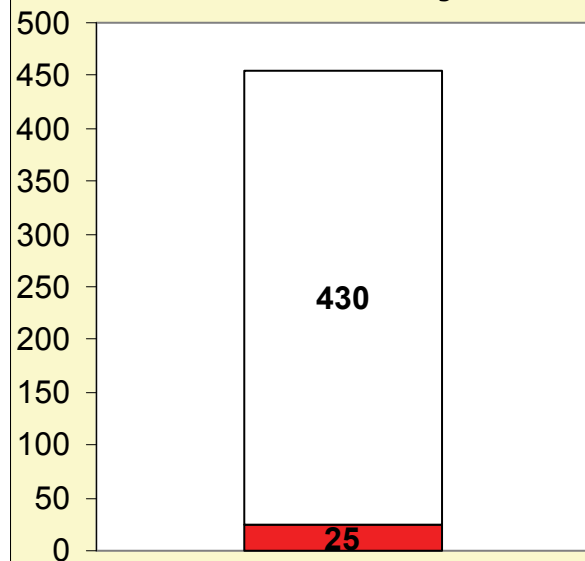
Among those sites with a small projected annual volume (≤ 20) of women less than 55 with AMI, site #208 **St. Elizabeth's** leads the pack with an astounding 12 participants enrolled. Once again we would like to send a special thank you to site #197 **Good Samaritan** which has enrolled 11 participants, exceeding their expected annual enrollment goal! Site #191 **Stanford University Medical Center** and Site # 202 **Saddleback Memorial Medical Center** have both enrolled 5 participants and are performing well above their monthly targets! Site #160 **Torrance Memorial Medical Center** is over halfway to their goals with 7 enrolled in 4 months.

Thank you to all of our sites who are actively screening! Please be on the lookout for your April Site Enrollment reports which will be sent out in early May. If you have any questions please feel free to contact the Yale Coordinating Center.

VIRGO Enrollment Progress



IMJOVEN Enrollment Progress



IM-JOVEN

Infarto de miocardio en la Mujer Joven (IMJOVEN), is a study in Spain that closely parallels VIRGO and presents an unprecedented opportunity to learn

about the presentation, clinical management, and outcomes for young patients with acute myocardial infarctions (AMI) internationally. IMJOVEN has adopted all VIRGO policies and protocols to ensure complete alignment and data quality across all sites, and will facilitate ancillary studies using data collected both in the United States and Spain. Through this partnership, IMJOVEN hopes to recruit 300 women and 150 men between 18 and 55 years hospitalized with an AMI in Spain. To date, 25 participants have been successfully enrolled in IMJOVEN since screening and enrollment began at 28 sites across Spain. For more information visit the Partnership link at www.virgostudy.org.

Ongoing Regulatory Activities and IRB Amendment Update

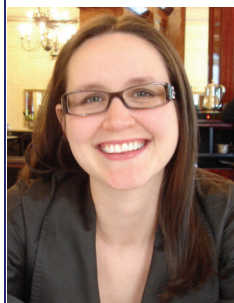
The most recent IRB amendment was made available to participating sites in late March via the VIRGO website (www.virgostudy.org). The website provides sites with instructions about the documents required for IRB submission for both new approvals as well as amending IRB approved applications. Also available on the VIRGO website are summary tables of amendment changes and tracked versions of both the protocol and consent form amendments.

Participating sites presently working from the 08/05/08 amendment will find a complete list of documents to submit to their IRB posted on the VIRGO website. Those sites working from an earlier or later amendment should contact the VIRGO Regulatory Specialist, Gabrielle Douglas, via email for this list of documents.

Reminders for ongoing activities:

- Remember to submit any consent form modifications to the VIRGO Regulatory Specialist prior to IRB review
- Use the track changes tool in Microsoft Word when making modifications to regulatory documents
- A copy of all IRB documentation is required by the VIRGO Coordinating Center, including a copy of approval letters, stamped consent forms, and approved protocols

Thank you for your continued patience and support. While the VIRGO Regulatory Specialist is working hard to meet IRB deadlines at participating sites, please be sure to allow for a two week turnaround for review. Please contact the VIRGO Regulatory Specialist if you have any questions or require assistance with regulatory activities.



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Kudos!

In late March and early April, the Yale Coordinating Center hosted a series of informal conference calls with participating sites to exchange ideas aimed at troubleshooting common enrollment bottlenecks encountered by sites nationwide. The Yale Coordinating Center is particularly grateful to Bonita Schneider of St. Elizabeth's Hospital in Illinois, Diane Jasso and Jessica Norcini of Pepin Heart Research Institute in Florida, and Stacie VanOosterhout of Spectrum Health in Michigan for sharing their constructive approaches to enhancing patient enrollment.

A job well-done to Janice Fisher, Jeanne McAdams, Kathleen Myers-Rasmussen and Brenda Lynch of Memorial Medical Center (Sutter Gould Medical Foundation) in California, and Caroline Sloane of Genesis Medical Center in Iowa for their great

**PLEASE REMEMBER TO ALLOW TWO WEEKS
FOR DOCUMENT TURN-AROUND**

work on the case study. Debbie Steffen of St. John Hospital and Medical Center in Michigan did a particularly exceptional job abstracting her first medical record.

Thank you for your patience as we worked to rollout the Medical Record Abstraction and Training. We extend our heartfelt gratitude to Jane Humphrey at Washington University School of

Medicine in Missouri, Rosemarie Henschel of St. John Hospital and Medical Center in Michigan, and Cheryl Knapp of Waukesha Memorial Hospital in Wisconsin, for their recommendations to help improve the Medical Record Abstraction and Training. Please continue to share your feedback as we work with Outcome Sciences to finalize the Abstraction tool.

Timeframes For Completion of VIRGO Activities

- Screening**
- Screen for patients who meet eligibility criteria; patients must meet inclusion within first 24 hours of admission
 - Patients admitted from another hospital must transfer to your facility with 24 hours of presentation.
 - Follow patients with differential diagnoses
 - Patient must have diagnosis of AMI or ACS to be enrolled
 - *Complete online screening form within 24 hours of identifying patient who meets inclusion criteria*

- Consenting and Enrolling**
- Consent patient as soon as possible
 - Consent form must be signed by patient prior to hospital discharge
 - Patient is not considered enrolled in VIRGO until baseline interview is completed
 - *Complete online enrollment form within 24 hours of enrolling patient*

- Baseline Interview**
- Complete baseline interview as soon as possible
 - Obtain physical measurements prior to hospital discharge
 - Baseline interview must be completed within 1 week post hospital discharge
 - *Baseline interview form must be completed online within 4 days upon concluding the interview*

- Medical Record Abstraction**
- Medical record abstraction must be completed within 4-6 weeks of hospital discharge
 - Forward source documents within 1-2 weeks of completing medical record abstraction

- 1 Month Blood**
- Blood collection window is 4-6 weeks post hospital admission date
 - Blood collection may occur outside the 4-6 week window in extenuating circumstances
 - Do not draw blood earlier than 2 weeks post hospital admission date

Go Red For Women



Across the nation, various sites joined in the effort to raise awareness in the fight against heart disease in young women. At St. Elizabeth's Hospital in Illinois, over 200 employees wore red on Friday, February 6th 2009 to mark Go Red for Women.

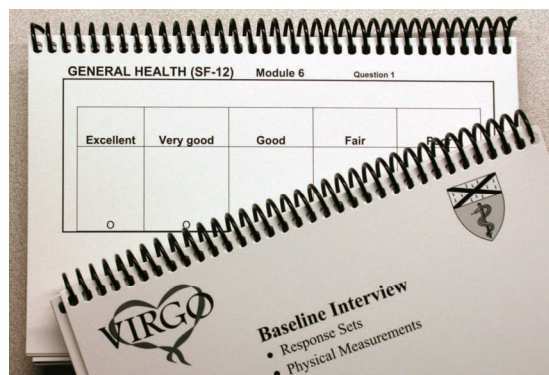


Observing Go Red for Women in Wisconsin, Milwaukee's 99.1 WMYX "Wellness Wednesday" featured Dr. Richard Staudacher, VIRGO principal investigator at ProHealth Care, as a guest on the air. The interview is featured on the "VIRGO in the News" page on the Study website.

Reminders

Flip Cards

In order to facilitate and expedite the baseline interview for participants, be sure to use the flip cards which accompanied your the Operations Manual. In



addition to engaging the patient, the flip cards assist the participant in identifying their responses to some of the multiple choice questions administered during the baseline interview.

Ship-a-Kits

Four complete blood draw kits are initially sent to sites when they commence screening for eligible patients.

- As you schedule 1 month blood draws, please ensure you have adequate blood draw kits on hand
- It is good practice to check the expiration date for the items contained each blood draw kit provided by VIRGO
- Sites are encouraged to retain one complete blood draw kit in reserve to be utilized in the event additional supplies are needed
- To ensure you have ample kits available, be sure to request additional kits in the EDC when entering completed blood draws

Kindly notify the VIRGO Coordinating Center as soon as possible if you require additional kits to ensure timely delivery of replacement supplies or kits.

The Yale Coordinating and Follow-up Centers joined in the campaign to support Go Red for Women.



Please visit the study website for the most recent version of the Frequently Asked Questions (Updated 5/1/09)