

The Cancer Research Network Connection

Ed's Corner of the World

Report from the CRN PI



There have been major developments in the management of the VDW as described in the article by Jeff Brown in this issue. The important point in these changes, which may seem to some as bureaucratic shuffling, is that our Center directors and other leaders now clearly recognize the value of the VDW. This value

is not just limited to multi-center projects. Several sites are now using their local VDW database as the primary source of automated data for their single site studies as well. The experience across the CRN strongly suggests that the more the local VDW is used, and the more programmers are familiar with it, the better and more reliable it becomes.

CRN investigators and site data managers have created a powerful resource; the goal now is to make it more complete and to improve its reliability and validity. This has to remain a high priority for the CRN.

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News from NCI

Here is a slightly belated recognition of the 10th Anniversary of the Division of Cancer Control and Populations Sciences. 2007 marked the 10th Anniversary of DCCPS. 1997 was the year that DCCPS became a Division at NCI and also the year that the CRN RFA was initially conceptualized. I think everyone would agree that both CRN and DCCPS have come a long way and achieved many accomplishments in the intervening decade.

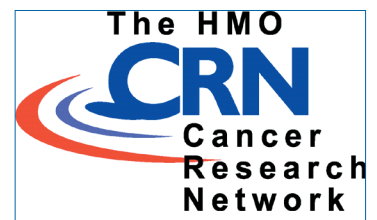
The existence and continuance of DCCPS provides a "home," probably unique among NIH Institutes for the kind of population-based cancer control research that is the hallmark of CRN activities and, I think, greatly enhances the utility of the cooperative agreement collaboration between CRN and NCI.

I think one notable indication of the maturation of this relationship will be the unprecedented number of NCI and NIH staff attending this year's meeting of the HMORN, including many who will be participating in and/or lead sessions.

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- CRN News & Milestones



The Cancer Research Network (CRN) is a collaboration of 13 non-profit HMOs plus one CRN-affiliated HMO committed to the conduct of high-quality, public domain research in cancer control. The CRN is a project of NCI and AHRQ.

Update on VDW Strategic Initiatives

The HMO Research Network (HMORN) Virtual Data Warehouse (VDW) was developed by the CRN to facilitate multi-site cancer research within the HMORN. The importance of the VDW has risen substantially and it is now a key research resource throughout the HMORN. The VDW is used by a broad range of HMORN investigators for single- and multi-site studies across a variety of therapeutic areas and topics, including outcome and effectiveness studies, and post-marketing drug safety research. In addition to the CRN, the HMORN Centers

for Education and Research on Therapeutics (CERT) and the Cardiovascular Research Network (CVRN) both rely heavily on the VDW. In light of its importance, a series of recommendations to enhance the VDW was recently approved by the HMORN Governing Board.

The recommendations were based on short-term and long-term requirements that included improving VDW oversight, undertaking extensive data quality reviews, and enhancing the informatics

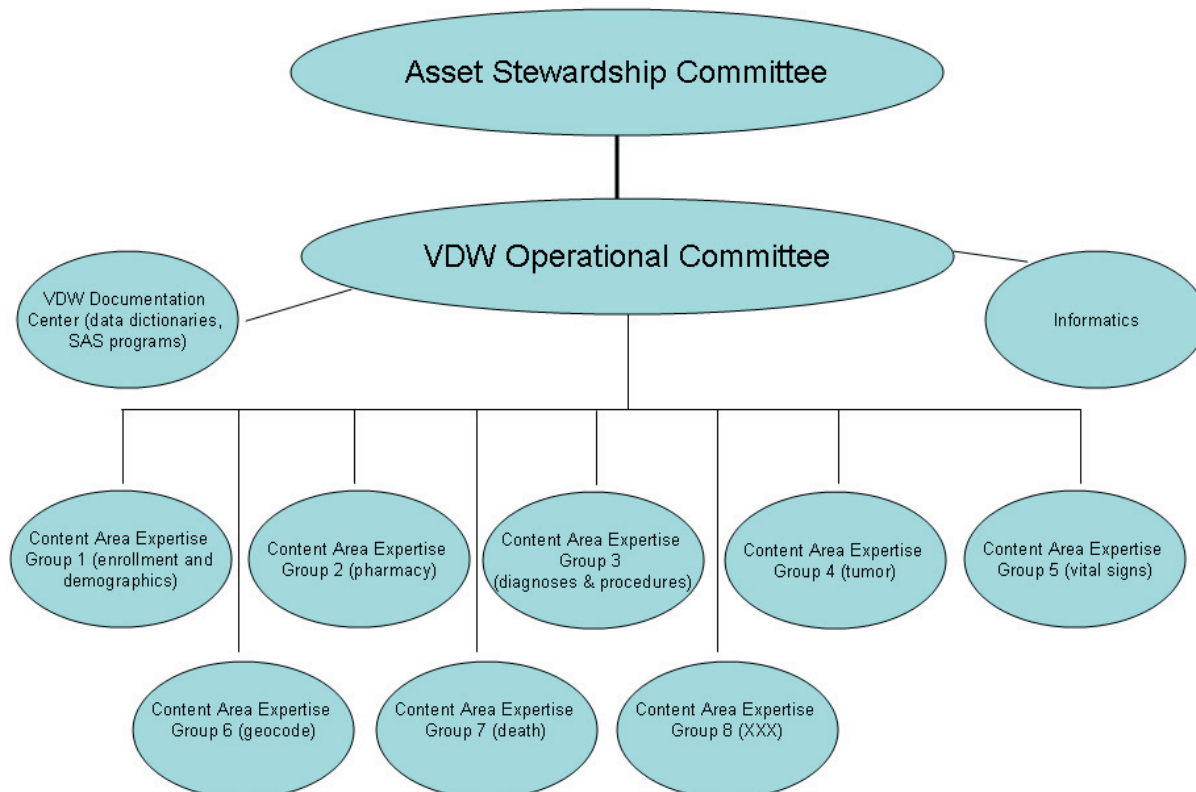
capabilities of the HMORN with respect to access to the VDW. IRB coordination and ongoing infrastructure funding also were identified as areas of concern and are being addressed separately.

The recommendations clearly state that the data resources of the network do not define the value of the network; the value resides with the investigators at the individual plans and access to the local delivery systems. The goal of the recommendations was

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Schematic of New VDW Oversight Structure



VDW Strategic Initiatives *Continued from Page 2*

to minimize the burden of accessing and using network data resources for public health research.

The recommendations yielded specific short-term steps that are currently being implemented under

the auspices of the newly-established VDW Operational Committee. The Operational Committee will make recommendations to the HMORN Asset Stewardship Committee (see Figure on Page 2) and has representation from CRN, CERT, and CVRN

investigators and research analysts.

The primary short-term activity of the VDW Operational Committee is the creation of content area expertise groups consisting of 2-3 investigators and 2-3 programmer/analysts who will be responsible for implementation of comprehensive data quality reviews within their content area. These content area expertise groups will report their findings to the Operational Committee. The Operational Committee also will be responsible for making recommendations regarding additions to and required maintenance and upkeep of the VDW, maintaining current documentation through a documentation committee, and improving informatics through an informatics committee.

- Jeffrey Brown (HPHC)

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CRN News & Milestones

CRN project teams are busy publishing results and receiving kudos!

The **Chemo-Stroke** team's abstract "Is stroke a late effect of chemotherapy?" was ranked among the top 16 submissions & was chosen for oral presentation at the **American Society of Preventive Oncology** meeting in Bethesda MD, March 2008.

The **MENU** team's abstract "Diet Change for Cancer Prevention: Outcomes of the Online MENU Choices Intervention" received a citation award & was selected for two poster presentations at the **Society of Behavioral Medicine** meeting in San Diego CA, March 2008.

Study results published by the **BOW** team continue to stimulate discussion in the scientific community. The January 2008 Cancer Bulletin referenced Cynthia Owusu's **tamoxifen** paper (*J Clin Oncol*, Dec. 2007) and Terry Field's paper on **surveillance mammography** (*J Gen Intern Med*, Dec. 2007). The February 2008 issue of the Journal of Clinical Oncology featured an editorial by KL Kahn, in which the tamoxifen paper was also discussed. Meanwhile, Marianne Ulcickas Yood's **mortality** paper was published (*J Am Coll Surg*, Jan. 2008).

CRN investigators and colleagues are busy preparing new project proposals!

The call for applications for CRN Pilot Activity funds elicited a fantastic response – **25 abstracts** were submitted. Congratulations to all applicants for getting your abstracts in on time! The CRN Executive Committee is selecting expert reviewers, and applicants are hard at work preparing their full project proposals. Watch this space for updates and notification of awards.

CRN Connection

The CRN Connection is a publication of the CRN developed to inform and occasionally entertain CRN collaborators. It is produced with oversight from the CRN Communications Committee.

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Please send comments or suggestions on this newsletter to Sarah McDonald, mcdonald.sj@ghc.org.

The Devil's Definitely in the Details - Piloting an Alternative Approach to Multi-site IRB Review

Arguably, traversing the gauntlet of multiple IRBs is one of the more daunting aspects of multi-site research projects. The CRN3 RFA contained an explicit mandate to develop strategies to ease this often time-consuming and complex process. Fortunately, the Coordinated Clinical Studies Network (CCSN)—another HMO Research Network collaboration with a specific focus on infrastructure enhancement—has spent the past three years collaborating with IRB administrators and researchers to address specific local and transcendent barriers to help streamline the IRB review process. These efforts came to fruition this summer when an alternative review model was pilot-tested successfully by the researchers in the newly-funded Cardiovascular Research Network.

We have adapted the NCI Central IRB approach. For

An overarching goal of this effort has been to create strategies that enable VDW studies to be mounted more rapidly.

our purposes, since the HMORN does not have a Central IRB, we define a lead IRB—the site where the study's principal investigator resides. That PI completes his or her IRB application using the site's own forms. Upon review by the lead IRB, the participating sites can designate the lead IRB as the IRB of record for that study using an IRB Authorization Agreement, and may also elect to conduct an expedited review of the lead site's IRB application.

One clear benefit to this model is that only one application packet is created. However, it obliges the IRB to review an application on an

unfamiliar form.

This approach also requires more upfront discussion between all site PIs to ensure that the IRB application proactively addresses potentially unique considerations of the participating sites' IRBs.

The HMORN IRB pilot is initially designated for minimal-risk data only studies only. An overarching goal of this effort has been to create strategies that enable VDW studies to be mounted more rapidly. As collective comfort with this approach grows, we hope to test it as an alternative for minimal risk studies that may also entail primary data collection (for example, a coded mail survey).

Although the CCSN's funding ended in December, we have a no-cost extension to enable continued work on additional details of this process. Many important considerations need elaboration, including division of responsibilities during the annual continuation review, and possibly standardizing the definition of a "significant modification" that would trigger another iteration of IRB

Paradigm shifts take time, commitment, resources, energy and trust.

Inaugural Projects for Alternative IRB Pilot:

Cardiovascular Research Network (CVRN) Core Projects

Instrumental CVRN Investigators:

David Magid, Alan Go, Patrick O'Connor, Joe Selby, Jerry Gurwitz

Intrepid IRB Folks & Others Who Have Made This Work:

Jeff Braff, Andy Nelson, Bobette Godding, Jared Rowe, David Brand

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NCI Colleague Works & Learns in Rwanda

Wendy McLaughlin, the CRN Program Analyst in the Applied Research Program at NCI, recently completed a 3-month assignment with the Centers for Disease Control (CDC) in Kigali, Rwanda. This international training fellowship allowed Wendy to provide budget, grants, and contracts assistance to HIV/AIDS programs.

Living in the capital city of a post-conflict country offered many opportunities for learning about Rwandan culture and experiencing the positive restoration of community.

Wendy learned a great deal about the challenge of integrating delivery of health services among 13 NGO partners in Rwanda.

The US Secretary of Health and Human Services visited Kigali in August with a large delegation to view the progress of the President's Emergency Plan for AIDS Relief (PEPFAR) program. Wendy helped plan the visit and toured the sites with visitors.

Wendy has a greater understanding of the effort it takes to manage international, collaborative, multi-US agency initiatives like PEPFAR. Rwanda is one of 15 focus PEPFAR countries;



the HIV prevalence among at-risk adults is 3.1%; Rwanda PEPFAR funding totaled \$103M in 2007; and this is a collaborative effort between USAID, CDC, and the US Embassy.

Wendy learned a great deal about the challenge of integrating delivery of health services among 13 NGO partners in Rwanda. She

brings a refreshed perspective on creative and strategic planning

back to NCI, as well as enhanced experience with budget planning.

Highlights of personal travel include sitting with a silverback gorilla; hiking to chimpanzees in the rainforest; safari in South Africa; swimming in the Indian Ocean in Mozambique; and bird watching in Uganda.



-Wendy McLaughlin (NCI)

News From NCI

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For some other notable facts about DCCPS support of research over the past decade, see http://www.cancercontrol.cancer.gov/10years/10_years.asp

Additional material will be added to this link as the Division finalizes a "Briefing Book" report on accomplishments of its first ten years.

-Martin Brown (NCI)

IRB Review

Continued from Page 4

review.

Additionally, incomplete knowledge about HMORN sites' data sharing and data security guidelines remains a significant barrier that could be aided by the placing them an accessible web-based repository.

Paradigm shifts take time, commitment, resources, energy and trust. The VA Health System is working toward a central IRB, which has also been a multi-year effort. Since consortium research is becoming de rigueur, it is imperative that the research infrastructure evolve to keep pace with the needs of these larger and more complex studies.

- Sarah Greene (GHC)

Site Profile: Geisinger Center for Health Research

Geisinger Health System joined the Cancer Research Network in 2006, and is the CRN's newest affiliated member. Welcome, Geisinger!



Geisinger's CRN site PI is **Bob Langer, MD, MPH**, Director of the

Outcomes Research Institute. Bob joined Geisinger in mid-2005 after nearly 20 years in the Department of Family and Preventive Medicine at UC San Diego, where, among other things, he was PI for the Women's Health Initiative. Although Geisinger receives no funding from the CRN, Bob undauntedly leads participation in many CRN activities. He is a current member of the Steering Committee and a past member of the Pilot Studies Process Development Committee.

Geisinger boasts not one, but two participants in the CRN Scholars program! **Nirav Shah** and **JB Jones** are collaborating on Scholar projects, with Bob Langer as their mentor.

Geisinger is also participating in two recently funded HMORN initiatives:

The Distributed Research Network funded by AHRQ, and the **Cardiovascular Research Network** supported by NHLBI. Congratulations, Geisinger!

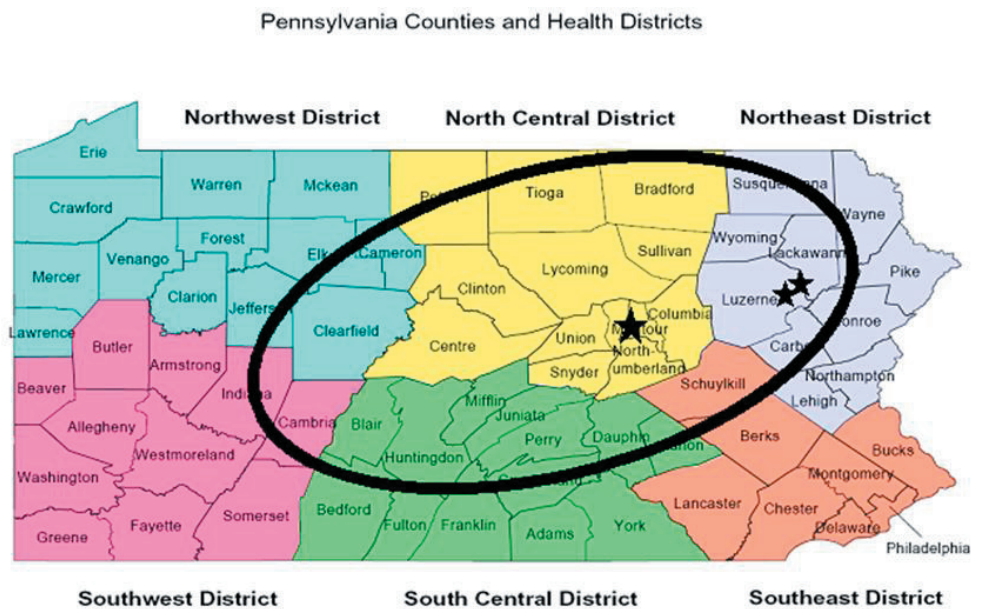
Founded in 1915, Geisinger is a physician-led integrated health care system, dedicated to health care, education, research and service spanning 40 counties of 20,000 square miles and serving 2.5 million people.

The Geisinger Health System includes:

- Geisinger Clinic
- Geisinger Center for Health Research
- Geisinger Health Plan
- Weis Center for Research
- Three Geisinger Hospitals

And is affiliated with the **Fox Chase Cancer Center** in Philadelphia, PA.

Geisinger service area (hospitals located at stars)



Did You Know?

Geisinger Center for Health Research is housed in a brand-new, green-built facility. The \$21 million, 63,000 square foot building opened in March 2007. The building was certified by LEED (Leadership in Energy and Environmental Design), a voluntary rating system for buildings that are environmentally responsible, economically efficient and healthy places to live and

work. And, since the **2009 HMORN Annual Meeting** will be hosted there, you may have a chance to see it yourself next spring.

