

OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

Partnership Update

Announcements

The Observational Medical Outcomes Partnership (OMOP) remains on track to successfully complete the goals outlined in the original research plan by the first quarter of 2011. Our fundraising activities have progressed to the point where the partnership can remain active throughout 2011. In anticipation of OMOP becoming an ongoing effort, the Executive Board is in the process of expanding its membership to represent additional stakeholder communities. In this edition of the OMOP newsletter, we introduce you to our newest board members and share with you their insights into the importance of the partnership and its research agenda.

We are also pleased to announce that the *Annals of Internal Medicine* published a paper by the OMOP team that provides an overview of the partnership.

Lastly, OMOP will hold the second annual OMOP Symposium on January 11, 2011, in Washington, DC. Please stay tuned to the OMOP website (omop.fnih.org) for the latest updates.

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Executive Board Q & A

With Dr. Steven Jacobsen and Dr. Marcus Wilson

The OMOP Executive Board is a multi-stakeholder group overseeing OMOP operations. The 13-member board has diverse membership from academia, regulatory agencies, the pharmaceutical industry, health care payers, patient advocacy groups, and health care providers. Representing the perspective of their respective stakeholder groups, the members have several responsibilities, including monitoring adherence to the OMOP mission and operational principles, participating in the scientific review process, evaluating budgets, contracts, and grant processes, and developing plans for specific scientific, technical, or policy issues. The FNIH Board of Directors works with the OMOP Executive Board to ensure successful management of OMOP.

Recently two members, Marcus D. Wilson, PharmD., President, HealthCore, and Steven J. Jacobsen, MD, PhD, Director of Research, Kaiser Permanente Southern California, were added to the OMOP Executive Board. In November, 2010, both board members shared with us their thoughts about using observational healthcare data sets for research and the opportunities that lie ahead.

Q: What are the opportunities and challenges you see to use observational data within your own organization?

SJ: There are so many important questions for medical practice which are not always answerable through clinical trials so we have to turn to observational data – the use of observational data presents an opportunity to help with decision making. Kaiser Permanente is heavily steeped in clinical guideline development, so it is important to determine which treatment is most effective. This [determination] heavily relies on trials and can be informed with observational data. When conducting observational data studies, we have to deal with confounders and know how to take these into account with the results – the devil is in the details. We must know with observational databases the characteristics and ability (or lack) of the data to answer the question being put forth.

MW: HealthCore is a research organization working with observational data to generate knowledge to help support the decision making and health policy within health plans, including our parent company WellPoint, the pharmaceutical industry, and government organizations. It [WellPoint] has the raw materials (e.g., data) that have the potential to generate clinical knowledge – real world evidence – turning raw materials into assets. There is enormous potential with observational data, but we, as an industry, are very early in knowing how best to use electronic data resources to generate knowledge. We must evaluate and test these data sources and include close consideration as to the context of where the data comes from when using multiple sources of data (validation is critical).

Q: Within the OMOP research plan, what interests you the most?

SJ: I am interested in the use of data across data sources and understanding the databases multi-institutional efforts. The purchase or lease of a database is never that easy. We have to understand the metadata – information about the data. We need to know what is consistent across the data sources and what is different. Since OMOP is also using EHR data, an additional interest is how to use text notes found in EHRs and use the natural language within the clinical notes; this is very difficult but can allow us to do more surveillance for syndromic manifestation, using healthcare data that may precede diagnosis.

Steven J. Jacobsen, MD, PhD



Dr. Jacobsen was appointed Director of Research in Kaiser Permanente's Southern California Region in March, 2006. He oversees research programs in the Southern California Region, including the Department of Research and Evaluation, and the infrastructure that supports those programs. The research programs encompass a broad range of clinical, epidemiologic, and health services research that capitalize on the rich research resources in the Region, including its 3.2 million diverse members.

Prior to joining Kaiser Permanente, Dr. Jacobsen was Professor and Chair of the Division of Epidemiology in the Mayo Clinic College of Medicine in Rochester, Minnesota. He was the Principal Investigator of two major NIH-funded studies: the Rochester Epidemiology Project (AR30582) from 1999 to 2006 and the Olmsted County Study of Urinary Symptoms (DK58859) from 1992 to 2006. He played an active role in teaching and mentoring in the Medical School, Clinical Research Training Program (K30-RR022296), and the Clinical Research Scholars Program (K12-RR023263).

Dr. Jacobsen is a chronic disease epidemiologist with a long-standing interest in men's urological health, cardiovascular diseases, developmental disorders, and vaccines. He is continuing this work at Kaiser Permanente and has established a new program in vaccine safety.

Dr. Jacobsen has extensive experience in developing research infrastructure at the project, departmental, and institutional level. He provided oversight for development of numerous user-friendly tools to expedite population-based research that supported over four hundred publications during his leadership of the Rochester Epidemiology Project. He led numerous initiatives to improve the quality of research within the Division, including the centralization of oversight and training of research support staff and active internal peer-review programs in his Division. He also was a founding and is an active member of the Clinical Research Subcommittee, which had oversight of clinical research infrastructure at Mayo Clinic.

Dr. Jacobsen received his MD and an MS in biostatistics from the Medical College of Wisconsin in Milwaukee and his PhD in Public Health Sciences (Epidemiology) from the University of Illinois at Chicago. He has authored or co-authored more than three hundred papers in peer-reviewed literature and has served on numerous editorial boards and NIH study sections and panels.

MW: Within OMOP's research plan, in addition to the performance of the analytical methods, it is very interesting and important to understand the differences of the data sources. They [data sources] are built with different business models, different implementations, and purposes, and evaluating these differences and similarities is critical and could add significant value to the initiative. Using the OMOP tools and methods to show the similarities and differences is a step in the right direction. We need to work more with the OMOP methods and tools to understand what the inherent biases in the data sources are [and] we need to know what noise is inherent in observational data sources.

Q: **How do you see drug safety getting more attention in research institutions, outside of clinical trials?**

SJ: We owe it to our Kaiser Permanente members to know about the safety of a pharmaceutical that gets deployed. In our vaccine safety studies – we have grown comfortable with the methods and are starting to employ these on the operational side for the drugs that we deploy via our pharmacy. We have the mission

Marcus Wilson, PharmD



Marcus Wilson is President of HealthCore, which he co-founded in 1996. He has been extensively involved in real-world outcomes research for more than 17 years. While on faculty at the University of Sciences in Philadelphia, he led efforts at Blue Cross/Blue Shield of Delaware to evolve the drug formulary process from the traditional P&T approach into a broader health outcomes management process that incorporates comparative effectiveness research endpoints, including value-based assessments, and disease management into evaluation, decision-making, and pull-through programs. It was during this time that Dr. Wilson helped develop an outcomes research and patient education program within a division of BC/BS Delaware that was purchased in 1996 and used as the foundation of HealthCore.

Dr. Wilson received his Bachelor of Science in Biochemistry from Virginia Tech and his Doctor of Pharmacy degree from the Medical College of Virginia. He joined the faculty of the University of the Sciences in Philadelphia after completing his residency and spent seven years with USP in didactic and experiential training for doctor of pharmacy students.

In addition to his role as president of HealthCore, Dr. Wilson serves as co-chair of the eHealth Initiative Workgroup on Comparative Effectiveness, is a member of the FDA Mini-Sentinel Program's Project Operations Council, the Brookings Active Safety Surveillance Council, the Observational Medical Outcomes Partnership (OMOP) Executive Board, and the Board of Visitors for the Mayes College of Healthcare Business & Policy at the University of Sciences in Philadelphia. He serves on a number of WellPoint committees, including the Clinical Product Development and Innovations Council, the Enterprise Regulatory Council, and the Public Policy Steering Committee. He is a past member of the Board of Directors for the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), and is a reviewer for multiple journals. His publications, including book chapters, span various clinical, healthcare safety, and health outcomes topics.

to do this within our own population base. Then it is a matter of taking it to the next level and expanding the drug safety research to the overall population, not just the Kaiser population.

MW: There is a lot of interest and a lot of concern, but a lot to learn about when to use observational data and when not to use observational data – “predictable skepticism.” We cannot rush drug safety -- there remains a lot of work still to identify safety issues in the post-market world. We may need to do primary research in certain cases – this is just one piece of the puzzle. False positives will be generated from various analyses and from this, unnecessary headlines potentially can also be generated -- we do not want to run the risk of being discredited due to false positives.

Q: **How do you see OMOP’s research extending into comparative effectiveness and health outcomes research?**

SJ: OMOP’s research could easily extend into comparative effectiveness and health outcomes research as this is a natural extension of the current work. I think this is a promising frontier for the application of the methods implemented in the OMOP research.

MW: The potential to leverage the methods developed in addressing a CER agenda is certainly there. However, for the time being it is my opinion [that] OMOP focus on completing its original mission and finish what was started prior to opening the next OMOP chapter – for now, stay the course and focus.

Q: **What would you say are OMOP’s contributions to drug safety research?**

SJ: The learnings from the OMOP research team and the distributed research partners regarding the strengths and weaknesses about the data sources. The researcher needs to know these and what challenges they may encounter in obtaining results. There is a great deal of promise for OMOP – data characteristic tools, analytical methods, and experiment results are all very exciting and provide contributions to this field.

MW: The work done to date has yielded impressive results in terms of methods development and tool development. There is a lot of work remaining -- we must continue to approach this methodically and learn how to best understand and control for confounders, both apparent and non-apparent. We need to understand from the OMOP experiment, when and when not to use observational data and how best to use it. It [and certain methods] may not be reliable or perform the best for certain scenarios.

Follow OMOP

Upcoming Events

OMOP 2011 Symposium

January 11, 2011
Renaissance Dupont Hotel
Washington, DC

11th Annual FDA/PhRMA/AASLD Hepatotoxicity Conference

“Drug-Induced Liver Injury: Are We Ready to Look?”

March 23-24, 2011
National Labor College
Silver Spring, MD 20903

2nd Annual FDA/DIA Computational Science Meeting

Post-Market Safety Session

March 14-15, 2011
Washington, DC

2011 OMOP Symposium

[Register Now!](#)

OMOP 2011 Symposium

January 11, 2011
Renaissance Dupont Circle Hotel
1143 New Hampshire NW Avenue
Washington, DC 20037

Overview

The Observational Medical Outcomes Partnership (OMOP) initial two-year program of work was designed to develop, implement, and empirically test the performance of a number of methods in identifying drug outcomes across multiple observational data sources. The research results will provide empiric evidence to inform the implementation of any systematic surveillance system regarding the methods, data, and infrastructure necessary to identify and track emerging safety issues. Study results and lessons learned will be shared in accordance with the public health mission of the Partnership.

Symposium Overview and Goals

During the OMOP 2011 Symposium, stakeholders will gather to discuss key OMOP results, tools, and lessons learned. During the OMOP Symposium, you will:

- **Hear about study results** regarding the performance of the methods implemented across the databases in the research lab and the distributed network
- **Explore the utility of OMOP-created tools for** data characterization, quality assurance, and outcome definitions to support standardized processes within an active surveillance system
- **Review lessons learned** along the initial OMOP two-year journey
- **Learn about applications** of the OMOP research beyond active surveillance
- **Meet with stakeholders and leaders in** pharmacovigilance to understand their perspectives on drug safety systems and the impact of the OMOP research

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