Center for Translational and Policy Research on Personalized Medicine

NEWS

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A Letter from Center Director Kathryn A. Phillips, PhD

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Dear Colleagues,

As we approach the end of our first three years at The Center for Translational and Policy Research on Personalized Medicine (TRANSPERS), we thought it would be a good time to take stock of our progress and accomplishments. We're proud to have published close to 60 articles and abstracts, with nearly as many presentations at scientific meetings and to academic, clinical, industry, and government audiences around the world.

These accomplishments are largely a reflection of the fine people we have working with us. In particular, we would like to congratulate one of our key affiliates, Deborah Marshall from the University of Calgary, on her recent election as president of The International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Thanks for joining us for the first three years of TRANSPERS. We look forward to continued success and progress over the next three years - and beyond.

Best,

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TRANSPERS in its 1st Three Years: Findings & Accomplishments

The first three years at TRANSPERS have been busy and productive. We've published 41 articles in such widely-read journals such as JAMA, New England Journal of Medicine, and Cancer. As this newsletter goes to press, an additional 11 manuscripts are being prepared or are under review. Our collaborators have made more than 50 presentations to national and international groups. We are gratified that our research findings have had an impact on personalized medicine research. Highlights from some of our key findings are listed below.

We demonstrated that gaps in the evidence base on the testing continuum-from initial access to acting on results-hinder use of appropriate personalized medicine technologies. Using HER2 testing (a well-known personalized medicine technology that has been widely available for more than a decade) as our empirical example, we found a lack of data on whether all eligible patients receive testing, the impact on care practices such as follow-up testing and changes in treatment decisions, and whether underserved populations have access to care. Illustrating these gaps in the existing evidence base helps propel new research forward.

Understanding practice patterns and cost-effectiveness in real-world clinical settings is critical to developing appropriate policies to guide use and coverage decisions of personalized medicine technologies. For example, we found few studies of gene expression profiling (GEP) utilization took place in clinical practice settings outside of academic centers. Similarly, we found no studies that examine how health plans make decisions about whether to cover GEP testing. We showed that conclusions about GEP cost-effectiveness rely on data that may not reflect actual use.

Lastly, we provided insight on the impact of patient and family member preferences for care. We found that national universal colorectal tumor testing could be highly cost-effective to identify families with Lynch syndrome, but that it's especially important to identify and counsel relatives of the persons being tested as well. Our preferences studies also showed that most individuals want genetic testing for a condition such as Lynch syndrome, but are concerned about false negatives and sharing information with anyone other than their primary care doctors.

TRANSPERS findings have implications for developing programs and policies to facilitate appropriate testing and for educating patients, family members, and providers. Our findings also shed light on the gaps in the evidence base on personalized medicine that we intend to address in our future research.

For more information on TRANSPERS publications, please see http://clinicalpharmacy.ucsf.edu/Transpers/research/pubs.asp.

TRANSPERS Leverages Resources to Expand Research Scope

Although the majority of TRANSPERS' funding over the past three years has come from an NIH-funded Program Project grant, **we continued to leverage our resources and expand our research capabilities though spin-off grants. To date, TRANSPERS researchers have received over $1 million**, awarded by foundations and research organizations including the Veterans Health Administration (VHA), Canadian Institutes of Health Research, Cancer Care Ontario/Ontario Institute for Cancer Research, Aetna Foundation, and Avon Foundation.

TRANSPERS postdoctoral scholar **Grace Wang** received a training award from the University of California, San Francisco to conduct pilot analyses for a project titled **Translation of Personalized Medicine Technology at an Academic Center: Example of KRAS Genetic Testing, Cutuximab, and Panitumumab**.

Another UCSF-based TRANSPERS collaborator, **R. Kate Kelley**, received a grant from Genomic Health to conduct a study titled **Recurrence Risk Assessment and Chemotherapy Decisions in Stage 2 Colon Cancer: Do New Molecular Markers Improve Physician Agreement**.

University of Calgary-based TRANSPERS member **Deborah Marshall** received funding from the Ontario Institute for Cancer Research to conduct a study titled **Understanding risk-benefit trade-offs of genetic testing in chemotherapy treatment decisions for breast cancer**.

Publication Highlights

TRANSPERS work was well represented in a recent joint issue of the Journal of Oncology Practice and the American Journal of Managed Care. Three papers from TRANSPERS collaborators were included in this special theme issue focusing on reconciling new developments in expensive cancer therapeutics and the utilization of limited resources.

Genomic Testing and Therapies for Breast Cancer in Clinical Practice by Jennifer S. Haas, Kathryn Phillips, Su-Ying Liang, et al examined the utilization patterns of human epidermal growth factor receptor 2 (HER2) testing, and trastuzumab and gene expression profiling (GEP) for risk stratification and chemotherapy decision-making. They found that almost all women received HER2 testing (96.9%), and 24.9% of women with an accepted indication received GEP. GEP use increased with income. A majority of women (57.7%) with HER2-positive disease received trastuzumab; those in the lowest-income category were more likely than those in the high-income category to receive the treatment. Read More

Do Economic Evaluations of Targeted Therapy Provide Support for Decision Makers?, by Ilia L. Ferrusi, Natasha B. Leighl, Nathalie A. Kulin and Deborah Marshall, presented a systematic review of economic evaluations of adjuvant trastuzumab, and assessed the extent to which decision support recommendations were adopted. This paper concluded that authors of adjuvant trastuzumab economic evaluations rarely use local data beyond costs and that quantification of uncertainty and its representation fall short of guideline recommendations. Economic evaluations of adjuvant trastuzumab, as an example of targeted cancer therapy, could be improved for decision-making support. Read More

Do private payers use health technology assessment (HTA)?by Julia R. Trosman, Stephanie L. Van Bebber and Kathryn Phillips examined current use of HTA by private payers in coverage decisions for personalized medicine. Using a literature review and semi-structured interviews, they found that all 11 major US private payers reviewed used HTA in coverage decisions, but the number of HTA organizations used by an individual payer ranged. They also found that payers relied more extensively on HTAs for reviews of personalized medicine (64%) than for other technologies. Read More

TRANSPERS Center Recent Research

Haas J, Phillips KA, Liang S, Hassett M, Keohane C, Elkin E, Armstrong J, Toscano M. **Genomic Testing & Therapies for Breast Cancer in Clinical Practice** *Journal of Oncology Practice* 2011;7(3S):e1s-e7s. [Abstract]

Ferrusi IL, Leigh NB, Kulin NA, Marshall DA. **Do Economic Evaluations of Targeted Therapy Provide Support for Decision Makers?** *Journal of Oncology Practice*. 2011;7(3S):36s-45s. [Abstract]

Kelley RK, Van Bebber SL, Phillips KA, Venook AP. **Personalized Medicine and Oncology Practice Guidelines: A Case Study of Contemporary Biomarkers in Colorectal Cancer**. *Journal of the National Comprehensive Cancer Network*. 2011;9(1):13-25. [Abstract]

Liang SY, Phillips KA, Wang G, Keohane C, Armstrong J, Morris WM, Haas JS. **Tradeoffs of Using Administrative Claims and Medical Records to Identify the Use of Personalized Medicine for Patients With Breast Cancer**. *Medical Care*. 2011. [Abstract]

Pletcher MJ, Pignone M. **Evaluating the clinical utility of a biomarker: a review of methods for estimating health impact**. *Circulation*. Mar 15 2011;123(10):1116-1124. [Abstract]

Trosman JR, Van Bebber SL, Phillips KA. **Health Technology Assessment and Private Payers' Coverage of Personalized Medicine**. *Journal of Oncology Practice*. 2011;7(3S):18s-24s. [Abstract]

Studies Highlight Preferences for Genetic Testing

People may be reluctant to get genetic testing for a number of reasons, such as unwanted potential anxiety conferred by positive test results, potential testing errors, cost issues or fear of having future insurance reimbursement issues. Delving into people's preferences for genetic testing is a topic TRANSPERS researchers are very interested in.

A recent TRANSPERS study, **Value of genetic testing for heritable disease in a population-based sample of older adults** (presented at the 2011 AcademyHealth annual research meeting) found that most individuals want genetic testing for heritable disease - even if the results aren't always 100% accurate - and are willing to pay for that information. However, cost and the potential for insurance discrimination are definite concerns. Indeed, with cost held constant, the most preferred scenario for testing included that the genetic test results would be shared with patients' primary care physicians and that there would be no chance of a false negative. In this best-case scenario, most would have testing (97%).

Our conclusions are consistent with those reported in a recent New York Times article that highlighted two recently published peer-reviewed articles on preferences for genetic testing. Results from those articles, including one by Tufts Medical Center-based TRANSPERS collaborator Peter Neumann, concluded that people will pay for genetic tests, even if their findings aren't always accurate, and that anxiety levels do not rise, on average, for people when they receive bad news.

Upcoming Event:

NCHPEG Annual Meeting

NCHPEG will hold its 14th Annual Meeting, Strategies for Evidence-Based Education in Genetics, September 26 -27 at the Marriott Bethesda North - Bethesda, Maryland. This year's theme provides an opportunity for health professionals, educators, patient advocates, and researchers to come together to learn about advances in genomics and the challenges and opportunities in the development, dissemination, and evaluation of genomics education for diverse audiences. Key note speakers include Dr. Dave Davis, Association of American Medical Colleges; Dr. Curtis Olson, University of Wisconsin-Madison; and Dr. W. Gregory Feero, Senior Advisor to the Director, National Human Genome Research Institute.

To learn more about TRANSPERS Center collaborators and our research, please visit our website at http://transpers.ucsf.edu