

Genome Alberta, Alberta Health Services and University of Alberta, Faculty of Medicine & Dentistry and School of Public Health are pleased to invite you to a Mini-Symposium entitled:

Genomics and Personalized Medicine – Health Policy and Barriers to Adoption

Date: June 18, 2015

Place: Edmonton Clinic Health Academy Building ECHA L1 190 (Basement of the Building)

1:30pm- 4:30pm

Web conference/livestreaming¹ <https://connect.srv.ualberta.ca/r59n7ebwydg/>

1:30 – 1:45 pm

Introduction and Welcome. Gijs van Rooijen, PhD, Chief Scientific Officer, *Genome Alberta*

1:45 pm – 2:30 pm

Choosing Personalised Medicine Wisely: realizing value through the ‘genomic’ revolution

Chris McCabe PhD, Professor and Capital Health Research Chair in Emergency Medicine Research, University of Alberta

2:30 pm – 3:15 pm

Binning the Genome for Precision Medicine: A Collective Policy Challenge. Wylie Burke MD PhD Professor, Department of Bioethics and Humanities, University of Washington,

3:15 - 3:45 pm

Coffee/Refreshment Break

3:45 pm – 4:30 pm

Changing the landscape of gene patents: social science at work. Richard Gold PhD, James McGill Professor, Faculty of Law, McGill University

¹ For the **Web Conferencing** please ensure your Adobe Flash has been updated. Firefox and Chrome are the best browsers for this program. On a Mac please do not use safari. XP will not run this program

Chris McCabe, Philip Akude, Mike Paulden, Reza Mahjoub and Timothy Caulfield
Choosing Personalised Medicine Wisely: realizing value through the 'genomic' revolution

As the proportion of developed economies that is consumed by health care continues to increase, health systems and their stakeholders are increasingly interested 'bending the health care cost curve'; driven by a perception that the current cost trajectory is not sustainable in the long run. Recently, the clinical professions have taken a pro active role through initiatives such as Choosing Wisely, Do Less and The Triple Aim. At the forefront of many of these programmes is the push to eliminate 'low value' tests from clinical practice. Personalised Medicine almost by definition, requires more testing rather than less, creating a prima facie conflict between two of the most important strategic developments in the delivery of health care. In this presentation we describe a framework for identifying the high value applications of molecular and genetic tests, that can truly personalize an individual's clinical journey, whilst promoting the optimum use of limited health care budgets.



I have worked on methodological and applied research for evaluating new technologies to inform health reimbursement decisions for the last 20 years, primarily in the United Kingdom, but also working for governments in Europe, North America and Australasia. I was co-author of the 2004 edition of the UK National Institute for Health and Clinical Excellence (NICE) Guide to the Methods of Health Technology Assessment, and an expert advisor to its update in 2008. With others, I have made key contributions to the application of Decision Analytic Modelling and Value of Information methods to health care resource allocation decisions. I was founding Director of the NICE Decision Support Unit, an academic collaboration of four Universities providing methodological support and expert peer review to the NICE Technology Appraisal programme. I was first author on one of the first papers to argue that regulatory authorities needed to consider cost effectiveness in order to incentivise manufacturers to design R&D processes to develop cost effective new technologies. Prior to moving to the University of Alberta I was the EPSRC Translational Research Professor in Health Economics at the University of Leeds, in the UK, as well as a founder member of the NICE Medical Technology Advisory Committee; which appraises non-drug technologies; including biomarkers, for the UK National Health Service. I am currently senior health economist on Co-Investigator on two UK NIHR funded biomarkers trials.

Wylie Burke: Binning the Genome for Precision Medicine: A Collective Policy Challenge

The vision for precision medicine includes increased use of next generation sequencing, a technology that enables sequencing the “whole genome”, comprising a person’s near complete DNA sequence, or “exome”, comprising protein-coding DNA and adjacent noncoding regions, at a cost less than that of many genetic tests currently in use. This testing approach can improve the diagnostic yield of a genetic work-up, increase the efficiency of testing for conditions involving multiple different genes, and offer innovative opportunities for guiding cancer treatment. However, it also generates large volumes of heterogeneous genetic data that are of limited clinical utility or difficult to interpret - a deluge that could overwhelm patients, practitioners and health care systems. The series of steps by which clinically relevant information is derived from DNA sequence offers opportunities for policy development to manage this potential information overload. A central consideration is the concept of “binning”, to organize genomic information into clinically meaningful subsets that can serve diagnostic and screening purposes. Bins can be designed to achieve specific clinical goals by aggregating information that supports evidence-based practice, while separating out information that is of low clinical utility or inappropriate for health care coverage. To succeed, however, this approach requires empiric data and policy-making that incorporates robust input from all stakeholders, including patients and clinical and public health experts.



Wylie Burke MD PhD is Professor and former Chair of the Department of Bioethics and Humanities at the University of Washington, Adjunct Professor of Medicine, and Member of the Fred Hutchinson Cancer Research Center. Her work focuses on the ethical and policy implications of genetic information in research and health care. She founded the University of Washington Center for Genomics and Healthcare Equality, an NHGRI Center of Excellence in Ethical, Legal, and Social Implications (ELSI) Research; and co-directs the Northwest-Alaska Pharmacogenomics Research Network, a research partnership involving universities and tribal communities in Alaska, Montana and Washington. Dr. Burke received a PhD in Genetics and an MD from the University of Washington. She trained in Internal Medicine at the University of Washington, where she was also a Medical Genetics Fellow. Dr. Burke is a member of the Institute of Medicine and the Association of American Physicians. She is a past President of the American Society of Human Genetics and was the 2013-2014 Presidential Chair at the University of California San Francisco.

Richard Gold: Changing the landscape of gene patents: social science at work

Patents covering human genes have been controversial around the world. While some jurisdictions, such as Latin America and Europe, have dealt these patents through legislation (albeit with different outcomes), common law jurisdictions have addressed gene patents through test cases. As a result, the United States has eliminated patents over genomic DNA while Australia and Canada are currently coming to terms with the issue.

This presentation will focus on the test cases in the common law world, with emphasis on the United States and Canada, which share similar patent statutes. The presentation will cover the history of the gene patent controversy, the business model adopted by the diagnostics industry, policy concerns and the need to resolve the issue through a test case. It will then summarize the test case in the United States that led to the invalidity of genomic DNA patents and methods of diagnostics before turning to the Canadian test case focusing on LongQT



Picture Courtesy of Claudio Calligans

Dr. Richard Gold is a James McGill Professor at McGill University's Faculty of Law and Department of Human Genetics in the Faculty of Medicine. He was the founding Director of the Centre for Intellectual Property Policy and teaches in the area of comparative intellectual property and innovation. His research centers on the nexus between innovation, development and commerce, with an emphasis on the life sciences. Professor Gold has provided advice to Health Canada, Industry Canada, the Canadian Biotechnology Advisory Committee, the Ontario Ministry of Health and Long-Term Care, the Organisation for Economic Cooperation and Development (where he was the lead author of the OECD Guidelines on the Licensing of Genetic Inventions and a report on Collaborative Mechanisms in Life Science Intellectual Property), the World Health Organization, the World Intellectual Property Organization and UNITAID. His research has been published in high-impact journals in science, law, philosophy and international relations including *Nature Biotechnology*, *The Lancet*, *PLoS Medicine*, the *McGill Law Journal*, *Public Affairs Quarterly*, *International Studies Quarterly*, and the *European Journal for International Relations*.