

Online Direct-To-Consumer Testing: A Public Health Perspective

GPS GE³LS SERIES

Ottawa, June 29, 2010

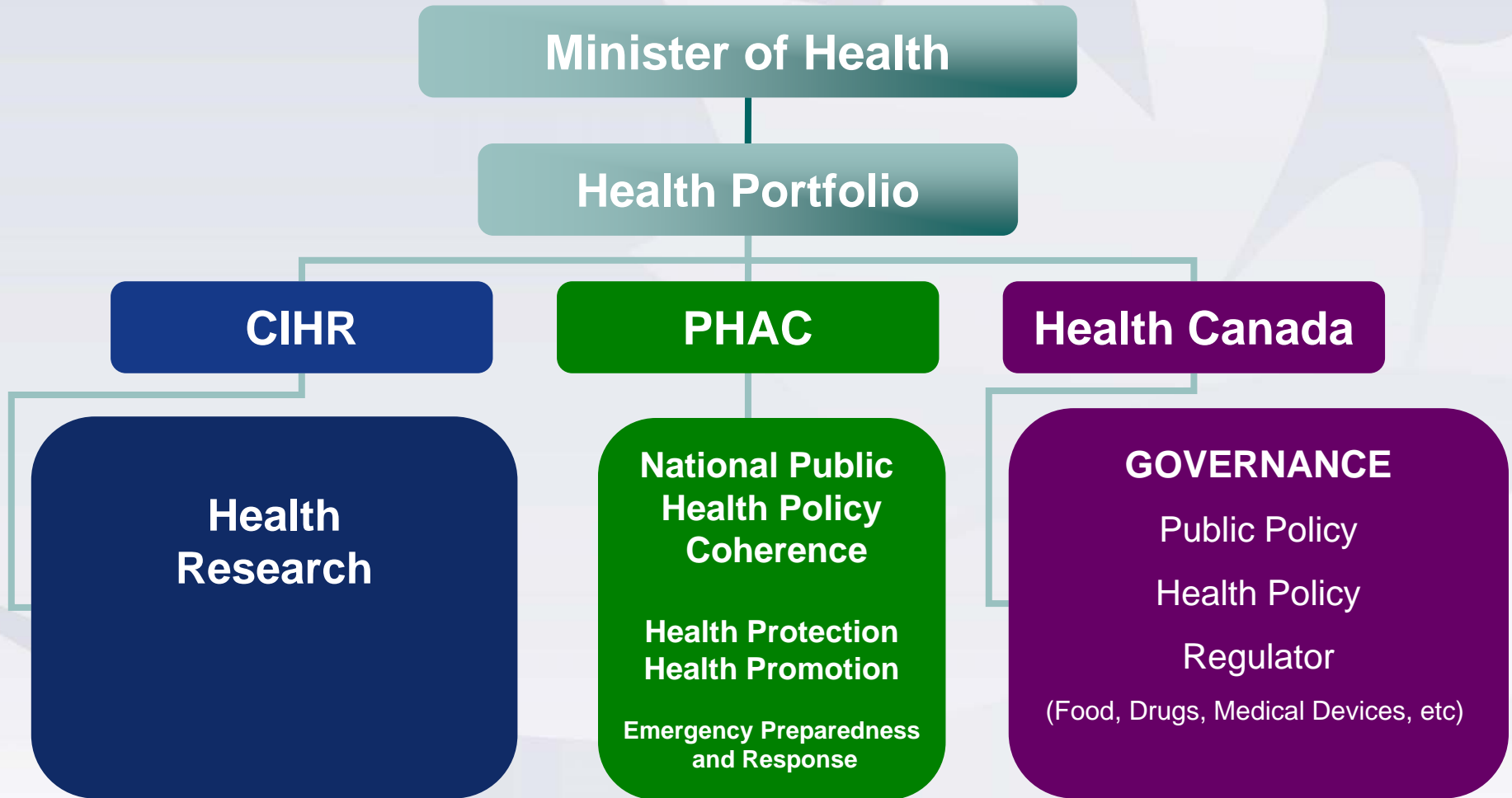
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Genome-Based Information (GBI) and the Federal Health Portfolio



Public Health Action is Guided by the Determinants of Health*

- **Income and Social Status**
- **Social Support Networks**
- **Education and Literacy**
- **Employment/Working Conditions**
- **Social Environments**
- **Physical Environments**
- **Personal Health Practices and Coping Skills**
- **Healthy Child Development**
- **Biology and Genetic Endowment**
- **Health Services**
- **Gender**
- **Culture**

*<http://www.phac-aspc.gc.ca/ph-sp/determinants/index-eng.php>

Main Interests of OBGPH and Lens Through Which We View DTC

- Public Health Genomics
 - Chronic Disease Prevention
 - Infectious Disease Prevention
- Population Screening
 - Primary Prevention
 - Secondary Prevention
- Public Education and Health promotion
 - Public Opinion Research on DTC advertising
- National Genetic Testing Databases

What Is Public Health Genomics?

(Institute of Medicine, 2005)

- An emerging field that assesses the impact of the interaction between genes and the environment (physical environment, diet and nutrition, behaviour, drugs, and infectious agents) on population health
 - Synthesize, and translate data on the relationships between genetic polymorphisms, disease, and environment
 - Use this information to develop strategies to promote health and prevent disease in populations
 - Target and evaluate population-based interventions

Population Screening in the Age of Genomic Medicine

Adapted from M. Khoury et al. NEJM 348:50-58

- Public Health Assessment
 - Is the condition an important public health problem?
 - Is the natural history of the disease understood?
 - Is the prevalence of the genetic trait in cases and controls known
- Evaluation of Tests and Interventions
 - Analytical validity, clinical utility and validity
 - Safety and effectiveness of interventions
- Policies and Screening Implementation
 - Evidence base
 - Costs and benefits
 - Quality assurance, training

Comments on the Policy Brief (1)

- I. CONTEXT
 - Discuss within the Canadian publicly-funded health care environment
- II. ISSUE
 - Note the limitation of analyzing DTC as an isolated test rather than from a holistic (whole person) perspective
- III. BACKGROUND
 - Compare DTC genetic tests with other DTC advertising in Canada
 - Note the need for a critical analysis of the clinical validity and utility of DTC tests and evidence of public good to guide policy makers
 - Analysis is focused too much on non-Canadian information sources.
 - Missing Canadian content and context (social, political, legal, ethical)
 - Missing economic and cost-benefit analyses
 - Discuss whether DTC of genetic tests should be regarded as a consumer product, a medical device or a form of “alternate medicine”

Comments on the Policy Brief (2)

- POLICY OPTION 1
 - Decision on access must be based on evidence of benefit
 - Difficulties of regulating the internet
- POLICY OPTION 2
 - Link this to availability of evidence of benefit
- POLICY OPTION 3
 - Good option
- POLICY OPTION 4
 - Rather than “wait and see” which means do nothing, it would be better to be proactive to generate an evidence base to support decisions

Research Questions

- How many DTC tests have been evaluated for clinical validity/utility?
- Does DTC represent a consumer product, medical device, or a form of “alternative medicine”
- What are Canadians’ opinions, perspectives, concerns, and advice to academics and governments on DTC?
- What are Canadian health care providers’, public health specialists’ and policy makers’ perspectives on DTC?
- What are the types of interventions recommended by DTC companies, how specific are they to the results of the genetic test, and how is response monitored?
- What are the costs and benefits?
- Discuss DTC within the context of the consumer’s best interest
- Should the publicly-funded system pay for consumers who seek advice from medical practitioners on interpretation of DTC tests