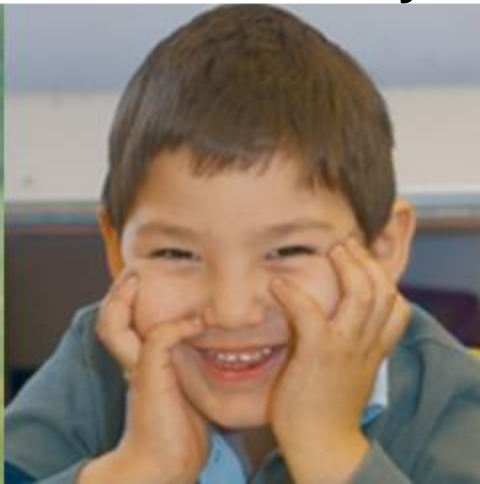




Personalized Medicine: Science Policy Perspectives from the Health Portfolio

Critical markers of Disease , Biomarkers and Personalized Medicine

**Narayanan Iyer, BSc, LLB, BCL
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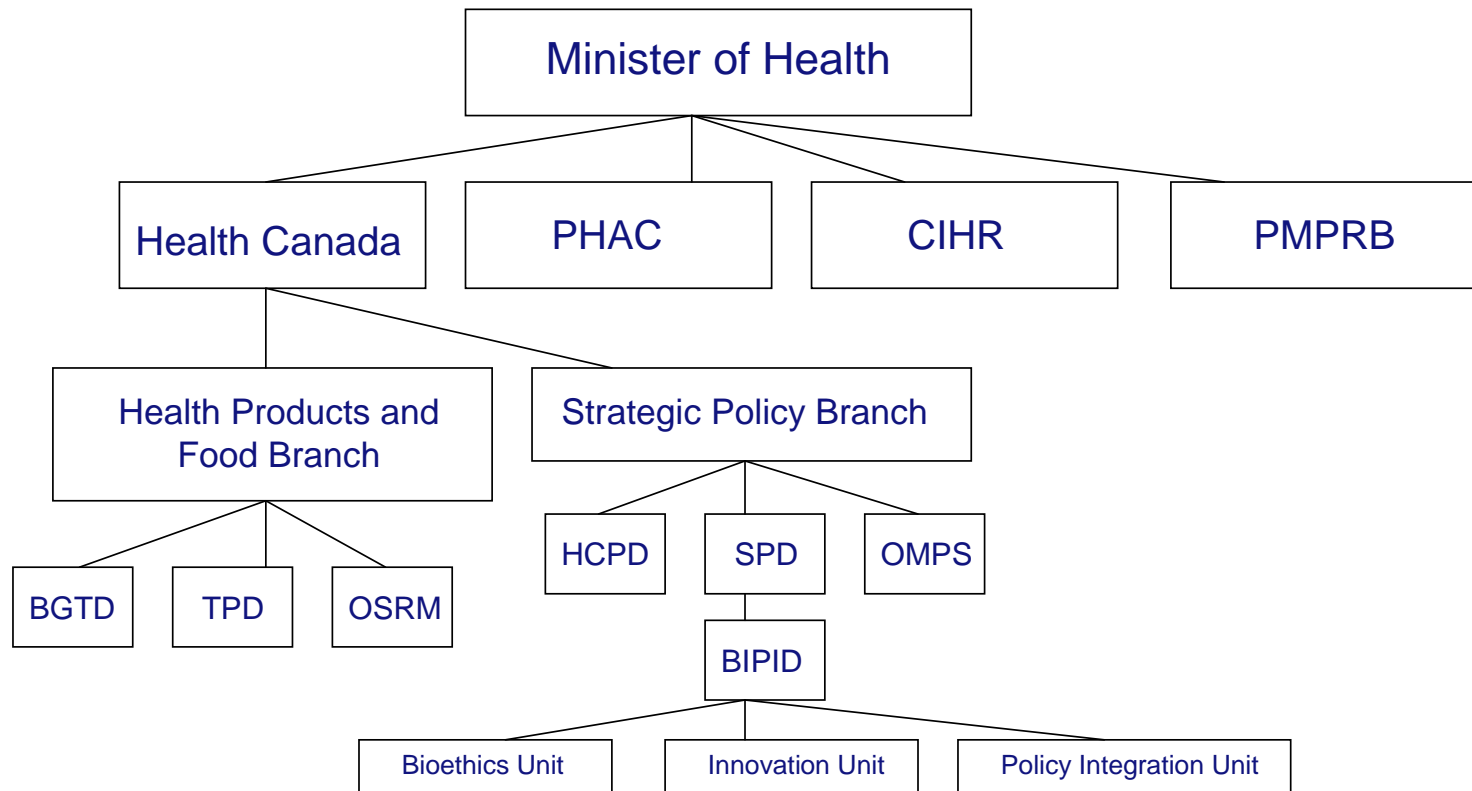
Presentation Outline

- Health Portfolio organization
- Concept and drivers
- Policy considerations
- Current activities and future directions



The Health Portfolio

Health Portfolio Organization



* See Annex A for acronyms glossary



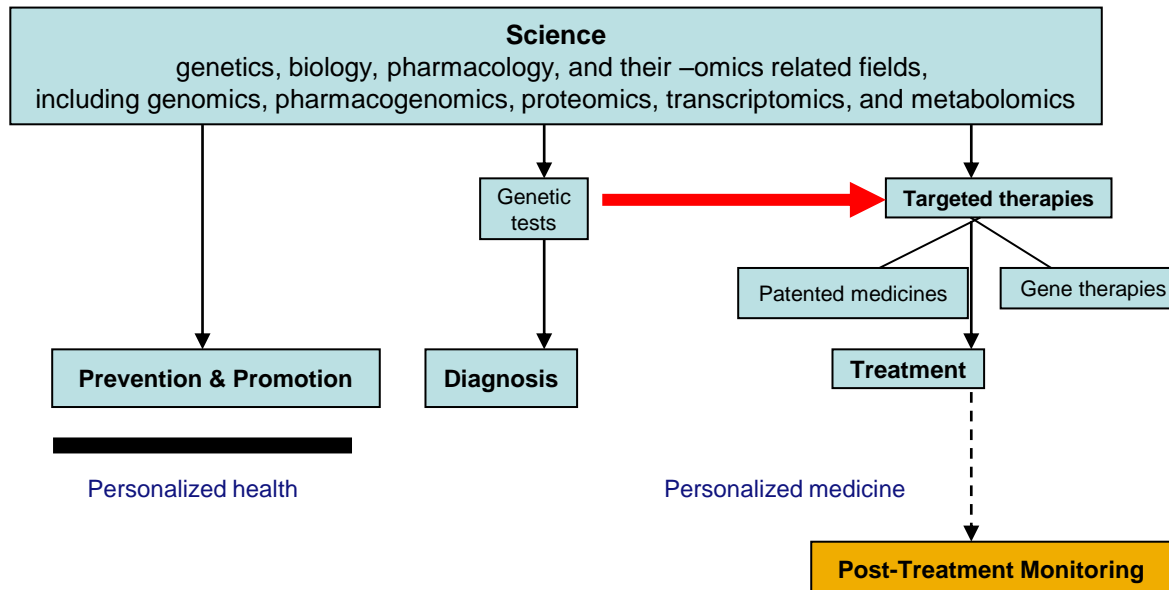
Definitions

- the use of an individual's genetic information, combined with other clinical information, "to stratify them into subpopulations that differ in susceptibility to a particular disease or response to a specific treatment." (President's Council of Advisors on Science and Technology, *Priorities for Personalized Medicine*, September 2008, 7.)
- diagnosing a disease in a particular patient to an ever greater level of granularity and then fine tuning treatment to precisely this information (Personalizing medicine: a systems biology perspective. 2009. *Molecular Systems Biology* 5: 249, pp. 1-3)
- the underlying scientific basis of "personalized medicine" could also have public health implications through the development of strategies better targeted to populations/subpopulations leading to healthier Canadians and contributing to disease/injury prevention, and health promotion (a.k.a. "personalized health")



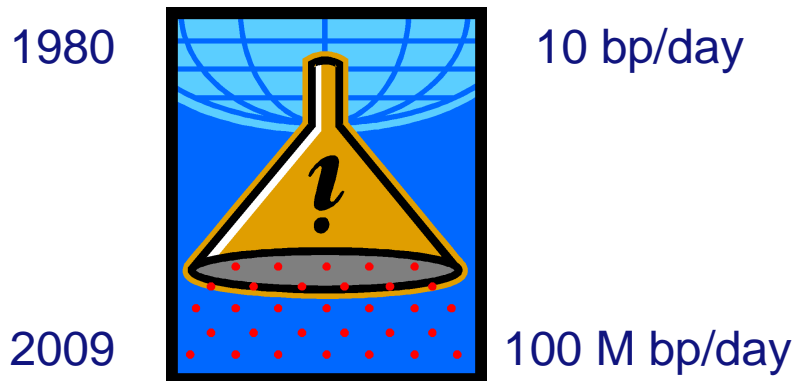
THE CONCEPT

- Personalized Health/ Personalized Medicine

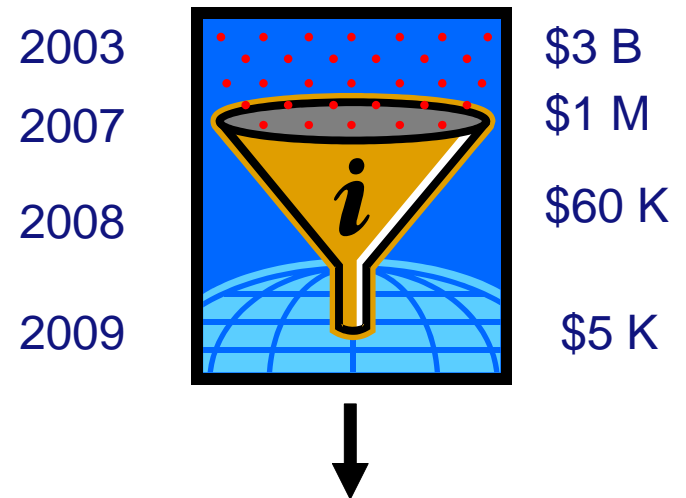


SCIENTIFIC DRIVERS

Sequencing capacity*



Cost of Sequencing the Human Genome**



*25th Session of the OECD Working Party on Biotechnology. June 2009.

**Personalized Medicine: From Concept to Reality. 2008. FierceBiotech.



OTHER DRIVERS

- Growing innovation deficit for pharmaceutical industry (only 20% of marketed drugs produce revenues that match or exceed their R&D costs*)
- Approaching end of the blockbuster drug era
- Rising drug and health costs as a result of aging population and management of chronic diseases (share of drugs in total health expenditures, nationally, is estimated at 17.4% in 2008 compared to just under 10% in 1985**)
- Patient advocacy groups calling for more effective therapies with fewer side effects and prevention strategies targeted to Canadian populations
- Rise in use of direct-to-consumer tests
- Development of electronic health records that allow for the integration of genetic and clinical data
- *Canadian Institute for Health Information. 2009. Drug Expenditure in Canada, 1985-2008
- **Personalizing medicine: a systems biology perspective. 2009. Molecular Systems Biology 5: 249, pp. 1-3



Personalized Medicine Research

- Federal government has and continues to make significant investments into genomic research (Genome Canada, CIHR, National Research Council, and Center of Excellence in Personalized Medicine).
- The globe and mail reports that the Government of Ontario recently announced that it is investing \$86 million into personalized medicine research
- Industry investment has been driven by a few companies and is primarily aimed at oncology where personalised medicine shows the most potential to deliver health benefits.
- Priorities in research include the need to validate biomarkers, understand better the interaction between genes and the environment, and translational research.



Costs/ Benefits of Personalized Medicine

- Cost-effectiveness ratios for currently approved personalised medicine drugs are high ranging from \$43,000-\$170,000/Quality Adjusted Life Years (QALY).
 - Commonly cited threshold is \$50,000/QALY
 - Testing can be cost-effective when performed on a patient with a family history of a particular disease (i.e., BRCA 1 testing is only cost-effective when used on patients with family history of breast cancer).
- Personalised medicine also incorporates expensive genetic testing (\$150-\$4000/per patient – depending on the test).
 - The costs of personalised medicine also include visits to physicians and genetic counsellors, provider education, and the creation and maintenance of electronic health records.
- Potential savings for the health care system resulting from reduced adverse events.



Policy Considerations for the Federal Government

RESEARCH:

- Deciding which research initiatives to fund is a key policy question for the federal government
 - Canada is a leader in genomic research, and stakeholders will expect the government to continue its support for the research
 - (e.g., CIHR, Genome Canada, National Research Council of Canada)
- Discovery will require funding for not only research initiatives but also for the development of large-scale genetic databases.
 - Bioethical issues include security and confidentiality of the databases, consent and benefit sharing

REGULATORY:

- Molecular diagnostic tests will require a regulatory regime that validates both the accuracy of tests and confirms the association between a biomarker and a disease.



Policy Considerations for the Federal Government (Cont'd)

- Validation of tests will require extensive clinical trials that are costly for industry to undertake, and are challenging for regulatory bodies to approve and develop standards.
- Regulatory review process will need to accommodate drugs with a required companion diagnostic.
- Companies that offer genetic testing services to consumers (i.e., Direct to consumer genetic testing) may require regulatory oversight.



Policy Considerations for the Federal Government (Cont'd)

ACCESS:

- Pressures on the reimbursement/ costing system – choices on which drugs and companion tests are supported may result in unmet expectations
- pricing of drugs that have a companion diagnostic poses challenges to our existing price control systems, particularly, when a costly genetic test is a necessary pre-requisite to the drug.
- Categorization of drugs to treat sub-populations of disease groups and the Orphan drug designation



Policy Considerations for the Federal Government (Cont'd)

PUBLIC HEALTH AND HEALTH SYSTEMS:

- Education of physicians and the public on the interpretation of genetic test results.
- The use and uptake of Electronic Health Records.

ETHICAL LEGAL SOCIAL ISSUES:

- Personalized medicine raises ethical and legal concerns over privacy and genetic discrimination (i.e. employment, insurance, and immigration).



The federal government can play a key role in the following aspects of personalized medicine...

- Development and promotion of guidance documents for genetic databases and national quality assurance standards of genetic tests
- Support for personalized medicine discovery and translational research
- Regulator of drugs and genetic tests sold as in-vitro diagnostic kits, and responsible for post-market surveillance of drugs and medical devices
- Support for the development of EHRs at the provincial/territorial level
- Providing information to public on the benefits and risks of genetic testing)
- Regulating price limits for patented medicines
- Facilitating inter-provincial collaboration and information exchange
- Policy development on federal government handling of genetic information and on genetic discrimination



Current activities and future Directions

- A number of PM drugs have been approved already by Health Canada – e.g. Herceptin, Vectibix etc.
- HC worked on the OECD Guidelines for Human Biobanks and Genetic Research Databases,
- HC work on the OECD Guidelines on the licensing of genetic inventions and the OECD guidelines for the quality assurance of genetic tests
- HC – PHAC project on the community of practice for Geneticists and Genetics labs
- HC Biobanking Guidelines (in draft)
- HC Pharmacogenomics guidance document
- Health Portfolio working group on personalized medicine – mandated to conduct comprehensive policy analysis on the issues and to develop a Health portfolio strategy on PM.



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