Industry Challenges Molecular Diagnostics, Targeted Therapies

Drug Pricing in Canada: Mobilizing Patients to Action

November 16, 2016, Toronto

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UNLEASHING INNOVATION: Excellent Healthcare for Canada

Report of the Advisory Panel on Healthcare Innovation The Advisory Panel on Healthcare Innovation received its mandate from the Honourable Rona Ambrose and began work in late June 2014. The Panel was charged with identifying five priority areas where action by the federal government could promote innovation in Canadian healthcare systems. It was also asked to advise the Minister on important enabling actions that could be taken by the Government of Canada, acting within its legitimate jurisdiction.

Pricing vs. Value Economizing vs. Innovation

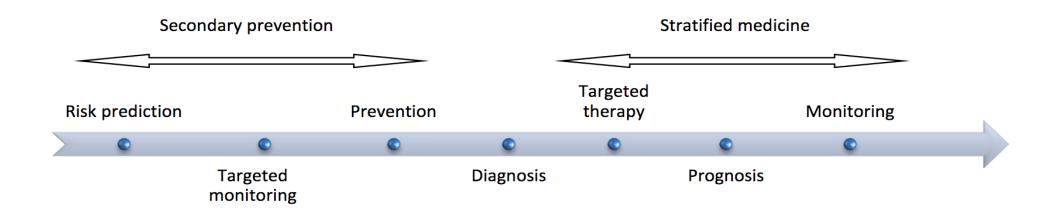
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Areas "where federal action is important to promote innovation and enhance the quality and sustainability of Canadian healthcare"



- 1. Patient engagement and empowerment
- 2. Health systems integration, workforce modernization
- 3. Technological transformation (digital health & precision medicine)
- 4. Better value from procurement, reimbursement and regulation
- 5. Industry as an economic driver and innovation catalyst

Terminology is a problem when we talk about personalized medicine



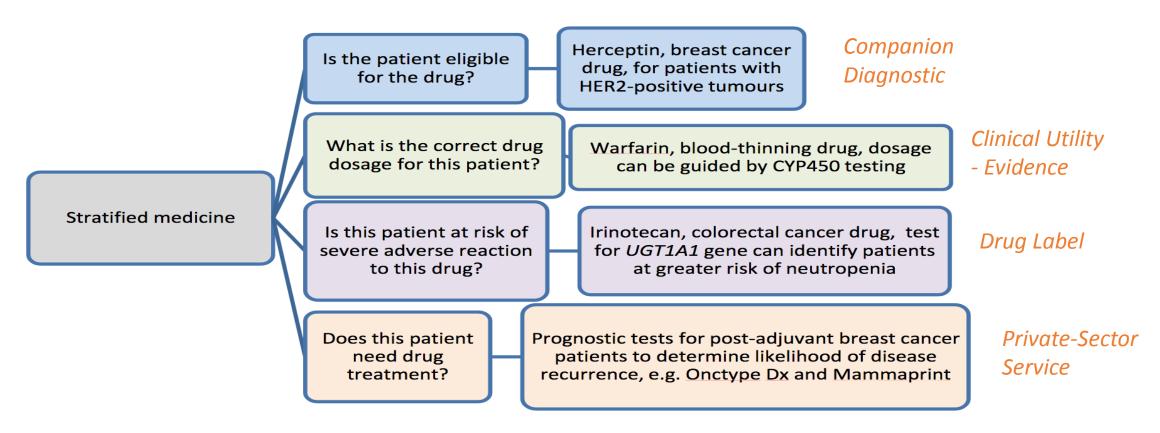
Molecular vs. Companion Diagnostic

Targeted Therapy vs. Companion Diagnostic

Personalized vs. Precision Medicine vs. Pharmacogenomics

"Direct to Consumer Testing" vs. "Proprietary Molecular Testing Service"

Terminology is a problem when we talk about personalized medicine



^{*} Extracted from Personalized Medicine - A Topology Briefing for CADTH, Hogarth 2016

Important Terms to Understand

- A. Companion Diagnostic, CDx required for prescription of associated drug (targeted therapy), indicated on drug label
- **B. Private Sector Molecular Diagnostic Test** not defined by clinical application, typically complex multi-biomarker test, also referred to as LTD or "Laboratory Developed Test"
- C. Direct to Consumer Testing does not required physician requisition, clinical value is questionable, very different from B.

Problems in the Adoption of CDx

Coverage Decisions

- Disjointed approval of test and drug
- Policy gaps related to evaluation process, in particular for CDx test
- Difficulty prioritizing CDx for evaluation, limited resources
- No consistent, coordinated national approach
- Hospital-based decisions, duplication of efforts



Problems in the Adoption of CDx

Funding Problems

- Disconnect between budget for drugs and for CDx
- Lack of new funding applied to specific tests
- Industry subsidizing cost of testing

Other Problems

- Patchwork regulation of diagnostic services (LDT)
- Challenges/cost of proving clinical utility
- Competing stakeholder values and incentives



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"There is no accountability for innovation adoption and spread; nor are there consequences for not embracing, rapidly adopting, and rapidly diffusing proven innovations. This is actually highly irresponsible given the volume of inventions and pilots that are financed by the public purse in Canada that never see the light of

Stakeholder Submission

lapter 11 Concluding Summary

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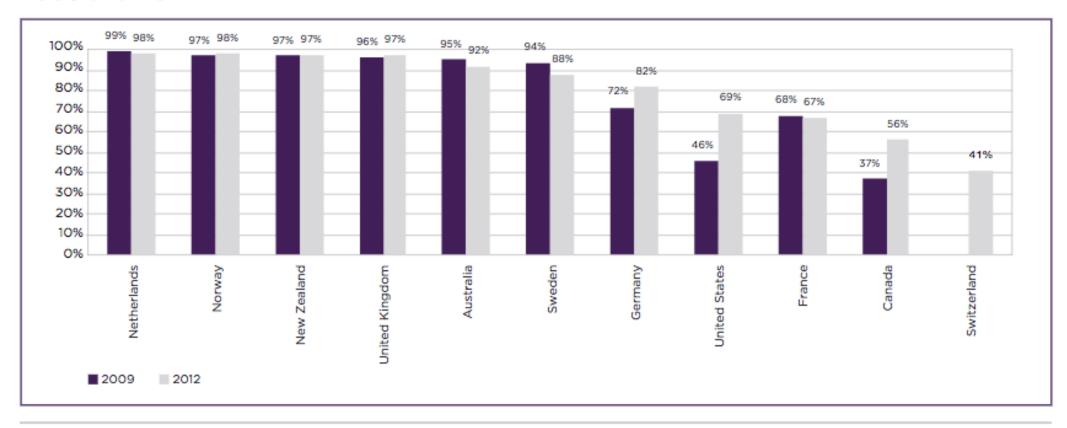
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day in terms of full value capture."

Figure 2.2 International comparison of health spending^v

	CANADA	OECD AVERAGE	CANADA'S OECD RANKING	CANADA'S RANK AMONG PEER COUNTRIES
TOTAL HEALTH EXPENDITURE AS A % OF GDP	10.2	8.9	10/34	7/11
TOTAL HEALTH EXPENDITURE PER CAPITA	\$4,351	\$3,453	10/34	7/11
PUBLIC EXPENDITURE ON HEALTH PER CAPITA	\$3,074	\$2,535	13/34	8/11
PUBLIC SHARE OF TOTAL HEALTH EXPENDITURE	70.6%	72.7 %	22/34	8/11
HOSPITAL EXPENDITURE PER CAPITA	\$1,338	\$1,316	15/29	9/9
PHYSICIAN EXPENDITURE PER CAPITA	\$720	\$421	4/27	4/8
DRUG EXPENDITURE PER CAPITA	\$761	\$517	2/31	2/9

Figure 7.1: Primary Care Physicians' Use of Electronic Medical Records in Their Practice, 2009 and 2012



Source: Adapted from: 2009 and 2012 Commonwealth Fund International Health Policy Survey of Primary Care Physicians. Available from: http://www.commonwealthfund.org/interactives-and-data/international-survey-data

Adapted from Unleashing Innovation: Excellent Healthcare for Canada, Government of Canada, 2015

Appendix 1: List of Recommendations

A. Collaboration for Healthcare Innovation: New Model, New Agency, New Money

Through Health Canada, request the federal Privacy Commissioner to work with provincial and territorial privacy commissioners to develop a common understanding on how to protect privacy while enabling innovation (e.g. in precision medicine and genomics, mHealth, and various forms of digitized health records) across Canada (5.3).

Through the new Healthcare Innovation Agency of Canada, with federal investments from the Healthcare Innovation Fund (5.1):

Support the development of policy and legislative tools to enable patient access to, and co-ownership of, their
own personal health records.

Convene a federal, provincial and territorial dialogue on a pan-Canadian framework that will protect Canadians while putting put Canada at the forefront of applied genomics and precision medicine, including (7.3):

 Regulatory and legislative amendments to prohibit genetic discrimination, Human Rights Act, the Criminal Code, the Personal Information Protection and Electronic Documents Act, and the federal Privacy Act.

