INSTITUTE OF HEALTH ECONOMICS
ALBERTA CANADA

Personalized Medicine – Policy Gaps and System Readiness:

Summary Report of Roundtable Discussion

July 30, 2012

Sponsored and conducted by the Institute of Health Economics (IHE).

Held in Conjunction with the Canadian Association for Population Therapeutics (CAPT) Annual Meeting, May 8th, 2012, Hyatt Regency, Montréal, QC.

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BACKGROUND

The IHE has established a series of methodologic forums with the intent of identifying and addressing major methodological challenges in informing policies and decisions around the funding and use of health technologies, in partnership with its private and public stakeholders that are involved in the production of evidence and use of assessment.

The concept of "personalised medicine" in health is garnering increased attention. Personalised medicine can be defined as the tailoring of preventive, diagnostic, or therapeutic interventions to the characteristics of an individual or population. This may involve genetic or laboratory biomarker information. As personalized medicine promises to increasingly change the paradigm of how medicine is practiced, questions remain as to whether current systems for the adoption and implementation of these services are ready and what the implications are for research and development activities in both the public and private sector.

ROUNDTABLE OBJECTIVES

The objectives of this roundtable are to:

1. **Discuss the current and potential state** of the adoption and implementation of personalized medicine in Canada.
2. **Articulate some directions, goals and components of a vision** for the adoption and implementation of personalized medicine in Canada.
3. Identify **opportunities and barriers** to achieving these goals and their **strengths and limitations**.

INTRODUCTION

Participants invited to this roundtable discussion reflected a breadth of viewpoints and depth of experience within the spheres of Canadian health research and delivery. A list of participants is presented in Table 1.

Although not strictly adhered to, key questions were provided to stakeholders ahead of the meeting to guide discussion. For the third question (below), participants were additionally asked to reflect on a vision statement developed by the UK National Health System. Emerging themes were captured and are summarized in the next section. Participants were instructed to speak freely, as the summary notes of this meeting will not contain specific comments or suggestions attributable to any individual participant.

Questions to guide the roundtable discussion were the following: 1) Is the current state of adoption and implementation ideal? 2) What should the goals be for personalized medicine in Canada? 3) What are

the components of a vision for health system readiness for personalized medicine in Canada? For each question, additional sub questions were suggested to guide discussion.

Several themes emerged during the introductory discussion as participants were asked to share their viewpoints and how these have been informed by their perspectives or the experience of the organizations in which they operate. These themes included:

- Definitions of personalized medicine
    - Personalized medicine (PM) embodies to at least two separate concepts - predictive genetic testing and co-dependent technologies (e.g., such as companion diagnostics) – it is helpful to separate these two when discussing PM
    - Personalized medicine does not always imply interventions – other factors related to treatment including setting, timing and sequencing could result in improved population health
    - Personalized medicine does not always imply commercialization or direct use in clinical decision making
- Perceived implications of personalized medicine
    - May require a change in the paradigm for technology assessment which is largely population focused rather than on individuals
    - Will likely impact research activities and costs associated with drug development and the production and reimbursement of innovation
    - May require a change in the paradigm for how health care providers make decisions– information about patients gathered ahead of time may help future clinical decisions
    - Has the potential to widen the slowly growing gap in access to health care in Canada based on ability to pay

POLICY GAPS AND SYSTEM READINESS

There was general consensus that the current state for adoption and implementation of personalized medicine is suboptimal. Many felt that current incentives are not properly aligned between those developing technologies in the private and public sector, those delivering care and those responsible for implementation and reimbursement. This leads to a lack of coordination among these key stakeholders. Some felt that because of the many implications for practice, research, and technology development, a higher level of coordination was required.

Similarly, existing initiatives that attempt to better bring together the delivery of health care with research and development hold promise for realigning incentives and would be welcome. Examples cited included innovation centres, such as the current Ontario initiative MaRS EXCITE, the UK Biobank Project and French-led diagnostic centres that use high throughput, low cost systems to collect data for studying populations.

When asked where changes are required to improve system readiness, several themes emerged:

Table 1 Emerging Themes Describing Challenges with System Readiness

Companion Diagnostics

- Better understanding
    - Need clear definitions surrounding their use
- Changes to the model of research and development
    - More public sector involvement required in private sector development
- Regulatory improvements
    - More emphasis on clinical utility
    - Model for looking at blockbuster drugs not relevant
- Changes to models of evaluation and uptake
    - More upstream involvement of stakeholders
    - A common framework
    - Need to understand implications for equity
    - Need to better understand affordability
    - Real-world assessment – specifically in a rapidly moving environment
- Changes to the delivery model
    - Diagnostic centres (requires improvements in regulation)

Predictive Testing

- Better understanding
    - Need clear definitions surrounding their use
- Regulatory improvements –
    - Specifically for testing centres/biobanks
- Changes to models of research and development
    - Improving access to biobank information

- Changes to models of evaluation and uptake/reimbursement
    - No common framework
    - Needs to be focused on effectiveness
- Changes to the delivery model
    - What education and tools are required?
    - Tools and education need to be evidence-based
    - Information infrastructure and communication tools required
    - How to manage public sector implications of private tests?

It was noted that in some specialty areas, like oncology, the system is almost in a state of readiness. For example, academic centres are already conducting predictive testing.

IMMEDIATE GOALS FOR PERSONALIZED MEDICINE

Participants were then asked to reflect on what immediate goals are feasible and achievable in the existing health care environment. Participants felt there might be opportunities, particularly in areas like oncology, where there already exists examples of the use and uptake of personalized medicine. Participants acknowledged that any initiative would require a high level of coordination and the development of National standards. It must also work within the constraints of decentralized systems of health. Participants felt the bulk of opportunity was in the realm after the development of technologies (i.e., in the implementation space) through developing diagnostic centres (see below) although another opportunity might occur in changing the current business model of technology development

Proposal 1 – Changing the delivery paradigm

Many participants felt that in terms of an area for immediate action, developing coordinated diagnostic centres held specific promise. Like the Biobank UK initiative, these centres may be associated with particular benefits:

- Information collected could be a valuable resource for health technology developers, health system researchers, and health care providers in an environment of scare resources – this avoids unnecessary duplication and facilitates coordination:
    - For providers
        - Common resources for diagnostic needs
        - Facilitate development of educational resources and use of tools for providers and consumers
    - For technology developers

        - Both *in silico* and *in vivo* research (including GE^{3}LS) and care delivery could be conducted
        - Provide opportunities for public and private sector arrangements including needed improvements in private sector model for the development companion diagnostics
        - Provide opportunities for both active and passive personalization approaches
        - Catalyze growth opportunities by providing infrastructure for research and technology development
    - For health system researchers
        - Provide opportunities for assessment of real world effectiveness
        - Adoption and development of similar standards for protecting patient privacy

Participants also acknowledged:

- Coordination across systems is already a strength in Canada's health/research systems
- Coordinated diagnostic centres can more easily develop/adhere to National standards of quality (i.e., in the absence of standards or regulations)
- Some coordination is lacking – for example, the processes to evaluate and approve funding for diagnostics are not linked to drug funding processes.

Proposal 2 – Changing the business model for R&D

Another initiative that some participants felt had merit was the development of real public-private sector partnerships between health systems/research funders/and private sector innovators of companion diagnostics

- This system – a change in the current business model for commercialization - would reduce current cost pressures on private sector research and development, and provide opportunities to increase innovative therapies and curb growth in drug expenditures.
- These arrangements would require careful management so as not to socialize losses and privatize benefits. A true partnership means profits and losses are shared.

A VISION FOR PERSONALIZED MEDICINE

In the final part of the meeting, participants were asked to reflect on a common vision for Canada. After reflecting on a Vision Statement for Genomics Medicine[1], participants suggested this could not be adopted in Canada. Some further reflections from the meeting group were:

- The clinical culture is different than that of Canada – research in the UK is a core business (active recruitment and participation in clinical trials) where as it is not so much in Canada.
    - But that is slowly changing – the need for more change was supported by the panel

[1] Building on our inheritance Genomic technology in healthcare. A report by the Human Genomics Strategy Group. January 2012

- A vision statement that more narrowly focuses on policy gaps and system might be welcome – it may be too soon to arrive at an overall vision
- We need a common agreement on some fundamental issues/assumptions/definitions (e.g. is the issue cost containment, cost effectiveness or something else) before developing an overall vision.
- The UK Vision may be too ambitious, unrealistic and impractical. We don't need to do all the things in the vision statement but focus on 1 or 2 things.
- Vision should include patients at the core.
- Better to focus on a few core priorities with high probability of success.
- It might be possible to have an overarching vision in a strategic area like oncology (i.e., personalized cancer medicine), which is in a higher state of readiness

OVERALL DISCUSSION AND FINDINGS

1. There are currently many barriers to the wholesale adoption and implementation of personalized medicine strategies. The major barrier is lack of incentives to align payers, providers, patients, and producers of technologies. For predictive testing, the current model of healthcare delivery leads to a lack of coordination among researchers, payers and providers. For the development of companion diagnostics and other personalized interventions, barriers in the regulatory and evaluative framework may be leading to suboptimal performance.

2. Two immediate goals may be worth exploring further

a. Diagnostic Centres – it was suggested that Canada could already build on current strengths in coordination and the use of predictive testing and diagnostics in cancer, to develop a biobank or diagnostic centre. These centres would align health researchers and providers, provide opportunities for creating National standards and the tools required to support patients.

b. Private-Public Sector Research and Development Partnerships – it was suggested that changing the current business model and engaging in a true public private sector partnership for the development of personalized interventions could lead to improvements in innovation, efficiency, adoption and implementation and provide a platform for changing the regulatory landscape.

3. It is too early to define a vision for personalized medicine and genomics. Although a vision for personalized medicine is desirable, it is early days. Roundtable participants felt it much better to explore immediate goals and have further discussion to create a vision for personalized medicine in Canada.

NEXT STEPS

The IHE provides this report free of charge to the wider community of researchers, providers, policymakers and patients as approaches to the use and governance of personalized medicine are developed in Canada. It is hoped the use of personalized medicine in policy and practice will be informed by the findings of the workshop.

APPENDIX – A. SESSION OUTLINE

Start	End	Activity	Lead
12:00	12:30	Lunch	John Sproule, IHE
12:30	1:15	Welcome, introductions and overview of current state of adoption and implementation of personalized medicine in Canada and activities underway. Note: (all participants will be asked to provide brief comment on their initiatives as appropriate).	Don Husereau, University of Ottawa & participants
13:15	13:45	**Roundtable Discussion –Assessment of System Readiness. Q1: Is the current state of adoption and implementation ideal?** • What does system 'readiness' look like? • What are the key issues which require attention? • What are the deficiencies/opportunities which need to be addressed?	Moderator: John Sproule
13:45	14:30	• **Roundtable Discussion 2 – Q2: What should the goals be for personalized medicine in Canada?** • Are current methods and approaches for evaluation adequate to address personalized approaches and small populations? • What are the key concerns from payors, industry and providers which need to be addressed?	Moderator: John Sproule

14:30 – 14:45 BREAK

14:45	15:45	**Roundtable Discussion 3 – Q3: What are the components of a vision for health system readiness for personalized medicine in Canada?** • What is an achievable vision that is attractive and inspiring to all stakeholders? • Where do key conflicts exist? • What mechanisms (policies, institutions, organizations, and individuals) are required for achieving this vision?	Moderator: John Sproule
Wrap Up			
15:45	16:30	Thanks and Next Steps	

APPENDIX B. SESSION PARTICIPANTS

Name (in alphabetical order, by first name)	**Institution**
Amalia Issa	University of the Sciences, Philadelphia, USA
Bernard Prigent	Pfizer Canada
Charles Butts	Alberta Health Services
Cindy Bell	Genome Canada
David King	CADTH Policy Forum
Deborah Marshall	University of Calgary
Don Husereau	University of Ottawa
Etienne Richer	Canadian Institutes of Health Research (CIHR)
Gillian Mulvale	CHSRF
Jeff Blackmer	Canadian Medical Association
John Sproule	Institute of Health Economics
Matthew Brougham	Canadian Agency for Drugs and Technologies in Health (CADTH)
Morag Park	CIHR, Institute of Cancer Research
Nolan Beanlands	Canadian Health Services Research Foundation (CHSRF)
Paul Laskow	CIHR, Institute of Genetics
Reiner Benken	INESSS
Robyn Tamblyn	CIHR, Institute of Health Services and Policy Research
Sandy Pagotto	CADTH
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