

Personalized Medicine Landscape

Clarissa Desjardins, Ph.D., CEO

Presentation at Critical Markers of Disease conference

May 17th, Ottawa, Canada

CEPMED

CENTER OF EXCELLENCE IN
PERSONALIZED MEDICINE

Outline

- Cepmed
- Personalized Medicine:
 - benefits and supporting evidence
 - healthcare challenge
 - pioneers
 - around the world

About Cepmed



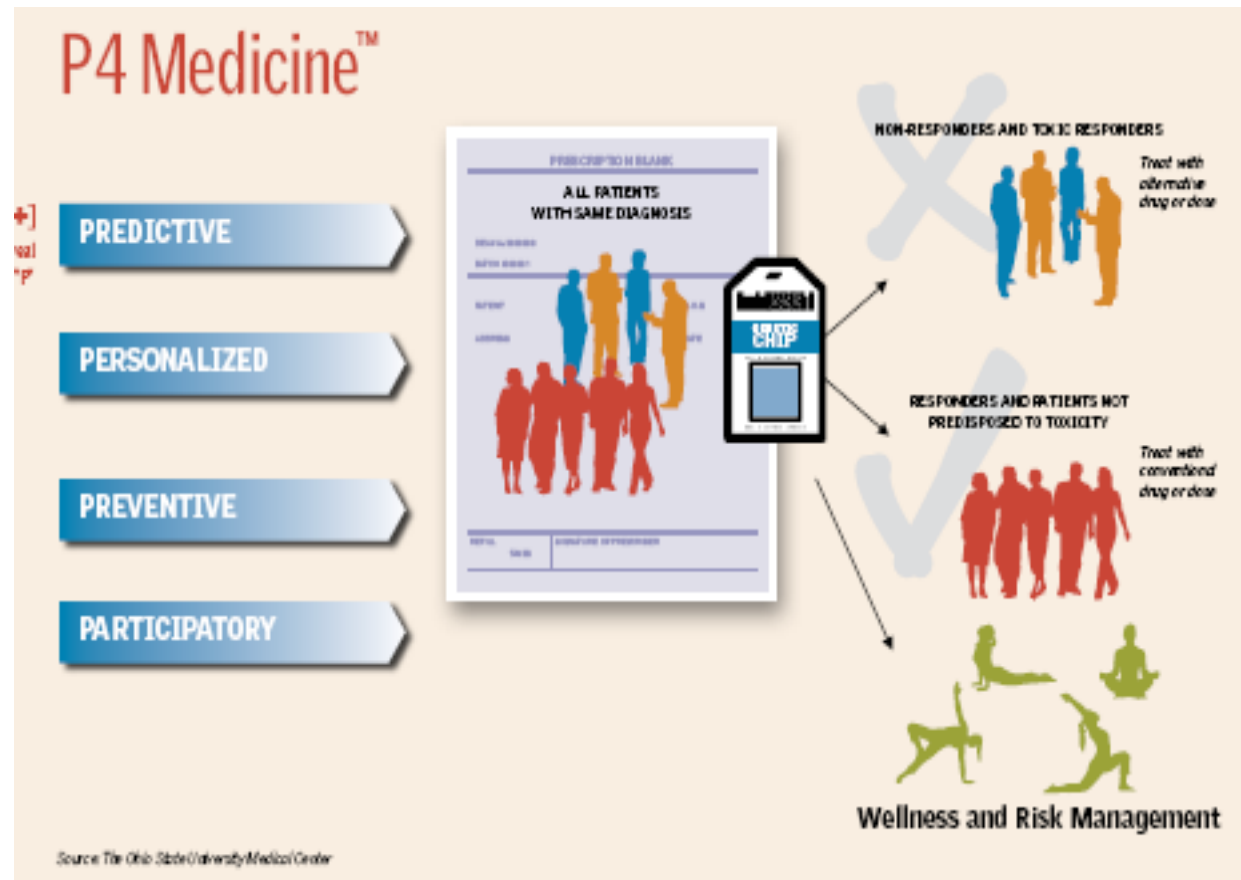
- Federally-funded Center of Excellence for Commercialization and Research
- \$~14 mm from Canadian government
- \$~2.5 mm from private and public sponsors
- Mission to promote Personalized Medicine through:
 - Education
 - Policy
 - Public-private partnerships which leverage technological platforms at the Montreal Heart Institute (MHI)
 - MHICC, Montreal Heart Institute Coordinating Center
 - MHI Biobank
 - MHI Pharmacogenomics Center
- Generate revenues from high-value services and retained commercial partners  :      with

Personalized medicine and P4 medicine

“Personalized medicine is the tailoring of medical treatment to individual characteristics of each patient.”

“Preventative and therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not.”

*President's Council of Advisors on Science and Technology for PEASW
 “Priorities for Personalized Medicine”
 September 2008*



Source: The Ohio State University Medical Center

*Adapted from "Art and Science of Personalized Medicine" in
 Clinical Pharmacology & Therapeutics, 81,311-315 (2007);
 Ohio State
 Leroy Hood, Institute for Systems Biology*

Personalized medicine, just beginning

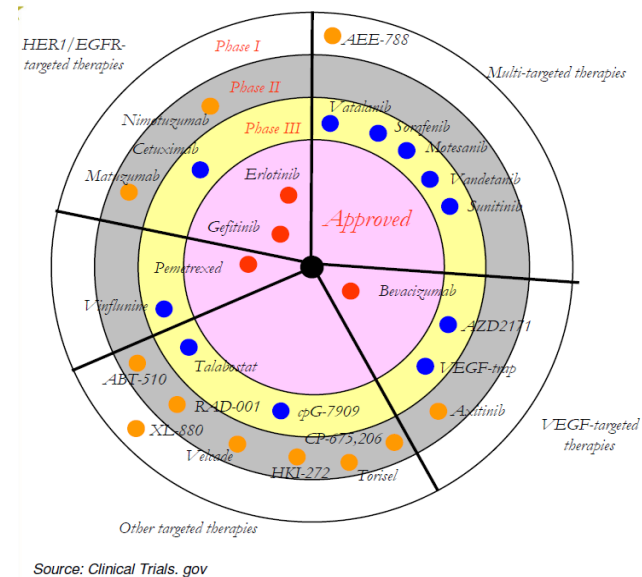
- Over 25% of currently prescribed drugs have PGx evidence on the label

- At least 26 drugs now in development have companion diagnostics associated with them

- Many widely prescribed drugs are efficacious only in 40-60% of patients

PGx Testing	FDA Approved Drugs
information on label	125
human information on the label	69
recommended	5

Frue F. et al. Pharmacotherapy 28(8) 2008.



The case for personalized medicine

- Shift emphasis in medicine from reaction to prevention (BRAC1/BRAC2, LQTS)
- Enable the selection of optimal therapy and reduce trial-and-error prescribing
 - Her-2, OncotypeDx, EGFR, KRAS, clopidogrel
- Make the use of drugs safer by avoiding adverse drug reactions
 - UGT1A1 assay, warfarin testing (VKOR and CYP2C9)
- Increase patient compliance with treatment
- Reduce the time and cost of clinical trials
- Revive drugs that are failing in clinical trials or were withdrawn from the market
- Reduce the overall cost of healthcare

Oncotype Dx: Leading example of emerging tests

- Predicts cancer recurrence risk at 10 year and helps patient choose if chemotherapy is likely to be beneficial (predictive & prognostic)
- Tumor biopsy tested for expression level of 21 genes; algorithm derives a score which places patient in high, medium or low risk of recurrence of breast cancer
- Recommended in the ASCO, NCCN and St. Gallen 's guidelines
- Over 90,000 patients have received the test in US, Canada and Europe
- The clinical value proven in nearly 4,000 patients , over 7,500 physicians have ordered
- Insurance coverage for Medicare patients, and 90% of privately insured lives in the U.S.
- Demonstrated cost effectiveness; ICER of \$61K/QALY at cost of \$3,500
- Only limited public funding in Ontario, not in rest Canada

Rising healthcare costs and the role of technology enablers

- Health expenditures rising faster than our GDP
- Health care costs represent almost 50% of many provincial budgets
- Demographic changes and medical advances are inescapable and in the latter, desirable
- Response to ration care instead of rationalizing treatment based on evidence
- Issue being faced by all industrialized countries

Personalized medicine is a technology enabler which is transforming medicine from intuitive, to empirical, to precision medicine*

*Christenden Clayton M, The Innovator's Prescription (2009)

Medco, a personalized medicine pioneer

- Largest Pharmacy Benefit Manager covering 65 million members, 590 million Rx's
- Observed negative drug cost trend in clients (40%+ penetration of mail Rx's)
- Already promotes and reimburses PGx testing for warfarin and clopidogrel
- Sponsored 10 outcome oriented clinical studies including Medco-Mayo warfarin study¹
- Bought DNA Direct, a genetic counseling company
- Collaborating with FDA, NIH, CDC, AMA, universities and companies
- Contributing to improvements in healthcare safety and effectiveness

1. J Am Coll Cardiol. Epub 2010 March 30

Medco Foundation: Patient toolkits



**PERSONALIZED
MEDICINE**

Do you know someone who may benefit from testing to determine their genetic response to certain medications?

Sharing this information with a friend or loved one could help them get the right drug at the right dose.

In medicine, one size doesn't fit all. Two people who take the same medication may have very different responses to it.

Researchers are now discovering the role that your genes play in affecting how you'll respond to your medications. In some cases, you may not be getting the full benefit of a drug, but in other instances, a drug may be harmful because of how your body processes or metabolizes it. This science is known as pharmacogenomics, but it is often referred to as personalized medicine because it offers your doctor a way to tailor your treatment based on your individual genetic makeup.

Medco Foundation: Patient toolkits

What tests are available?

Enzyme Test	Medications to Check
CYP2D6 - The CYP2D6 enzyme plays a role in the metabolism of approximately 25% of currently available medications	<p>How you metabolize the CYP2D6 enzyme can affect your response to these drugs:</p> <p>Some antiarrhythmics (heart drugs), such as propafenone (<i>Rythmol</i>®)</p> <p>Some antidepressants, such as bupropion (<i>Budeprion</i>®, <i>Wellbutrin</i>®), fluoxetine (<i>Prozac</i>®), sertraline (<i>Zoloft</i>®), and amitriptyline (<i>Elavil</i>®)</p> <p>Some antiemetic drugs (antinausea drugs), such as ondansetron (<i>Zofran</i>®)</p> <p>Some antiestrogen drugs (breast cancer drugs), such as tamoxifen</p> <p>Some antihistamines, such as diphenhydramine (<i>Benadryl</i>®), hydroxyzine (<i>Atarax</i>®, <i>Vistaril</i>®), and promethazine (<i>Phenergan</i>®)</p> <p>Some beta-blockers (heart drugs), such as carvedilol (<i>Coreg</i>®), propranolol (<i>Inderal</i>®), metoprolol (<i>Lopressor</i>®, <i>Toprol XL</i>®), and nebivolol (<i>Bystolic</i>®)</p> <p>Some narcotic analgesics (pain drugs), such as codeine (<i>Tylenol</i>® with Codeine), oxycodone (<i>OxyContin</i>®, <i>Percocet</i>®, <i>Percodan</i>®), and methadone</p> <p>Some psychotherapeutic drugs, such as aripiprazole (<i>Abilify</i>®), haloperidol (<i>Haldol</i>®), perphenazine (<i>Trilafon</i>®), and risperidone (<i>Risperdal</i>®)</p> <p>Some smoking cessation therapy drugs, such as bupropion (<i>Zyban</i>®)</p>

continued >

Medco Foundation: Patient toolkits

A few minutes of your time may help keep someone you love healthy.

What do you need to do?

- 1** Ask your family members or friends if their doctor knows about genetic tests for drugs that they are taking. Have them share this information with their doctors and pharmacists.
- 2** Print and share this information to inform others about genetic testing for drug-metabolizing genes.
- 3** If you are using one of the drugs listed above or other drugs and feel that you might not be tolerating treatment well, ask your doctor whether testing your drug-metabolizing genes could be helpful.
- 4** If you have had your drug-metabolizing genes tested, inform your doctor and pharmacist about your test results and ask them to note your test results in your drug profile.
- 5** If you want to learn more about physician adoption of pharmacogenomics, [see the research at www.medcoresearch.com](http://www.medcoresearch.com).*

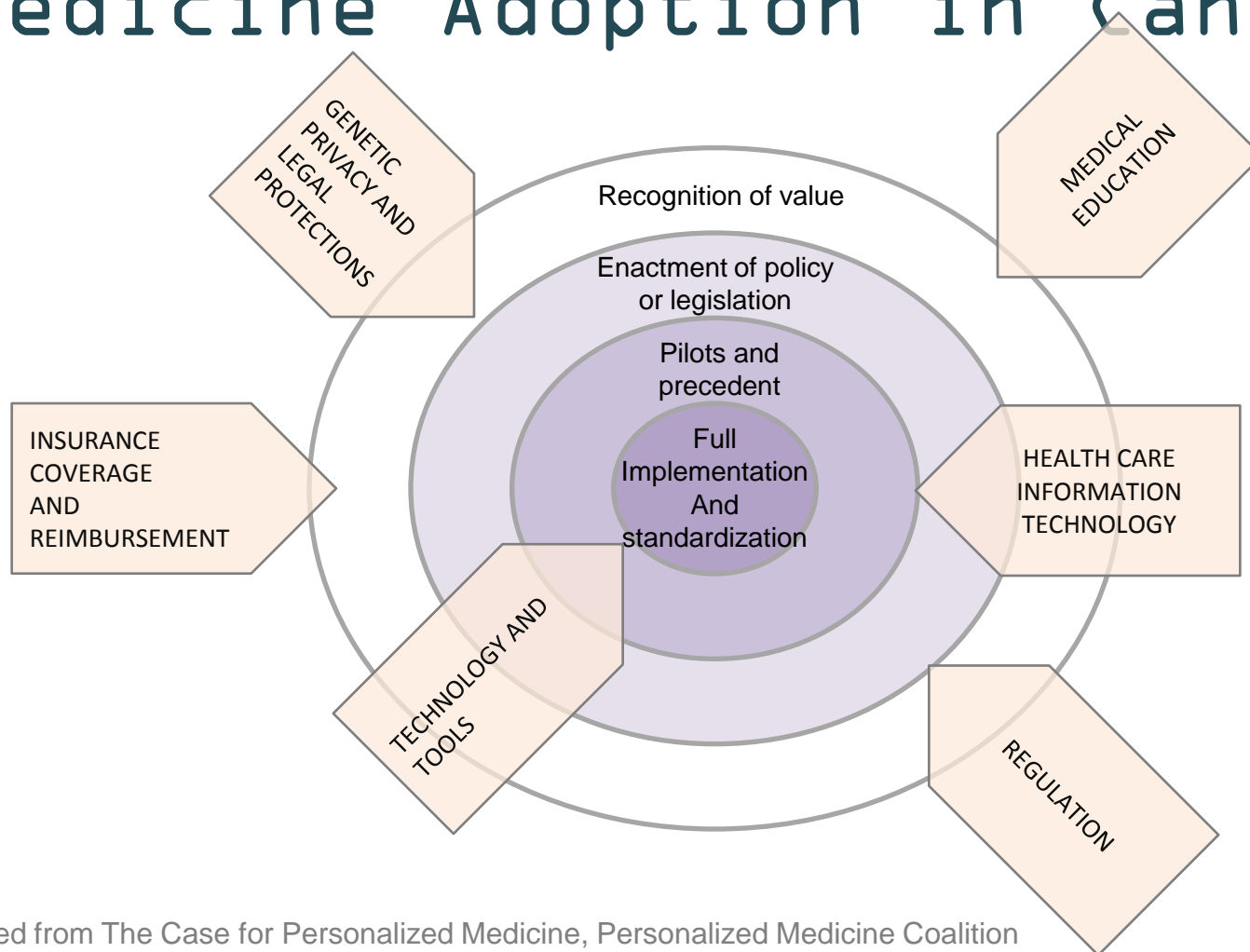
¹ Consumer Health Information Corporation. New genetic tests help doctors prescribe the right medicine for you. Accessed at <http://www.consumer-health.com/services/NewGeneticTestsHelpDoctorsPrescribetheRightMedicineforYou.htm> on Sept. 29, 2009.

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State of Personalized Medicine Adoption in Canada



Adapted from The Case for Personalized Medicine, Personalized Medicine Coalition

Personalized Medicine

Organizations around the world

- EPEMED - European Personalized Medicine Diagnostics association (Nantes, France)
 - "Promoting the concept of personalized medicine diagnostics across Europe to the public, government and private sectors"
- Integrated BioBank of Luxembourg, IBBL
 - "To establish an integrated biobank and technology centre that advances research in personalized medicine and benefits healthcare, education and the economy"
- Personalized Medicine Coalition (Washington DC)
 - "To educate opinion leaders and the public about the issues that will shape how personalized medicine develops"
- Partnership for Personalized Medicine (Phoenix, Arizona)
 - "Improving outcomes, reducing costs"
- Cepmed, Center of excellence in personalized medicine (Montreal, Canada)
 - "Promoting personalized medicine through education, policy and public-private research"

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Recommendations for the healthcare industry

- Research funding: Support research at the intersection of multiple disciplines and change the review process
- Support research at the cross sections Create public-private partnerships to accelerate personalized medicine solutions in areas of public health with limited profit potential for commercial companies
- Collaborate to ensure appropriate regulatory, reimbursement and legal frameworks are in place to support the development and commercialization of new products
 - Genetic non-discrimination law
 - Novel pathways of approval for combined Rx-Dx
 - Develop pharmacoeconomic data to support products
 - Create supporting legislation to enable easy pooling of health data
- Financial support for implementation of electronic medical-health records
 - Academic medical centers, hospitals and health-care providers
 - Pharmaceutical, biotech and diagnostic companies
 - Government, regulators and payors and others
- Support medical education and patient education initiatives
- Research granting agencies